



Mallinckrodt
Pharmaceuticals

THERAKOS® Photopheresis Patient Assistance Program



*Not an
actual patient.*

The information below is about the use of UVADEX® (methoxsalen) Sterile Solution with the THERAKOS® UVAR XTS® or THERAKOS CELLEX® Photopheresis Systems for the treatment of skin conditions associated with Cutaneous T-Cell Lymphoma (CTCL).

It is recommended that you discuss the therapy and your conditions with your doctor.

What is UVADEX (methoxsalen [meth-ox-sah-len]) Sterile Solution?

UVADEX (methoxsalen) Sterile Solution is used with the THERAKOS UVAR XTS or THERAKOS CELLEX Photopheresis Systems for the treatment of skin problems associated with CTCL in patients who have not responded to other types of treatment given by their doctor.

IMPORTANT SAFETY INFORMATION

UVADEX (methoxsalen) Sterile Solution should only be used by doctors who have special skills in the diagnosis and treatment of CTCL and who have received special training and have experience in the THERAKOS UVAR XTS or THERAKOS CELLEX Photopheresis Systems.

DO NOT USE UVADEX IF:

- You are allergic to methoxsalen, any product similar or related to it, such as psoralen, or any of the other ingredients in UVADEX.
- You have a history of a light-sensitive condition or disease.
- You have had an eye lens removed; use of UVADEX in this condition can increase the risk of retinal damage.

Please see additional Important Safety Information inside this brochure and accompanying Prescribing Information, including BOXED WARNING, for UVADEX.

For information on the Therakos Photopheresis System please ask your healthcare professional.



Help to Access THERAKOS® Photopheresis Therapy

The THERAKOS® Photopheresis Patient Assistance Program can provide support for eligible patients who cannot afford their prescribed therapy. It also serves as a central point of communication and coordination between healthcare professionals and Mallinckrodt Pharmaceuticals so that therapy may be initiated as soon as possible, and patients and caregivers are engaged and informed at every step along the way.

This program is administered for Mallinckrodt Pharmaceuticals by the National Organization for Rare Disorders (NORD), a nonprofit organization that has been serving the rare disease community with distinction for more than 35 years.



Please see additional Important Safety Information and the accompanying Full Prescribing Information, including the BOXED WARNING, for UVADEX.

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About NORD

NORD is an independent charity dedicated to the identification, treatment, and cure of rare diseases through education, advocacy, research, and patient/family services. NORD administers Patient Assistance Programs to help qualifying patients access therapies prescribed by their physicians.



Not actual patients.

About the THERAKOS® Photopheresis Patient Assistance Program

Available to eligible patients who do not have public or private prescription drug coverage and who meet income guidelines and other eligibility criteria

- ▶ No application fee
- ▶ Free product for a limited time for patients who meet income guidelines and other eligibility criteria
- ▶ Approved patients are enrolled for for a limited time and must reapply for continued assistance
- ▶ Patients must live in the United States

NORD is responsible for making all determinations of patient eligibility under this program.

Participation in this program is available by request only and subject to verification of financial need. NORD and Mallinckrodt Pharmaceuticals reserve the right to modify or discontinue the program at any time within their sole discretion.

Please see additional Important Safety Information and the accompanying Full Prescribing Information, including the BOXED WARNING, for UVADEX.

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IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS

- You may be at greater risk of sun sensitivity with UVADEX. Tell your doctor if you are taking other medications that cause sensitivity to sunlight, 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.
- If you are pregnant or plan to become pregnant, tell your doctor. Methoxsalen can harm your unborn baby. Tell your doctor right away if you become pregnant during your UVADEX treatment. If you are breastfeeding or plan to breastfeed, tell your doctor. It is not known if methoxsalen passes into your breastmilk.
- After UVADEX is given, exposure to sunlight and/or ultraviolet radiation may result in premature aging of your skin.
- Let your doctor know if you currently have skin cancer or if you had skin cancer in the past.



Not actual patients.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS

- If you are given too much UVADEX, you may get serious burns from UVA or sunlight (even through window glass).
- Avoid exposure to sunlight during the 24 hours after treatment.
- Exposure to UVA light when UVADEX is used can cause cataract formation if proper eye protection is not used.
- You must wear UVA light-absorbing, wrap-around sunglasses for the 24 hours after treatment with UVADEX when you are exposed to direct or indirect sunlight, whether you are outdoors or exposed through a window.
- If you are being treated for Graft vs Host Disease (GVHD), consult your physician for information regarding blood clots involving the lung and other parts of the body which have been reported in these patients. The use of UVADEX for the treatment of GVHD is not approved by the FDA.
- Safety of UVADEX in children has not been shown.

SIDE EFFECTS OF UVADEX

- Side effects of UVADEX used with the THERAKOS Photopheresis Systems are mainly related to low blood pressure.

For the THERAKOS UVAR XTS/CELLEX Photopheresis Systems procedure:

What is the THERAKOS Photopheresis Systems procedure?

The THERAKOS UVAR XTS/CELLEX Photopheresis Systems procedure is a medical procedure in which blood from a patient is collected into a specialized machine that separates the white blood cells from the other blood components. The other blood components are returned to the patient and white blood cells are then treated with UVADEX, which makes them sensitive to ultraviolet light. The treated white blood cells are exposed to UVA irradiation inside the machine, and then returned to the patient. This medical procedure is used to treat skin problems associated with CTCL in patients who have not been responsive to other forms of treatment given by their doctor.

DO NOT UNDERGO THE THERAKOS PHOTOPHERESIS SYSTEMS PROCEDURE IF:

- You have a condition that makes you unable to tolerate loss of blood volume.
- You are allergic or hypersensitive to 8-methoxypsoralen, methoxsalen, or psoralen compounds.

- Your doctor has diagnosed you with a blood-clotting or bleeding problem that can lead to either a blood clot or excessive bleeding.
- You have had your spleen removed.

WARNINGS FOR THE THERAKOS PHOTOPHERESIS SYSTEMS PROCEDURE

- Treatments with THERAKOS Photopheresis Systems should always be performed where standard medical emergency equipment is available.
- THERAKOS Photopheresis Systems procedures should not be performed on the same day as procedures that can cause fluid changes, such as renal dialysis.

SIDE EFFECTS OF THE THERAKOS PHOTOPHERESIS SYSTEMS PROCEDURE

- Low blood pressure can occur with the THERAKOS Photopheresis Systems procedure.
- You may get an infection and/or feel pain at the site of injection.
- Fevers of 100-102°F (37.7-38.9°C) have been seen in some patients within 6 to 8 hours after treatment. Redness of the skin may also occur with the fever.
- A decrease in red blood cells can occur if the THERAKOS Photopheresis Systems procedure is given too frequently. Low levels of red blood cells may cause you to feel tired.

These are not all of the possible side effects of the THERAKOS Photopheresis Systems procedure.

Tell your doctor about any side effects that bother you, or that do not go away. Call your doctor or pharmacist for medical advice about side effects. You may report side effects to the FDA. Call 1-800-FDA-1088 or visit www.fda.gov/medwatch. You may also report side effects by calling Mallinckrodt at 1-800-778-7898.

Please see the accompanying Full Prescribing Information, including the BOXED WARNING, for UVADEX.

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To learn more about the THERAKOS® Photopheresis Patient Assistance Program, visit NORD's website at www.rarediseases.org or call: 1-877-241-7220 Monday-Friday, 9:00 AM to 5:00 PM ET

You may also write to NORD at: NORD,
55 Kenosia Avenue, Danbury, CT 06810
or email: photopheresis@rarediseases.org

Please visit www.therakos.com for more information.

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