



Extracorporeal Photopheresis Treatment Center Directory

INDICATIONS AND USAGE

UVADEX® (methoxsalen) Sterile Solution is indicated for extracorporeal administration with the THERAKOS® UVAR XTS® or THERAKOS CELLEX® Photopheresis System in the palliative treatment of the skin manifestations of Cutaneous T-Cell Lymphoma (CTCL) that is unresponsive to other forms of treatment.

IMPORTANT SAFETY INFORMATION

CAUTION: READ THE THERAKOS UVAR XTS or THERAKOS CELLEX PHOTOPHERESIS SYSTEMS' OPERATOR'S MANUAL PRIOR TO PRESCRIBING OR DISPENSING THIS MEDICATION.

UVADEX (methoxsalen) Sterile Solution should be used only by physicians who have special competence in the diagnosis and treatment of cutaneous T-cell lymphoma and who have special training and experience in the THERAKOS UVAR XTS or THERAKOS CELLEX Photopheresis System. Please consult the appropriate Operator's Manual before using this product.

Please see additional Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.

Find the closest treatment center offering photopheresis near you

This is a directory of centers that offer photopheresis treatment, along with contact information for each center. The treatment centers are listed alphabetically by state for ease of reference. This resource is provided for informational use only and may not be comprehensive.

Extracorporeal photopheresis is available by prescription only.

Patients should always consult with their healthcare provider before initiating any treatment.

Treatment centers are independent, third-party facilities not owned or operated by Mallinckrodt.

Alabama

University of Alabama at Birmingham Hospital

625 19th Street South
Birmingham, AL 35233

Contact: Apheresis Department
Contact Phone: 205-975-4026

<http://www.uabmedicine.org/locations/the-kirklin-clinic-of-uab-hospital>

Alaska

Katmai Oncology Group

3851 Piper Street, Suite U340
Anchorage, AK 99508

Contact Phone: 907-562-0321

<http://katmaioncology.com>

Arizona

Banner MD Anderson Cancer Center

2946 E. Banner Gateway Drive
Gilbert, AZ 85234

Contact Phone: 480-256-6444

<https://www.bannerhealth.com/banner-md-anderson>

Banner - University Medical Center Phoenix

1111 E. McDowell Road
Phoenix, AZ 85006

Contact Phone: 602-839-2000

<https://www.bannerhealth.com/locations/phoenix/banner-university-medical-center-phoenix>

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.

HonorHealth Scottsdale Shea Medical Center

9003 E. Shea Boulevard
Scottsdale, AZ 85260

Contact: Dialysis/Apheresis Department

Contact Phone: 480-323-3035

Email: oncologynursenavigator@honorhealth.com

<https://www.honorhealth.com/locations/hospitals/scottsdale-shea-medical-center>



Mayo Clinic - Arizona

5777 E. Mayo Boulevard, Suite 4E, Room 100
Phoenix, AZ 85054

Contact: Apheresis Department

Contact Phone: 480-342-0103

<http://www.mayoclinic.org/departments-centers/mayo-clinic-cancer-center>

St. Joseph's Hospital and Medical Center - Phoenix

500 W. Thomas Road
Phoenix, AZ 85013

Contact Phone: 602-406-4000

<https://www.dignityhealth.org/arizona/locations/stjosephs>

The University of Arizona Cancer Center

3838 N. Campbell Avenue
Tucson, AZ 85719

Contact Phone: 520-694-2873

<http://uacc.arizona.edu/about/locations/UMCN>

▶ Arkansas

University of Arkansas for Medical Sciences

4301 W. Markham Street, #823
Little Rock, AR 72205

Contact: Cell Therapy/Apheresis Department

Contact Phone: 501-686-7930

<http://uamshealth.com>

▶ California

Alta Bates Summit Medical Center - Comprehensive Cancer Center

2001 Dwight Way
Berkeley, CA 94704

Contact: Apheresis Department

Contact Phone: 510-204-6578

<http://www.altabatesummit.org/cancer/cc>

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.

American Red Cross - Pomona Blood Donation Center

100 Red Cross Circle
Pomona, CA 91768

Contact: Donor Center

Contact Phone: 909-859-7281

<http://www.redcrossblood.org/locations/pomona-donor-center>

Cedars-Sinai Medical Center

8700 Beverly Boulevard
Los Angeles, CA 90048

Contact: Transfusion Medicine Division

Contact Phone: 310-423-8981

<https://www.cedars-sinai.edu/Patients/Programs-and-Services/Pathology-and-Laboratory-Medicine-/Consultation-Services/Transfusion-Medicine-.aspx>

City of Hope National Medical Center - Comprehensive Cancer Center

1500 East Duarte Road
Duarte, CA 91010

Contact: Therapeutic Apheresis Department

Contact Phone: 626-218-5910

<http://www.cityofhope.org/homepage>

Keck Medicine of USC

1500 San Pablo Street
Los Angeles, CA 90033

Contact Phone: 323-442-8363

<http://cancer.keckmedicine.org>

Ronald Reagan UCLA Medical Center

200 Medical Plaza, Suite 670
Los Angeles, CA 90095

Contact: Hemapheresis Unit

Contact Phone: 310-794-7177

<https://www.uclahealth.org>

Stanford Health Care - Stanford Cancer Center Palo Alto - Infusion Center

Advanced Medicine Center Building
875 Blake Wilbur Drive
Palo Alto, CA 94304

Contact: Apheresis Department

Contact Phone: 650-725-4656

<https://stanfordhealthcare.org/shc/en-tools/maps/programs-services/infusion-center-advanced-medicine-center-building.html>

UC Davis Medical Center - Department of Pathology & Laboratory Medicine

2315 Stockton Blvd
Sacramento, CA 95817

Contact: Apheresis Services

Contact Phone: 916-734-3732

http://ucdmc.ucdavis.edu/pathology/services/clinical/clinical_pathology/apheresis

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.

University of California Irvine Health Blood Donor Center

101 The City Drive South
Pavilion 3, Room 401
Orange, CA 92868

Contact Phone: 714-456-5433

<http://www.ucirvinehealth.org/locations/orange/blood-donor-center-medical-center>



University of California San Diego Health System - Hillcrest

9400 Campus Point Drive
3rd Floor, Room 3-601
San Diego CA 92037

Contact: Apheresis Program
Contact Phone: 858-249-3030

Email: apheresis@ucsd.edu

<https://health.ucsd.edu/specialties/apheresis/Pages/photopheresis.aspx>

University of California, San Francisco Medical Center

UCSF Medical Center - Infusion Services
400 Parnassus Ave. Fourth Floor, A430
San Francisco, CA 94143

Contact: Cutaneous Lymphoma Clinic

Contact Phone: 415-353-2421

https://www.ucsfhealth.org/clinics/cutaneous_lymphoma

► **Colorado**

Mercy Regional Medical Center - Infusion Center

1010 Three Springs Boulevard
Durango, CO 81301

Contact: Durango Nephrology
Contact Phone: 970-764-3825

<http://www.mercydurango.org/MDU/Home/#>

Presbyterian/St. Luke's Medical Center - Colorado Blood Cancer Institute

1719 E. 19th Avenue
Denver, CO 80218

Contact: Infusion Services
Contact Phone: 303-839-6394

<http://bloodcancerinstitute.com/services>

University of Colorado Cancer Center - Anschutz

Anschutz Cancer Pavilion
1665 Aurora Court, 3rd Floor
Aurora, CO 80045

Contact: Dermatology Clinic
Contact Phone: 720-848-0500

<https://www.uhealth.org/services/dermatology/>

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.

► **Connecticut**

Yale New Haven Hospital - Dermatology Photopheresis Unit

Hunter 4, Room 4097
15 York Street
New Haven, CT 06510

Contact: Department of Dermatology
Contact Phone: 203-688-6445

<https://medicine.yale.edu/dermatology/patient/services/photopheresis.aspx>

► **Delaware**

Christiana Care Health System - Helen F. Graham Cancer Center & Research Institute

4701 Ogletown-Stanton Road
Newark, DE 19713

Contact: Ambulatory Infusion Center
Contact Phone: 302-623-4500

<http://www.christianacare.org/lymphoma>

► **Florida**

Florida Hospital Cancer Institute

2501 North Orange Ave
Orlando, FL 32804

Contact: Florida Hospital Orlando Infusion Center
Contact Phone: 407-303-5865

<http://www.floridahospitalcancer.com>

H. Lee Moffitt Cancer Center

12902 USF Magnolia Drive
Tampa, FL 33612

Contact Phone: 1-888-663-3488

<https://moffitt.org/cancers/lymphomas-hodgkin-and-non-hodgkin>

Larkin Community Hospital - Florida Academic Dermatology Center at Larkin

7031 S.W. 62nd Avenue
South Miami, FL 33143

Contact Phone: 305-284-7516

<http://www.larkinhospital.com/site>

Mayo Clinic - Jacksonville

4500 San Pablo Road
Mayo 3-104S
Jacksonville, FL 32224

Contact: Therapeutic Apheresis Department
Contact Phone: 904-956-3312

<http://www.mayoclinic.org/diseases-conditions/cutaneous-t-cell-lymphoma/home/ovc-20179742>

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.



Memorial Hospital West

801 North Flamingo Road
Pembroke Pines, FL 33028

Contact: Memorial Cancer Institute
Contact Phone: 954-276-5365

<https://moffitt.org/locations-directions/moffitt-malignant-hematology-cellular-therapy-at-memorial-healthcare-system/>

OneBlood

10100 Dr Martin Luther King Jr. Street N.
St. Petersburg, FL 33716

Contact: Therapeutic Apheresis
Contact Phone: 727-568-1111

<https://www.oneblood.org>

University of Florida Health - Shands Cancer Hospital

1515 S.W. Archer Road
Gainesville, FL 32608

Contact Phone: 352-265-0111

<https://ufhealth.org/uf-health-shands-cancer-hospital>

University of Miami Hospital - Miller School of Medicine

University of Miami Hospital South Bldg, Suites K-M
1295 N.W. 14th Street
Miami, FL 33136

Contact: Department of Dermatology & Cutaneous Surgery

Contact Phone: 305-243-7357

<http://dermatology.med.miami.edu>

▶ Georgia

Emory University Hospital

Emory Healthcare Hemapheresis Department D627
1364 Clifton Road, N.E.
Atlanta, GA 30322

Contact: Hemapheresis Department

Contact Phone: 404-712-7028

<http://www.emoryhealthcare.org/dermatology/lymphoma.html>

Augusta University Medical Center

1120 15th Street
Augusta, GA 30912

Contact: Apheresis Department

Contact Phone: 706-721-3695

<http://www.augustahealth.org/dermatology/dermatology-services-page>

Northside Hospital - Atlanta Blood Services at BMT Inpatient Unit

5670 Peachtree Dunwoody Road, Suite 1075
Atlanta, GA 30342

Contact Phone: 404-459-8744

<http://www.northside.com/BMT-Facilities>

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.

▶ **Idaho**

St. Luke's Mountain States Tumor Institute: Boise

100 E. Idaho Street
Boise, ID 83712

Contact: Oncology Infusion
Contact Phone: 208-381-2918
[https://stlukesonline.org/health-services/procedures/extracorporeal-photopheresis](https://stlukesonline.org/health-services/procedures/procedures/extracorporeal-photopheresis)

▶ **Illinois**

Loyola University Medical Center

2160 S. 1st Avenue
Maywood, IL 60153

Contact: Dermatology Services
Contact Phone: 708-327-2609
<https://www.loyolamedicine.org/dermatology/dermatology-services>

Midwestern Regional Medical Center

2520 Emmaus Avenue
Zion, IL 60099

Contact: Stem Cell Laboratory
Contact Phone: 847-731-4177
<http://www.cancercenter.com/midwestern>

Northwestern Memorial Hospital

Rube Walker Blood Center
201 East Huron Street, 11th Floor, Suite 105
Chicago, IL 60611

Contact: Cutaneous Lymphoma Clinic
Contact Phone: 312-695-8106
<https://www.nm.org/locations/rube-walker-blood-center>

Rush University Medical Center - Dermatology Patient Services

1725 W. Harrison Street, Suite 264
Chicago, IL 60612

Contact: Cutaneous T-Cell Lymphoma Clinic
Contact Phone: 312-942-2195
<https://www.rush.edu/services/dermatology>

The University of Chicago Hospital - Duchossois Center for Advanced Medicine

5758 S. Maryland Avenue, Suite 3A
Chicago, IL 60637

Contact: Dermatology Clinic
Contact Phone: 773-702-1611
<http://www.uchospitals.edu/visitor/directions/maps/dcam.html>

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.

University of Illinois, Chicago ITxM Diagnostics

1740 W Taylor St. Suite #1106
Chicago, IL 60612 (UIH)

Contact Phone: 312-996-6970
Email: mkeller@itxm.org or mkelle34@uic.edu
<https://vitalant.org/Home.aspx#>



▶ **Indiana**

Franciscan Health Indianapolis

8111 S. Emerson Avenue
Indianapolis, IN 46237

Contact Phone: 317-859-5252
<https://www.franciscanhealth.org/Indy>

IU Health University Hospital

550 N. University Boulevard
Indianapolis, IN 46202

Contact: Apheresis
Contact Phone: 317-944-3921
<http://iuhealth.org/university>

▶ **Iowa**

University of Iowa Hospitals & Clinics

200 Hawkins Drive
Iowa City, IA 52242

Contact: DeGowin Blood Center
Contact Phone: 319-356-2058
<https://uihc.org/degowin>

▶ **Kansas**

American Red Cross - Kansas Capital Area Chapter

707 N. Main Street
Wichita, KS 67203

Contact: Apheresis Services
Contact Phone: 316-268-9071
<http://www.redcrossblood.org/hospitals/clinical-services/therapeutic-apheresis>

The University of Kansas Hospital

3901 Rainbow Boulevard
Kansas City, KS 66160

Contact: Blood and Marrow Transplant Program/Apheresis Services
Contact Phone: 913-588-1725
<http://www.kumed.com>

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.

► **Kentucky**

Norton Healthcare - Norton Healthcare Pavilion

411 E. Chestnut St.
Louisville, KY 40202

Contact: Outpatient Medical Unit

Contact Phone: 502-629-6993

<https://nortonhealthcare.com/services-and-conditions/cancer-care/services/skin-cancers/>

University of Kentucky

1000 S. Limestone
Lexington, KY 40536

Contact: UK Markey Cancer Center

Contact Phone: 859.257.4488

<http://ukhealthcare.uky.edu/markey-cancer-center>

University of Louisville Hospital - James Graham Brown Cancer Center

529 S. Jackson Street
Louisville, KY 40202

Contact: Cancer Center

Contact Phone: 502-681-1359

<http://www.kentuckyonehealth.org/browncancercenter-cancer-care>

► **Louisiana**

LSU Health Shreveport

1501 Kings Highway
Shreveport, LA 71103

Contact: Feist-Weiller Cancer Center

Contact Phone: 318-675-5972

<http://www.feistweiller.org>

Ochsner Medical Center

1514 Jefferson Highway
Jefferson, LA 70121

Contact: Hematology/Oncology Department

Contact Phone: 504-842-3910

<https://www.ochsner.org/services/melanoma-and-other-skin-cancers>

Tulane University School of Medicine

1415 Tulane Avenue, 5th Floor
New Orleans, LA 70112

Contact: Apheresis Clinic

Contact Phone: 504-988-3613

<http://www2.tulane.edu/som/departments/dermatology/index.cfm>

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.

► **Maine**



Eastern Maine Medical Center Cancer Care

33 Whiting Hill Road
Brewer, ME 04412

Contact: Photopheresis Room
Contact Phone: 207-973-7895
<https://www.emmc.org/Cancer-Care.aspx>

► **Maryland**

Johns Hopkins Hospital - Outpatient Center

601 N. Caroline Street, 8th Floor
Baltimore, MD 21287

Contact: Dermatology
Contact Phone: 410-955-5933
<http://www.hopkinsmedicine.org/dermatology>

University of Maryland Medical Center

22 S. Greene Street, 9th Floor
Baltimore, MD 21201

Contact: Marlene and Stewart Greenebaum Comprehensive Cancer Center
Contact Phone: 410-328-7508
<http://umm.edu/programs/cancer>

► **Massachusetts**

Brigham and Women's Hospital - Dana-Farber Cancer Institute

Jimmy Fund Building, Room 122
450 Brookline Avenue
Boston, MA 02215

Contact: Kraft Family Blood Donor Center
Contact Phone: 617-632-3394
http://www.brighamandwomens.org/bwhcancer/dfcibwh_cancer_treatment.aspx?id=24267#tabs-1

Boston Medical Center

Boston Medical Center Moakley Building
830 Harrison Avenue
Boston, MA 02118

Contact: Cancer Care Center
Contact Phone: 617-638-7131
<https://www.bmc.org/cutaneous-lymphoma>

Beth Israel Deaconess Medical Center - Infusion and Apheresis

330 Brookline Avenue
Boston, MA 02215

Contact: Infusion Apheresis Unit
Contact Phone: 617-667-1522
<https://www.bidmc.org/conditions-and-treatments/cancers-tumors-and-blood/cutaneous-lymphoma>

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.

Massachusetts General Hospital

55 Fruit Street
Boston, MA 02114

Contact: Apheresis Unit
Contact Phone: 617-726-8164
http://www.massgeneral.org/pathology/clinical/blood_transfusion.aspx

Tufts Medical Center - The Neely Cell Therapy and Collection Center

800 Washington Street
Boston, MA 02111

Contact: The Neely House
Contact Phone: 617-636-6453
<https://www.tuftsmedicalcenter.org/>

► Michigan

Karmanos Cancer Institute

4100 John R Street
Detroit, MI 48201

Contact: Apheresis Department
Contact Phone: 313-576-9259
Email: info@karmanos.org
<http://www.karmanos.org/cancer-care>

Michigan Blood

1036 Fuller N.E.
Grand Rapids, MI 49503

Contact: Therapeutic Apheresis
Contact Phone: 616-233-8569
Email: info@miblood.org
<https://www.versiti.org/medical-professionals/precision-medicine-expertise/transfusion-medicine>

University of Michigan Hospital - C&W Mott Hospital

Extracorporeal Photopheresis Clinic 8-951
1500 E. Medical Center Drive
Ann Arbor, MI 48109

Contact: Extracorporeal Photopheresis Clinic 8-891
Contact Phone: 734-232-8891
<http://www.mcancer.org/lymphoma>

► Minnesota

Mayo Clinic Medical Center

200 First Street S.W.
Rochester, MN 55905

Contact: Dermatology Department
Contact Phone: 507-284-2536
<http://www.mayoclinic.org/diseases-conditions/cutaneous-t-cell-lymphoma/home/ovc-20179742>

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.

University of Minnesota

909 Fulton Street S.E.
Minneapolis, MN 55455

Contact: Masonic Cancer Clinic
Contact Phone: 612-625-5656

<https://www.mhealth.org/care/conditions/cutaneous-t-cell-lymphoma-adult>



▶ **Mississippi**

University of Mississippi Medical Center

2500 N. State Street
Jackson, MS 39216

Contact: Apheresis Lab
Contact Phone: 601-815-1589

https://www.ummchealth.com/Health_Care_Services/Cancer/Cancer_landing_page_with_videooplayer.aspx

▶ **Missouri**

Barnes-Jewish Hospital

4921 Parkview Place, 4th Floor, CAM, Suite 4E
St. Louis, MO 63110

Contact: Siteman Cancer Center
Contact Phone: 314-454-8445

<https://siteman.wustl.edu>

St. Louis University Hospital

3655 Vista Avenue
St. Louis, MO 63110

Contact Phone: 314-577-8883
Email: contact_sluh@ssmsluh.com

<https://www.ssmhealth.com/locations/saint-louis-university-hospital>

University of Missouri - Dermatology Clinic

1020 Hitt Street, 2nd Floor
Columbia, MO 65212

Contact Phone: 573-882-1296

<http://www.muhealth.org/services/dermatology>

▶ **Nebraska**

American Red Cross - Nebraska & Southwest Iowa Region

3838 Dewey Avenue
Omaha, NE 68105

Contact: Apheresis Clinical Services
Contact Phone: 402-401-7909

<http://www.redcrossblood.org/hospitals/clinical-services/therapeutic-apheresis>

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.

▶ **Nevada**

United Blood Services

6930 W. Charleston Blvd
Las Vegas, NV 89117

Contact Phone: 702-228-1111
<https://www.vitalant.org/Home.aspx>

▶ **New Hampshire**

Dartmouth-Hitchcock Medical Center

1 Medical Center Drive
Lebanon, NH 03756

Contact: Norris Cotton Cancer Center
Contact Phone: 603-653-3775
Email: bmtransplant@hitchcock.org
<https://cancer.dartmouth.edu/blood-marrow.html>

▶ **New Jersey**

Hackensack University Medical Center

92 Second Street
Hackensack, NJ 07601

Contact: John Theurer Cancer Center and Apheresis Department
Contact Phone: 551-996-8326 or 551-996-4018
<https://www.hackensackumc.org/services/cancer-care/services/blood-marrow-stem-cell>

Morristown Medical Center

100 Madison Avenue
Morristown, NJ 07960

Contact: Photopheresis Center
Contact Phone: 973-971-4192
<http://www.atlantichealth.org/morristown/our+services/photopheresis+center>

Robert Wood Johnson University Hospital - Clinical Academic Building

125 Patterson Street
New Brunswick, NJ 08901

Contact Phone: 732-235-8100 ext. 225
<http://www.rwjuh.edu/rwjuh/therapeutic-apheresis.aspx>

▶ **New Mexico**

Presbyterian Infusion Center and Apheresis Services

201 Cedar Ave. S.E.
Albuquerque, NM 87106

Contact: Infusion Services
Contact Phone: 505-563-1309
<https://www.phs.org/doctors-services/services-centers/Pages/infusion-center.aspx>

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.



Columbia University Medical Center

Herbert Irving Pavilion
161 Fort Washington Avenue
New York, NY 10032

Contact: Cutaneous Lymphoma Center
Contact Phone: 212-305-5550

<http://www.cumc.columbia.edu/lymphoma/cutaneous-lymphoma>

Memorial Sloan Kettering Cancer Center - Blood Donor Room

1250 First Avenue
New York, NY 10065

Contact Phone: 212-639-6178

<https://www.mskcc.org/cancer-care/patient-education/frequently-asked-questions-about-photopheresis>

Montefiore Medical Center

111 East 210th Street
Bronx, NY 10467

Contact: Montefiore Einstein Center for Cancer Care

Contact Phone: 718-920-4818

<http://www.montefiore.org/pathology-services-clinical>

Mount Sinai Hospital

1450 Madison Avenue
New York, NY 10029

Contact: Apheresis Center

Contact Phone: 212-241-8810

<http://www.mountsinai.org/patient-care/service-areas/dermatology/medical-dermatology/hyperhidrosis-mycosis-fungoides-and-unknown-rashes>

Northwell Health

1991 Marcus Avenue
Lake Success, NY 11042

Contact: Department of Dermatology

Contact Phone: 516-719-3376

<https://www.northwell.edu/find-care/locations/department-dermatology-0>

Perlmutter Cancer Center - Langone Medical Center

160 East 34th Street
New York, NY 10016

Contact Phone: 646-929-7845

<http://nyulangone.org/conditions/cutaneous-t-cell-lymphoma-in-adults/treatments/photopheresis-for-cutaneous-t-cell-lymphoma>

Roswell Park Cancer Institute

Elm and Carlton Streets
Buffalo, NY 14263

Contact: Therapeutic Apheresis Unit

Contact Phone: 716-845-2385

<https://www.roswellpark.org>

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.

Stony Brook University Hospital Cancer Center

101 Nicolls Road
Stony Brook, NY 11794

Contact Phone: 631-444-2630
<https://cancer.stonybrookmedicine.edu>

University of Rochester

601 Elmwood Avenue
Rochester, NY 14642

Contact: Wilmot Cancer Institute
Contact Phone: 585-275-7447
<https://www.urmc.rochester.edu/cancer-institute.aspx>

Upstate University Hospital

750 E. Adams Street
Syracuse, NY 13210

Contact Phone: 315-464-6720
<http://www.upstate.edu/nursing/units/downtown/apheresis10i.php>

Westchester Medical Center - Cancer Center

19 Bradhurst Avenue, Suite 2300N
Hawthorne, NY 10532

Contact: Outpatient Infusion Center
Contact Phone: 914-493-2220
<http://www.wcmc.com/wmc/medical-services/408.aspx>

North Carolina

Atrium Health - Carolinas HealthCare System - Apheresis Department

1000 Blythe Boulevard, Suite 04M200
Charlotte, NC 28203

Contact Phone: 704-446-9750
<http://www.carolinashealthcare.org/medical-services/specialty-care/cancer-care>

Duke Blood and Marrow Transplant Clinic

2400 Pratt Street, Suite 1100D
Durham, NC 27710

Contact: Division of Hematologic Malignancies & Cellular Therapy
Contact Phone: 919-668-4360
<https://www.dukehealth.org/locations/duke-adult-blood-and-marrow-transplant-clinic>

UNC Health Care

101 Manning Drive
Chapel Hill, NC 27514

Contact: Transfusion Medicine/Blood Bank
Contact Phone: 919-966-4011
<http://www.unccmedicalcenter.org/unccmc/care-treatment/dermatology>

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.

Wake Forest Baptist Health



Wake Forest Baptist Medical Center
Comprehensive Cancer Center 3rd Floor
1 Medical Center Drive
Winston Salem, NC 27157

Contact: Apheresis Unit
Contact Phone: 336-713-5475

<https://www.wakehealth.edu/Locations/Clinics/a/Apheresis-Cancer-Center>

► Ohio

Cleveland Clinic

9500 Euclid Avenue
Cleveland, OH 44195

Contact: Apheresis M12
Contact Phone: 216-444-2633

http://my.clevelandclinic.org/health/treatments_and_procedures/hic_Phopheresis

Jewish Kenwood

4777 E Galbraith Rd
Cincinnati, OH 45236
(513) 686-3000

Contact: The Jewish Hospital-Mercy Health Blood Cancer Center
Contact Phone: 513-686-5250

<https://www.mercy.com/locations/hospitals/cincinnati/the-jewish-hospital-mercy-health/centers-programs/blood-cancer-center>

The Ohio State University Wexner Medical Center - The James Cancer Hospital

460 West 10th Avenue
Columbus, OH 43210

Contact: Apheresis Department, 1st Floor
Contact Phone: 614-293-8672

<https://cancer.osu.edu/cancer-specialties/cancer-care-and-treatment/cutaneous-lymphoma>

University Hospitals Case Medical Center

11100 Euclid Avenue
Cleveland, OH 44106

Contact: Seidman Cancer Center
Contact Phone: 216-844-3951

<http://www.uhhospitals.org/seidman>

University of Cincinnati Hoxworth Blood Center

3130 Highland Avenue
Cincinnati, OH 45267

Contact: Department of Pathology, Microbiology, and Immunology
Contact Phone: 513-558-1333

<http://www.hoxworth.org/patient-services.html>

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.

▶ **Oklahoma**

Oklahoma Blood Institute

1001 N. Lincoln Boulevard
Oklahoma City, OK 73104

Contact Phone: 405-297-5800

<https://obi.org/about-us/therapeutic-apheresis>

▶ **Oregon**

American Red Cross Cascades Region

3131 N. Vancouver Avenue
Portland, OR 97227

Contact Phone: 503-284-1234

<http://www.redcross.org/local/oregon>

Oregon Health & Science University

3181 SW Sam Jackson Park Road, Mail Code: CR145
Portland, OR 97239

Contact: Apheresis Dept

Contact Phone: 503-494-0526

<http://www.ohsu.edu/xd/health/services/dermatology/our-services/specialty-services/phototherapy.cfm>

▶ **Pennsylvania**

Allegheny Health Network

4800 Friendship Avenue
Pittsburgh, PA 15224

Contact: West Penn Hospital

Contact Phone: 412-578-1210

<https://www.ahn.org/cancer-institute/leukemia-lymphoma>

American Red Cross Eastern Pennsylvania Region

2221 Chestnut Street
Philadelphia, PA 19103

Contact Phone: 866-805-3500

<http://www.redcrossblood.org/hospitals/clinical-services/therapeutic-apheresis>

Geisinger Health System

100 North Academy Avenue
Danville, PA 17822

Contact Phone: 570-214-8162

<https://www.geisinger.org/patient-care/conditions-treatments-specialty/2017/03/21/16/33/cancer>

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.

Geisinger Wyoming Valley Medical Center

1000 E. Mountain Boulevard
Wilkes-Barre, PA 18702

Contact Phone: 570-808-7415

<https://www.geisinger.org/patient-care/find-a-location/geisinger-wyoming-valley-medical-center#>



Hospital of the University of Pennsylvania

3400 Civic Center Boulevard, Suite 1-330
Philadelphia, PA 19104

Contact: Photopheresis Department

Contact Phone: 215-662-2737

<https://www.pennmedicine.org/for-patients-and-visitors/find-a-program-or-service/dermatology/photopheresis>

Jeanes Hospital

7600 Central Avenue
Philadelphia, PA 19111

Contact: Bone Marrow Transplant Outpatient

Contact Phone: 215-214-3100

<http://www.jeanes.com/content/default.htm>

The Institute for Transfusion Medicine

3636 Blvd of the Allies
Pittsburgh, PA 15213

Contact: Therapeutic Apheresis Department

Contact Phone: 412-209-7433

<https://www.vitalant.org/Home.aspx>

Thomas Jefferson University Hospital

1014 College Building
1025 Walnut Street
Philadelphia, PA 19107

Contact: Oncology Department

Contact Phone: 215-955-8874

<https://hospitals.jefferson.edu/diseases-and-conditions/cutaneous-t-cell-lymphoma.html>

University of Pittsburgh Medical Center Shadyside - Cancer Center

5115 Centre Avenue, 3rd and 4th Floors
Pittsburgh, PA 15232

Contact: General Dermatology

Contact Phone: 412-864-7610

Email: bloodcancers@upmc.edu

<http://www.upmccancercenter.com/oneteam/#1>

Washington Health System Greene

350 Bonar Avenue
Waynesburg, PA 15370

Contact Phone: 724-627-3101

<http://southwestregionalmedical.com>

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.

► **Rhode Island**

Roger Williams Medical Center - Cutaneous Lymphoma Clinic

Cancer Center
50 Maude Street
Providence, RI 02908

Contact: General Dermatology
Contact Phone: 401-456-5793
<http://www.rwmc.org/services/dermatology-services>

► **South Carolina**

American Red Cross - South Carolina Region

Trident Medical Center
9330 Medical Plaza Drive
North Charleston, SC 29406

Contact: Apheresis Department
Contact Phone: 803-394-6005
<http://www.redcrossblood.org/hospitals/clinical-services/therapeutic-apheresis>

Greenville Health System

Cancer Center 2nd Floor
900 West Faris Road
Greenville, SC 29605

Contact: Apheresis Department
Contact Phone: 864-455-5592
<http://www.ghs.org/healthcareservices/cancer>

Medical University of South Carolina

165 Ashley Ave, Suite 201
Charleston, SC 29425

Contact: Hemapheresis Unit
Contact Phone: 843-792-4389
<http://www.muschealth.org/dermatology/index.html>

Bon Secours St. Francis Cancer Center

104 Innovation Drive
Greenville, SC 29607

Contact Phone: 864-603-6200
<http://stfranciscancercenter.org/services/treatments/infusion-services>

► **South Dakota**

Avera McKennan Hospital & University Health Center

1325 S. Cliff Avenue
Sioux Falls, SD 57105

Contact: Hospital Infusion Center
Contact Phone: 605-322-8509
<http://www.avera.org/services/cancer-care>

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.

▶ Tennessee



HCA TriStar Centennial Medical Center

Sarah Cannon Center for Blood Cancer At TriStar Centennial Medical Center
2410 Patterson Street, 5th Floor
Nashville, TN 37203

Contact: Oncology Services
Contact Phone: 615-342-7457
<http://tristarcentennial.com/service/cancer-care>

Methodist Le Bonheur Healthcare

1265 Union Avenue
3rd Floor - Crews Wing
Memphis, TN 38104

Contact Phone: 901-516-8695
<http://www.methodisthealth.org/locations/methodist-university-radiology-department>

Vanderbilt University Medical Center

The Vanderbilt Clinic, Room 2512A
1301 Medical Center Drive
Nashville, TN 37232

Contact: Apheresis/Photopheresis
Contact Phone: 615-322-9390
<https://ww2.mc.vanderbilt.edu/vmcpathology/43053>

VA Tennessee Valley Healthcare System

1310 24th Avenue South
Nashville, TN 37212

Contact: Photopheresis
Contact Phone: 615-327-4751
<http://www.va.gov/directory/guide/facility.asp?id=95>

▶ Texas

Baylor University Medical Center - T. Boone Pickens Cancer Hospital

Apheresis Unit, Suite 1030
3535 Worth Street
Dallas, TX 75246

Contact: Apheresis
Contact Phone: 214-865-1040
<https://www.bswhealth.com/locations/dallas/specialties/cancer-care/>

Carter BloodCare

5550 LBJ Freeway, Suite 350
Dallas, TX 75240

Contact: Clinical Apheresis Department
Contact Phone: 972-788-0650
<http://www.carterbloodcare.org>

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.

Medical City Dallas Hospital

7777 Forest Lane
Dallas, TX 75230

Contact Phone: 972-566-6755

<http://medicalcityhospital.com/hi/?/19881/Other-treatments>

Methodist Hospital of San Antonio

7700 Floyd Curl Drive
San Antonio, TX 78229

Contact: Apheresis

Contact Phone: 210-575-4681

<http://sahealth.com/hi/?/33753/Lymphoma-Center----Non-Hodgkin-s-Lymphoma>

Parkland Memorial Hospital

5201 Harry Hines Boulevard
Dallas, TX 75235

Contact: Hematology and Oncology Clinic

Contact Phone: 214-590-5582

<http://www.parklandhospital.com/phhs/cancer.aspx>

St. David's South Austin Medical Center

901 W. Ben White Boulevard
Austin, TX 78704

Contact: Oncology Department

Contact Phone: 512-816-7612

<http://stdavids.com/service/cancer-care>

University of Texas MD Anderson Cancer Center

1515 Holcombe Boulevard
Houston, TX 77030

Contact: Cutaneous T-Cell Lymphoma Clinic

Contact Phone: 713-792-6404

<https://www.mdanderson.org/patients-family/diagnosis-treatment/care-centers-clinics/melanoma-skin-center/cutaneous-tcell-lymphoma-clinic.html>

The University of Texas Southwestern Medical Center

5939 Harry Hines Boulevard
Dallas, TX 75390

Contact: General Dermatology

Contact Phone: 214-645-8300

<http://www.utswnmedicine.org/conditions-specialties/dermatology/general/phototherapy.html>

► Utah

American Red Cross - Salt Lake Blood Donation Center

6616 South 900 East
Salt Lake City, UT 84121

Contact Phone: 801-892-4001

<http://www.redcrossblood.org/hospitals/clinical-services/therapeutic-apheresis>

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.

Huntsman Cancer Institute

1950 Circle of Hope
Salt Lake City, UT 84112

Contact: Blood and Marrow Transplant Program
Contact Phone: 801-587-4652

<http://healthcare.utah.edu/huntsmancancerinstitute/patient-care/clinics-and-care-teams/blood-and-marrow-transplant/about-us>



▶ Virginia

Inova Fairfax Hospital

3300 Gallows Road
Falls Church, VA 22042

Contact: Inova Schar Cancer Institute
Contact Phone: 703-776-2610 or 571-472-4724

<https://www.inova.org/cancer/treatments/apheresis>

Virginia Commonwealth University

The Gateway Building, 6th Floor
1200 East Marshall Street
Richmond, VA 23298

Contact: Department of Pathology
Contact Phone: 804-828-0256

<http://www.pathology.vcu.edu>

▶ Washington

Inland Northwest Blood Center

210 W. Cataldo Avenue
Spokane, WA 99201

Contact Phone: 800-423-0151 ext. 4444

<http://inbcaves.org>

Seattle Cancer Care Alliance

825 Eastlake Avenue E
Seattle, WA 98109

Contact Phone: 206-288-2167

<http://www.seattlecca.org/diseases-treatments.cfm>

▶ Washington, DC

MedStar Georgetown University Hospital

3800 Reservoir Road N.W.
Washington, DC 20007

Contact: Apheresis Department
Contact Phone: 202-444-3667

<http://www.medstargeorgetown.org/our-services/cancer-care/blood-cancer/conditions/lymphoma/#q={}>

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.

► **West Virginia**

West Virginia University Cancer Institute - Mary Babb Randolph Cancer Center

Health Sciences Center
1 Medical Center Drive
Morgantown, WV 26506
Contact Phone: 304-598-4500
<http://www.wvucancer.org>

► **Wisconsin**

Froedtert Hospital

9200 W. Wisconsin Avenue
Milwaukee, WI 53226
Contact: Apheresis and Transfusion Services
Contact Phone: 414-422-8171
<http://www.froedtert.com/leukemia-lymphoma-myeloma/conditions/lymphoma>

BloodCenter of Wisconsin

638 North 18th Street
Milwaukee, WI 53233
Contact: Therapeutic Apheresis
Contact Phone: 414-937-6154
<https://www.bcw.edu/bcw/Medical-Services-Blood-Products/therapeutic-apheresis-sp/index.htm>

University of Wisconsin Hospital

600 Highland Avenue
Madison, WI 53792
Contact: Infusion Center
Contact Phone: 608-263-8369
<http://www.uwhealth.org/infusion-center/12230>

► **Canada**

CancerCare Manitoba - MacCharles

675 McDermot Avenue
Winnipeg, MB R3E 0V9
Contact: Chemotherapy Department
Contact Phone: 204-787-2197/Toll Free: 1-866-561-1026
<http://www.cancercare.mb.ca/home>

Foothills Medical Centre

Special Services Building, Room 4748
1403 29 Street N.W.
Calgary, AB T2N 2T9
Contact: Apheresis Clinic
Contact Phone: 403-944-4712
<http://www.albertahealthservices.ca/fmc/fmc.aspx>

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.

Hôpital Maisonneuve - Rosemont



5415 Boulevard de l'Assomption
Montréal, QC H1T 2M4

Contact: Apheresis Department
Contact Phone: 514-252-3400 ext. 6589

<http://www.maisonneuve-rosemont.org/pages/H/index.aspx?lang=FR-CA>

Hôpital du Saint-Sacrement

1050 Ch Ste-Foy
Ville de Québec, QC G1S 4L8

Contact Phone: 418-649-0252 ext. 87790

<http://www.chudequebec.ca/centre-hospitaliers/hopital-du-saint-sacrement.aspx>

The Ottawa Hospital

501 Smyth Road
Ottawa, ON K1H 8L6

Contact: Apheresis Department
Contact Phone: 613-798-5555 ext. 70933

<http://www.ottawahospital.on.ca/en>

Royal University Hospital

103 Hospital Drive
Saskatoon, SK S7N 0W8

Contact: Apheresis Services
Contact Phone: 306-655-2522

https://www.saskatoonhealthregion.ca/locations_services/locations/ruh/Pages/Home.aspx

Royal Victoria Hospital - McGill University Health Centre

1001 Boulevard Décarie
Montréal, QC H4A 3J1

Contact: Apheresis Department
Contact Phone: 514-934-1934

<https://muhc.ca/mission/hematology>

University Health Network - Toronto General Hospital Princess Margaret Cancer Centre

610 University Avenue
Toronto, ON M5G 2M9

Contact: Apheresis Unit
Contact Phone: 416-340-3999

http://www.uhn.ca/PrincessMargaret/PatientsFamilies/Clinics_Tests/Apheresis

Vancouver General Hospital - Centennial Pavilion

855 12th Avenue W
Vancouver, BC V5Z 1M9

Contact: Apheresis Unit
Contact Phone: 604-875-4626

http://www.vch.ca/locations-and-services/find-health-services/?program_id=12960

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.

Notes:

Please see Important Safety Information, including **BOXED WARNING**, on page 29, and accompanying full Package Insert.



Notes:

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.

Notes:

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.



Notes:

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.

INDICATIONS AND USAGE

UVADEX® (methoxsalen) Sterile Solution is indicated for extracorporeal administration with the THERAKOS® UVAR XTS® or THERAKOS CELLEX® Photopheresis System in the palliative treatment of the skin manifestations of Cutaneous T-Cell Lymphoma (CTCL) that is unresponsive to other forms of treatment.

IMPORTANT SAFETY INFORMATION

CAUTION: READ THE THERAKOS UVAR XTS or THERAKOS CELLEX PHOTOPHERESIS SYSTEMS' OPERATOR'S MANUAL PRIOR TO PRESCRIBING OR DISPENSING THIS MEDICATION.

UVADEX (methoxsalen) Sterile Solution should be used only by physicians who have special competence in the diagnosis and treatment of cutaneous T-cell lymphoma and who have special training and experience in the THERAKOS UVAR XTS or THERAKOS CELLEX Photopheresis System. Please consult the appropriate Operator's Manual before using this product.

CONTRAINDICATIONS

UVADEX is contraindicated in patients exhibiting idiosyncratic or hypersensitivity reactions to methoxsalen, other psoralen compounds, or any of the excipients. Patients possessing a specific history of a light-sensitive disease state should not initiate methoxsalen therapy.

Diseases associated with photosensitivity include lupus erythematosus, porphyria cutanea tarda, erythropoietic protoporphyria, variegate porphyria, xeroderma pigmentosum, and albinism.

UVADEX is contraindicated in patients with aphakia because of the significantly increased risk of retinal damage due to the absence of lenses.

Patients should not receive UVADEX if they have any contraindications to the photopheresis procedure.

WARNINGS AND PRECAUTIONS

- Patients who are receiving concomitant therapy (either topically or systemically) with known photosensitizing agents such as anthralin, coal tar or coal tar derivatives, griseofulvin, phenothiazines, nalidixic acid, halogenated salicylanilides (bacteriostatic soaps), sulfonamides, tetracyclines, thiazides, and certain organic staining dyes such as methylene blue, toluidine blue, rose bengal, and methyl orange may be at greater risk for photosensitivity reactions with UVADEX
- Oral administration of methoxsalen followed by cutaneous UVA exposure (PUVA therapy) is carcinogenic. Methoxsalen also causes DNA damage, interstrand cross-links and errors in DNA repair
- Methoxsalen may cause fetal harm when given to a pregnant woman. There are no adequate and well-controlled studies of methoxsalen in pregnant women. If UVADEX is used during

pregnancy, or if the patient becomes pregnant while receiving UVADEX, the patient should be apprised of the potential hazard to the fetus. Women of childbearing potential should be advised to avoid becoming pregnant. It is not known whether this drug is excreted in human milk

- After methoxsalen administration, exposure to sunlight and/or ultraviolet radiation may result in "premature aging" of the skin
- Since oral psoralens may increase the risk of skin cancers, monitor closely those patients who exhibit multiple basal cell carcinomas or who have a history of basal cell carcinomas
- Serious burns from either UVA or sunlight (even through window glass) can result if the recommended dosage of methoxsalen is exceeded or precautions are not followed
- Patients should be advised to avoid all exposure to sunlight during the 24 hours following photopheresis treatment
- Exposure to large doses of UVA light causes cataracts in animals. Oral methoxsalen exacerbates this toxicity. Serum methoxsalen concentrations are substantially lower after extracorporeal UVADEX treatment than after oral methoxsalen treatment. Nevertheless, if the lens is exposed to UVA light while methoxsalen is present, photoactivation of the drug may cause adducts to bind to biomolecules within the lens
- Instruct patients emphatically to wear UVA-absorbing, wrap-around sunglasses for 24 hours after UVADEX treatment
- Safety in children has not been established
- Thromboembolic events, such as pulmonary embolism and deep vein thrombosis, have been reported with UVADEX administration through photopheresis systems for treatment of patients with graft-versus-host disease, a disease for which UVADEX is not approved.

ADVERSE REACTIONS

- Side effects of photopheresis (UVADEX used with the THERAKOS Photopheresis System) were primarily related to hypotension secondary to changes in extracorporeal volume (>1%)

For the THERAKOS® UVAR XTS®/CELLEX® Photopheresis Procedure:

INDICATIONS

The THERAKOS UVAR XTS Photopheresis System/THERAKOS CELLEX Photopheresis System is indicated for use in the ultraviolet-A (UVA) irradiation, in the presence of the photoactive drug 8-methoxypsoralen (8-MOP®), of extracorporeally circulating leukocyte-enriched blood, in the palliative treatment of the skin manifestations of cutaneous T-cell lymphoma (CTCL), in persons who have not been responsive to other forms of treatment.

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.



IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

The THERAKOS UVAR XTS or THERAKOS CELLEX Photopheresis Systems are not designated, sold, or intended for use except as indicated.

Certain underlying medical conditions contraindicate THERAKOS Photopheresis, including patients:

- who cannot tolerate extracorporeal volume loss during the leukocyte-enrichment phase
- exhibiting idiosyncratic or hypersensitivity reactions to 8-methoxypsoralen/psoralen compounds
- with coagulation disorders
- who have had previous splenectomy

WARNINGS AND PRECAUTIONS

- THERAKOS Photopheresis treatments should always be performed in locations where standard medical emergency equipment is available. Volume replacement fluids and/or volume expanders should be readily available throughout the procedure
- Patients who may not be able to tolerate the fluid changes associated with extracorporeal photopheresis should be monitored carefully

- Procedures, such as renal dialysis, which might cause significant fluid changes (and expose the patient to additional anticoagulation) should not be performed on the same day as extracorporeal photopheresis

- Individual patients may require a heparin dosage that varies from the recommended dose to prevent post-treatment bleeding or clotting during a treatment

ADVERSE REACTIONS

- Hypotension may occur during any treatment involving extracorporeal circulation. Closely monitor the patient during the entire treatment for hypotension
- Transient pyretic reactions, 37.7-38.9°C (100-102°F), have been observed in some patients within six to eight hours of reinfusion of the photoactivated leukocyte-enriched blood. A temporary increase in erythroderma may accompany the pyretic reaction
- Treatment frequency exceeding labeling recommendations may result in anemia
- Venous access carries a small risk of infection and pain

Please see accompanying Full Prescribing Information, including the BOXED WARNING for UVADEX, and see the appropriate THERAKOS Photopheresis System Operator's Manual.

Please see Important Safety Information, including BOXED WARNING, on page 29, and accompanying full Package Insert.



For more information, please contact a
Mallinckrodt Customer Service Representative
by calling 1-877-566-9466, 24/7.

For patients, please consult your
healthcare provider for more information.

**Please see Important Safety Information, including BOXED WARNING, on page 29,
and accompanying full Package Insert.**



www.therakos.com
Mallinckrodt, the "M" brand mark and the Mallinckrodt Pharmaceuticals
logo are trademarks of a Mallinckrodt company.
Other brands are trademarks of a Mallinckrodt company
or their respective owners.
© 2019 Mallinckrodt. US-1900502 04/19



UVADEX® (Methoxsalen)

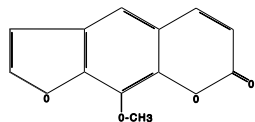
STERILE SOLUTION, 20 mcg/mL
Rx ONLY.

CAUTION: READ THE THERAKOS® UVAR XTS® or THERAKOS® CELLEX® PHOTOPHERESIS SYSTEM OPERATOR'S MANUAL PRIOR TO PRESCRIBING OR DISPENSING THIS MEDICATION.

UVADEX® (methoxsalen) Sterile Solution should be used only by physicians who have special competence in the diagnosis and treatment of cutaneous T-cell lymphoma and who have special training and experience in the THERAKOS® UVAR XTS® or THERAKOS® CELLEX® Photopheresis System. Please consult the appropriate Operator's Manual before using this product.

DESCRIPTION

Methoxsalen is a naturally occurring photoactive substance found in the seeds of the Ammi majus (Umbelliferae) plant. It belongs to a group of compounds known as psoralens or furocoumarins. The chemical name of methoxsalen is 9-methoxy-7H-furo[3,2-g][1]-benzopyran-7-one; it has the following structure:



Each mL of UVADEX® (methoxsalen, 8-methoxypsoralen) Sterile Solution contains methoxsalen 20 mcg, propylene glycol 50 mg, sodium chloride 8 mg, sodium acetate 1.75 mg, ethanol 40.550 mg, glacial acetic acid 1.260 mg, and Water for Injection q.s. to 1.0 mL. Glacial acetic acid and sodium hydroxide are used to adjust the pH of the solution if necessary. UVADEX® is a clear, colorless to pale yellow liquid.

UVADEX® is used in combination with the THERAKOS® UVAR XTS® and THERAKOS® CELLEX® Photopheresis Systems to extracorporeally treat leukocyte enriched buffy coat.

CLINICAL PHARMACOLOGY

Mechanism of action: The exact mechanism of action of methoxsalen is not known. The best-known biochemical reaction of methoxsalen is with DNA. Methoxsalen, upon photoactivation, conjugates and forms covalent bonds with DNA which leads to the formation of both monofunctional (addition to a single strand of DNA) and bifunctional adducts (crosslinking of psoralen to both strands of DNA). Reactions with proteins have also been described. The formation of photoadducts results in inhibition of DNA synthesis, cell division and epidermal turnover.

For the palliative treatment of Cutaneous T-Cell Lymphoma, Photopheresis consists of removing a portion of the patient's blood and separating the red blood cells from the white cell layer (buffy coat) by centrifugation. The red cells are returned to the patient and the UVADEX® Sterile Solution is then injected into the instrument and mixed with the buffy coat. The instrument then irradiates this drug-cell mixture with ultraviolet light (UVA light, 320–400 nm) and returns the treated cells to the patient. See the

appropriate Operator's Manual for details of this process. Although extracorporeal phototherapy exposes less than 10% of the total body burden of malignant cells to methoxsalen plus light, some patients achieve a complete response. Animal studies suggest that the photopheresis may activate an immune-mediated response against the malignant T-cells.

Use of the UVAR and UVAR XTS[®] Systems after oral administration of methoxsalen were previously approved for the treatment of Cutaneous T-Cell Lymphoma. Interpatient variability in peak plasma concentration after an oral dose of methoxsalen ranges from 6 to 15 fold. UVADEX[®] is injected directly into the separated buffy coat in the instrument in an attempt to diminish this interpatient variability and to improve the exposure of the cells to the drug.

Methoxsalen is reversibly bound to serum albumin and is also preferentially taken up by epidermal cells. Methoxsalen is rapidly metabolized in humans, with approximately 95% of the drug excreted as metabolites in the urine within 24 hours.

Systemic administration of methoxsalen followed by UVA exposure leads to cell injury. The most obvious manifestation of this injury after skin exposure is delayed erythema, which may not begin for several hours and peaks at 48–72 hours. The inflammation is followed over several days to weeks, by repair which is manifested by increased melanization of the epidermis and thickening of the stratum corneum.

The total dose of methoxsalen delivered in UVADEX[®] is substantially lower (approximately 200 times) than that used with oral administration. More than 80% of blood samples collected 30 minutes after reinfusion of the photoactivated buffy coat had methoxsalen levels below detection limits of the assay (<10 ng/ml), and the mean plasma methoxsalen concentration was approximately 25 ng/ml.

CLINICAL STUDIES

Three single-arm studies were performed to evaluate the effectiveness of photopheresis in the treatment of the skin manifestations of Cutaneous T-Cell Lymphoma (CTCL). In the first study (CTCL 1), 39 patients were treated with the oral formulation of methoxsalen in conjunction with the UVAR Photopheresis System. The second study (CTCL 2) was a 5-year post approval follow-up of 57 CTCL patients that was conducted to evaluate long-term safety. This study also used the oral dosage formulation of methoxsalen. In the third study (CTCL 3), 51 patients were treated with the UVADEX[®] formulation of methoxsalen in conjunction with the UVAR Photopheresis System. In study CTCL 3, 86% of the patients were Caucasian, the median age was 62 years, and the average number of prior therapies was 4.3.

In study CTCL 1, prednisone up to 10 mg/day was permitted in addition to topical steroids. In CTCL 2, there was no concomitant medication restriction. In CTCL 3, topical steroids were permitted only for the treatment of fissures on the soles of the feet and the palms of hands. All other steroids, topical or systemic, were prohibited.

In all three studies, patients were initially treated on two consecutive days every four to five weeks. If the patient did not respond after four cycles, treatment was accelerated to two consecutive days every other week. If the patient did not respond after four cycles at the accelerated schedule, the patient was treated on two consecutive days every week. If the patient still did not respond after four cycles of weekly treatments, the schedule was increased to three consecutive days every week for three cycles. In study CTCL 3, 15 of the 17 responses were seen within six months of treatment. Only two patients responded

to treatment after six months. Clinical experience does not extend beyond this treatment frequency and there is no evidence to show that treatment with UVADEX[®] beyond six months or using a different schedule provided additional benefit.

Overall skin scores were used in the clinical studies of photopheresis to assess the patient's response to treatment. The patient's baseline skin score was used for comparison with subsequent scores. A 25% reduction in skin score maintained for four consecutive weeks was considered a successful response to photopheresis therapy. Table 1 indicates the percent of successful responses within six months of beginning therapy for all patients who received at least one course of photopheresis. Only patients with patch plaque, extensive plaque and erythrodermic disease were enrolled in these studies. No patients with disease in the tumor phase were treated. There are no data available regarding the efficacy of UVADEX[®] in patients with disease in the tumor phase.

Table 1:
Percentage of Successful Responses Within Six Months of Beginning Therapy

Study	Response % Within Six Months
CTCL 3 (UVADEX [®])	17/51 (33)
CTCL 2 (oral methoxsalen)	16/57 (28)
CTCL 1 (oral methoxsalen)	21/39 (54)

Although the response rate with UVADEX[®] in CTCL 3 was similar to with oral methoxsalen in CTCL 2, the possibility that UVADEX[®] is inferior in efficacy to oral methoxsalen cannot be excluded due to the design and size of the clinical trials. The higher response rate with oral methoxsalen in CTCL 1 may be partly due to patients receiving more treatments (mean of 64 in CTCL 1, 31 in CTCL 2, and 20 in CTCL 3), and to the administration of systemic steroids in CTCL 1.

Retrospective analyses of three clinical benefit parameters from the Body Area Severity Scores in CTCL 3 suggested a correlation between skin score response and improvement in edema, scaling and resolution of fissures.

INDICATIONS AND USAGE

UVADEX[®] (methoxsalen) Sterile Solution is indicated for extracorporeal administration with the THERAKOS[®] UVAR XTS[®] or THERAKOS[®] CELLEX[®] Photopheresis System in the palliative treatment of the skin manifestations of Cutaneous T-Cell Lymphoma (CTCL) that is unresponsive to other forms of treatment.

CONTRAINDICATIONS

PHOTOSENSITIVITY: UVADEX[®] (methoxsalen) Sterile Solution is contraindicated in patients exhibiting idiosyncratic or hypersensitivity reactions to methoxsalen, other psoralen compounds or any of the excipients. Patients possessing a specific history of a light sensitive disease state should not initiate methoxsalen therapy. Diseases associated with photosensitivity include lupus erythematosus, porphyria cutanea tarda, erythropoietic protoporphyria, variegate porphyria, xeroderma pigmentosum and albinism.

UVADEX[®] Sterile Solution is contraindicated in patients with aphakia, because of the significantly increased risk of retinal damage due to the absence of lenses.

Patients should not receive UVADEX[®] if they have any contraindications to the photopheresis procedure.

WARNINGS

Concomitant Therapy: Patients who are receiving concomitant therapy (either topically or systemically) with known photosensitizing agents such as anthralin, coal tar or coal tar derivatives, griseofulvin, phenothiazines, nalidixic acid, halogenated salicylanilides (bacteriostatic soaps), sulfonamides, tetracyclines, thiazides, and certain organic staining dyes such as methylene blue, toluidine blue, rose bengal and methyl orange may be at greater risk for photosensitivity reactions with UVADEX[®].

Carcinogenicity, Mutagenesis, Impairment of Fertility: Oral administration of methoxsalen followed by cutaneous UVA exposure (PUVA therapy) is carcinogenic. In a prospective study of 1380 patients given PUVA therapy for psoriasis, 237 patients developed 1422 cutaneous squamous cell cancers. This observed incidence of cutaneous carcinoma is 17.6 times that expected for the general population. Previous cutaneous exposure to tar and UVB treatment, ionizing radiation or arsenic increased the risk of developing skin carcinomas after PUVA therapy. Because the dose of methoxsalen with UVADEX[®] therapy is about 200 times less than with PUVA and the skin is not exposed to high cumulative doses of UVA light, the risk of developing skin cancer following UVADEX[®] therapy may be lower.

Methoxsalen was carcinogenic in male rats that were given the drug by oral gavage five days per week for 103 weeks at doses of 37.5 and 75 mg/kg. The 37.5 mg/kg dose is about 1900 times greater than a single human methoxsalen dose during extracorporeal photopheresis treatment on a body surface area basis. The neoplastic lesions in rats included adenomas and adenocarcinomas of the tubular epithelium of the kidneys, carcinoma or squamous cell carcinoma of the Zymbal gland and alveolar or bronchiolar adenomas. Topical or intraperitoneal methoxsalen is a potent photo-carcinogen in albino mice and hairless mice.

With S9 activation, methoxsalen is mutagenic in the Ames test. In the absence of S9 activation and UV light, methoxsalen is clastogenic in vitro (sister chromatid exchange and chromosome aberrations in Chinese hamster ovary cells). Methoxsalen also causes DNA damage, interstrand cross-links and errors in DNA repair.

Pregnancy: Methoxsalen may cause fetal harm when given to a pregnant woman. Doses of 80 to 160 mg/kg/day given during organogenesis caused significant fetal toxicity in rats. The lowest of these doses, 80 mg/kg/day, is over 4000 times greater than a single dose of UVADEX[®] on a mg/m² basis. Fetal toxicity was associated with significant maternal weight loss, anorexia and increased relative liver weight. Signs of fetal toxicity included increased fetal mortality, increased resorptions, late fetal death, fewer fetuses per litter, and decreased fetal weight. Methoxsalen caused an increase in skeletal malformation and variations at doses of 80 mg/kg/day and above. There are no adequate and well-controlled studies of methoxsalen in pregnant women. If UVADEX[®] is used during pregnancy, or if the patient becomes pregnant while receiving UVADEX[®], the patient should be apprised of the potential hazard to the fetus. Women of childbearing potential should be advised to avoid becoming pregnant.

PRECAUTIONS

General: *ACTINIC DEGENERATION:*

After methoxsalen administration, exposure to sunlight and/or ultraviolet radiation may result in “premature aging” of the skin.

BASAL CELL CARCINOMAS:

Since oral psoralens may increase the risk of skin cancers, monitor closely those patients who exhibit multiple basal cell carcinomas or who have a history of basal cell carcinomas.

SERIOUS SKIN BURNS:

Serious burns from either UVA or sunlight (even through window glass) can result if the recommended dosage of methoxsalen is exceeded or precautions are not followed. Advise patients to avoid all exposure to sunlight during the 24 hours following photopheresis treatment.

CATARACT FORMATION:

Exposure to large doses of UVA light causes cataracts in animals. Oral methoxsalen exacerbates this toxicity. The concentration of methoxsalen in the human lens is proportional to the concentration in serum. Serum methoxsalen concentrations are substantially lower after extracorporeal UVADEX[®] treatment than after oral methoxsalen treatment. Nevertheless, if the lens is exposed to UVA light while methoxsalen is present, photoactivation of the drug may cause adducts to bind to biomolecules within the lens. If the lens is shielded from UVA light, the methoxsalen will diffuse out of the lens in about 24 hours.

Patients who use proper eye protection after PUVA therapy (oral methoxsalen) appear to have no increased risk of developing cataracts. The incidence of cataracts in these patients five years after their first treatment is about the same as that in the general population.

Instruct patients emphatically to wear UVA absorbing, wrap-around sunglasses for twenty-four (24) hours after UVADEX[®] treatment. They should wear these glasses any time they are exposed to direct or indirect sunlight, whether they are outdoors or exposed through a window.

VENOUS AND ARTERIAL THROMBOEMBOLISM:

Thromboembolic events, such as pulmonary embolism and deep vein thrombosis, have been reported with UVADEX administration through photopheresis systems for treatment of patients with graft-versus-host disease, a disease for which UVADEX is not approved.

Information for Patients:

Patients should be told emphatically to wear UVA-absorbing, wrap-around sunglasses and cover exposed skin or use a sunblock (SP 15 or higher) for the twenty-four (24) hour period following treatment with methoxsalen, whether exposed to direct or indirect sunlight in the open or through a window glass.

Drug Interactions:

See **Warnings** Section.

Carcinogenesis, Mutagenesis, and Impairment of Fertility:

See **Warnings** Section.

Pregnancy:

Pregnancy Category D. See **Warnings** Section.

Nursing Mothers:

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when methoxsalen is administered to a nursing woman.

Pediatric Use:

Safety in children has not been established. Potential hazards of long-term therapy include the possibilities of carcinogenicity and cataractogenicity as described in the Warnings Section as well as the probability of actinic degeneration which is also described in the Warnings Section.

Patients with Renal or Hepatic Impairment

UVADEX[®] has not been evaluated in patients with renal or hepatic impairment

Renal impairment: Although renal transplant recipients with poor renal function have been treated with photopheresis using UVADEX[®], little additional information is available on the use of UVADEX[®] in patients with varying degree of renal impairment. No reduction of dose or prolongation of UV light protection were reported in the renal transplant recipients who have undergone photopheresis treatment.

Hepatic impairment: No specific information is available on the use of photopheresis with UVADEX[®] in patients with hepatic impairment. In view of the very low systemic exposure to methoxsalen, it is unlikely that patients with severe hepatic impairment will be at greater risk than patients with normal hepatic function. However, the potential benefits of photopheresis treatment should be weighed against any possible risk before embarking on the procedure.

ADVERSE REACTIONS

Side effects of photopheresis (UVADEX[®] used with the THERAKOS[®] Photopheresis System) were primarily related to hypotension secondary to changes in extracorporeal volume (>1%). In study CTCL 3 (UVADEX[®]), six serious cardiovascular adverse experiences were reported in five patients (5/51, 10%). Five of these six events were not related to photopheresis and did not interfere with the scheduled photopheresis treatments. One patient (1/51, 2%) with ischemic heart disease had an arrhythmia after the first day of photopheresis that was resolved the next day. Six infections were also reported in five patients. Two of the six events were Hickman catheter infections in one patient, which did not interrupt the scheduled photopheresis. The other four infections were not related to photopheresis and did not interfere with scheduled treatments.

POSTMARKETING: An analysis of postmarketing data shows the following events occurred with an incidence of <0.01%: rash, allergic reaction, pyrexia, nausea, dysgeusia.

OVERDOSAGE

There are no known reports of overdose with extracorporeal administration of methoxsalen. However, in the event of overdose, the patient should be kept in a darkened room for at least 24 hours.

DRUG DOSAGE AND ADMINISTRATION

Each UVADEX[®] treatment involves collection of leukocytes, photoactivation, and reinfusion of photoactivated cells. UVADEX[®] (methoxsalen) Sterile Solution is supplied in 10 mL vials containing 200 mcg of methoxsalen (concentration of 20 mcg/mL). The THERAKOS[®] UVAR XTS[®] or THERAKOS[®] CELLEX[®] Photopheresis System Operator's Manual should be consulted before using this product. UVADEX[®] should not be diluted. The contents of the vial should be injected into the THERAKOS[®] UVAR

XTS[®] or THERAKOS[®] CELLEX[®] Photopheresis System immediately after being drawn up into a syringe. Do not inject directly into patients. The UVADEX[®] vial is for single use only. Any UVADEX[®] that is not used during a procedure should be immediately discarded. UVADEX[®] can adsorb onto PVC and plastics, therefore only THERAKOS[®] UVAR XTS[®] or THERAKOS[®] CELLEX[®] photopheresis procedural kits supplied for use with the instrument should be used to administer this medicinal product. Once UVADEX[®] is drawn into a plastic syringe it should be immediately injected into the photoactivation bag. UVADEX[®] exposed to a plastic syringe for more than one hour should be discarded.

During treatment with the THERAKOS[®] UVAR XTS[®] or THERAKOS[®] CELLEX[®] Photopheresis System, the dosage of UVADEX[®] for each treatment will be calculated according to the treatment volume.

- The prescribed amount of UVADEX[®] should be injected into the recirculation bag prior to the Photoactivation Phase using the formula:

$TREATMENT\ VOLUME \times 0.017 = \text{mL of UVADEX}^{\text{®}}$ for each treatment

Example: Treatment volume of 240 mL X 0.017 = 4.1 mL of UVADEX[®]

Frequency/Schedule of Treatment:

Normal Treatment Schedule: Treatment is given on two consecutive days every four weeks for a minimum of seven treatment cycles (six months).

Accelerated Treatment Schedule: If the assessment of the patient during the fourth treatment cycle (approximately three months) reveals an increased skin score from the baseline score, the frequency of treatment may be increased to two consecutive treatments every two weeks. If a 25% improvement in the skin score is attained after four consecutive weeks, the regular treatment schedule may resume. Patients who are maintained in the accelerated treatment schedule may receive a maximum of 20 cycles. There is no clinical evidence to show that treatment with UVADEX[®] beyond six months or using a different schedule provides additional benefit. In study CTCL 3, 15 of the 17 responses were seen within six months of treatment and only two patients responded to treatment after six months.

HOW SUPPLIED

UVADEX[®] (methoxsalen) Sterile Solution 20 mcg/mL in 10 mL amber glass vials (NDC 64067-216-01), and cartons of 12 vials (NDC 64067-216-01). One vial of 10 mL contains 200 micrograms methoxsalen. The drug product must be stored between 59°F (15°C) and 86°F (30°C)

REFERENCES

1. Recommendations for the Safe Handling of Parenteral Antineoplastic Drugs, NIH Publication No. 83-2621. For sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.
2. AMA Council Report, Guidelines for Handling of Parenteral Antineoplastics. JAMA, 1985; 2.53 (11): 1590–1592.
3. National Study Commission on Cytotoxic Exposure- Recommendations for Handling Cytotoxic Agents. Available from Louis P. Jeffrey, ScD., Chairman, National Study Commission on Cytotoxic Exposure, Massachusetts College of Pharmacy and Allied Health Sciences, 179 Longwood Avenue, Boston, Massachusetts 02115.
4. Clinical Oncological Society of Australia, Guidelines and Recommendations for Safe Handling of

Antineoplastic Agents. Med J Australia, 1983; 1:426–428.

5. Jones, RB, et al. Safe Handling of Chemotherapeutic Agents: A Report from The Mount Sinai Medical Center. CA- A Cancer Journal for Clinicians, 1983;(Sept/Oct) 258–263.
6. American Society of Hospital Pharmacists Technical Assistance Bulletin of Handling Cytotoxic and Hazardous Drugs. Am J. Hosp Pharm, 1990;47:1033–1049.
7. Controlling Occupational Exposure to Hazardous Drugs. (OSHA Work-Practice Guidelines), AM J. Health-Syst Pharm, 1996; 53: 1669–1685.

January 2018

NDA 20-969

1460544E_US

Manufactured by Patheon Manufacturing Services LLC, Greenville, NC 27834

For Therakos, Inc., 10 North High Street, Suite 300, West Chester, PA 19380-3014 USA