

Understanding Treatment With THERAKOS® Photopheresis

THERAKOS® Photopheresis is a type of immunotherapy¹



THERAKOS® Photopheresis is a type of treatment called immunotherapy.¹

Immunotherapy is not chemotherapy or radiation.¹



Immunotherapy works by **helping** the body's own immune system fight cancer.¹

Immunotherapies take time to activate the immune system response.²



The information below is about the use of UVADEX® (methoxsalen) Sterile Solution with the THERAKOS® CELLEX® Photopheresis System 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) Sterile Solution?

UVADEX (methoxsalen) Sterile Solution is used with the THERAKOS CELLEX Photopheresis System 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 CELLEX Photopheresis System.

SIDE EFFECTS OF THE THERAKOS PHOTOPHERESIS SYSTEM PROCEDURE

- Low blood pressure can occur with the THERAKOS Photopheresis System 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.

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

Please see additional Important Safety Information on back and accompanying Full Prescribing Information, including the BOXED WARNING for UVADEX. It is recommended that you discuss the therapy and your conditions with your doctor.

THERAKOS® Photopheresis treats from the inside out*



CTCL skin symptoms are on the outside of the body, but CTCL cells may also be found in the blood, bone marrow, lymph nodes, and some organs.¹

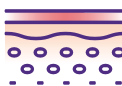


Going inside the body with immunotherapy to target the source of outside symptoms may help CTCL skin symptoms.

What happens inside the body:



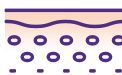
In CTCL, cancerous T-cells grow at a faster rate and suppress normal T-cells. The result is an imbalance of cancer cells and cancer-fighting cells.¹



More cancer cells accumulate, causing skin symptoms like redness, scaling, flaking, and itching.¹



CTCL immunotherapy helps to restore balance to the immune response.¹

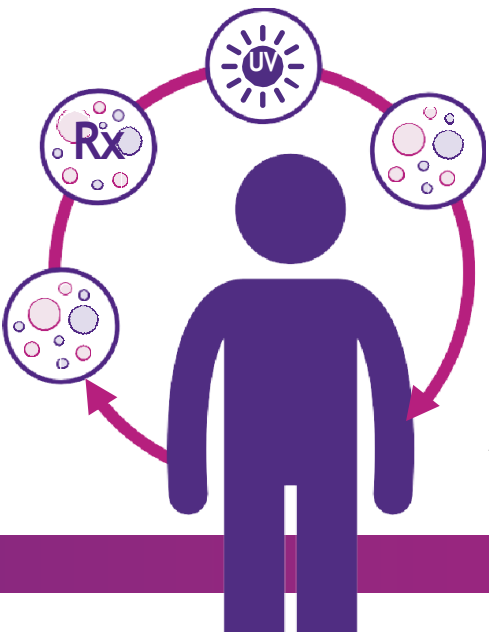


Over time, as more healthy immune cells take over, CTCL skin symptoms may improve.³

THERAKOS® Photopheresis involves¹:

- Collecting a small amount of blood, which contains white blood cells
- Treating the cells with a medication that is activated by UV light
- Returning the treated cells back into the body
- Repeating the process regularly for up to 6 months³

*The exact way it works is not known.



Treatment with THERAKOS® Photopheresis may take up to 6 months³



A change in the immune system may not be visible right away. It may take up to 6 months of treatment with **THERAKOS® Photopheresis** before skin symptoms begin to improve.^{3†}



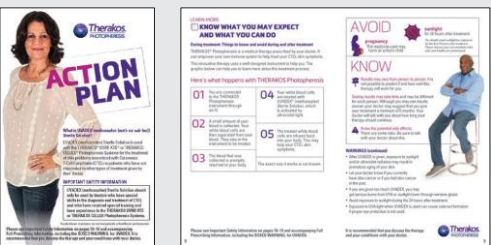
Consider taking photos of your skin throughout the treatment period to share with your healthcare team at each **THERAKOS® Photopheresis** treatment.



If you have any questions, be sure to ask your healthcare team. Each **THERAKOS® Photopheresis** treatment is another opportunity to get answers.



Stick with your doctor's recommended number of **THERAKOS® Photopheresis** treatments. Every treatment could be progress toward potential skin symptom improvement.



Download a treatment Action Plan at
<http://patient.therakos.com/plan/>

†Results may vary from person to person. It is not possible to predict if and how well this therapy will work for you.

Stick with your doctor's treatment plan

My friends and family
saw a change.
My skin was less red.

Staying with treatment
helps get results

Individual results may vary.
Lou, an actual patient, was compensated
for his time in sharing his story.



The information below is about the use of UVADEX® (methoxsalen) Sterile Solution with the THERAKOS® CELLEX® Photopheresis System 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) Sterile Solution?

UVADEX (methoxsalen) Sterile Solution is used with the THERAKOS CELLEX Photopheresis System 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 CELLEX Photopheresis System.

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.

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 breast milk.
- 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.
- 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 THERAKOS Photopheresis System are mainly related to low blood pressure.

For the THERAKOS CELLEX Photopheresis System procedure:

What is the THERAKOS Photopheresis System procedure?

The THERAKOS CELLEX Photopheresis System 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 SYSTEM 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 SYSTEM PROCEDURE

- Treatments with THERAKOS Photopheresis System should always be performed where standard medical emergency equipment is available.
- THERAKOS Photopheresis System procedure 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 SYSTEM PROCEDURE

- Low blood pressure can occur with the THERAKOS Photopheresis System 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 System 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 System 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 1-877-566-9466.

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

References 1. Leukemia & Lymphoma Society. Cutaneous T-Cell Lymphoma facts. https://www.lls.org/sites/default/files/file_assets/cutaneoustcellymphoma.pdf. Accessed February 7, 2023. 2. Oncolink.org. Trustees of the University of Pennsylvania, 2022. All about immunotherapy. <https://www.oncolink.org/cancer-treatment/immunotherapy/all-about-immunotherapy>. Accessed February 6, 2023. 3. Shiue LH, Couturier J, Lewis DE, Wei C, Ni X, Duvic M. The effect of extracorporeal photopheresis alone or in combination therapy on circulating CD4+Foxp3+CD25- T-cells in patients with leukemic cutaneous T-cell lymphoma. *Photodermatol Photoimmunol Photomed*. 2015;31(4):184-194. doi:10.1111/php.12175.

Please see Important Safety Information on adjacent pages and accompanying Full Prescribing Information, including the BOXED WARNING, for UVADEX. It is recommended that you discuss the therapy and your conditions with your doctor.

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.
© 2023 Mallinckrodt. US-2300061 02/23

