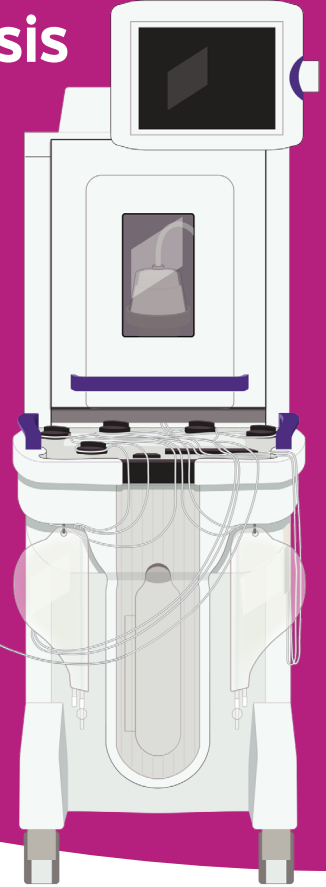


Understanding **THERAKOS[®] Photopheresis** and CTCL* Skin Symptoms



*Cutaneous T-Cell Lymphoma

What is UVADEX (methoxsalen [meth-ox-sah-len]) 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.

SELECT 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:

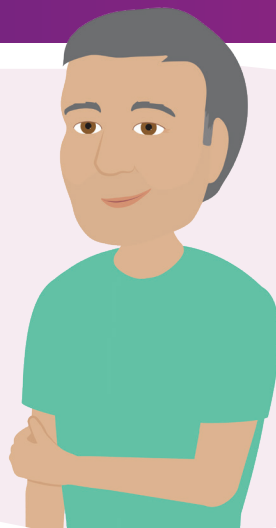
- You are allergic to methoxsalen, any product similar or related to it, such as psoralen, or any of the other ingredients in UVADEX.
- You have a history of a light-sensitive condition or disease.
- You have had an eye lens removed; use of UVADEX in this condition can increase the risk of retinal damage.

Please see Important Safety Information on pages 6-7 and the [Full Prescribing Information](#), including the **BOXED WARNING, for UVADEX. It is recommended that you discuss the therapy and your conditions with your doctor.**

LIVING WITH CTCL Skin Symptoms

As you know, CTCL skin symptoms can have a big impact on you. You may have experienced skin changes such as rash, peeling, redness, burning, itching and pain. These skin symptoms can be burdensome.

If you are not getting relief from your current medication, it may be time for you and your doctor to consider a different type of treatment.



TREATING the Skin Symptoms of CTCL

There are two main types of treatment for the skin symptoms of CTCL:

Skin-directed treatments

target skin lesions.

- Ultraviolet (UV) light
- Steroids
- Local radiation
- Chemotherapy
- Retinoids (put on the skin)

Systemic treatments

work throughout the body.

- Photopheresis
- Retinoids (taken by mouth)
- Interferon
- Chemotherapy

There are no treatments that can cure CTCL. Some treatments, though, are able to help manage the skin symptoms.

SELECT IMPORTANT SAFETY INFORMATION

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.

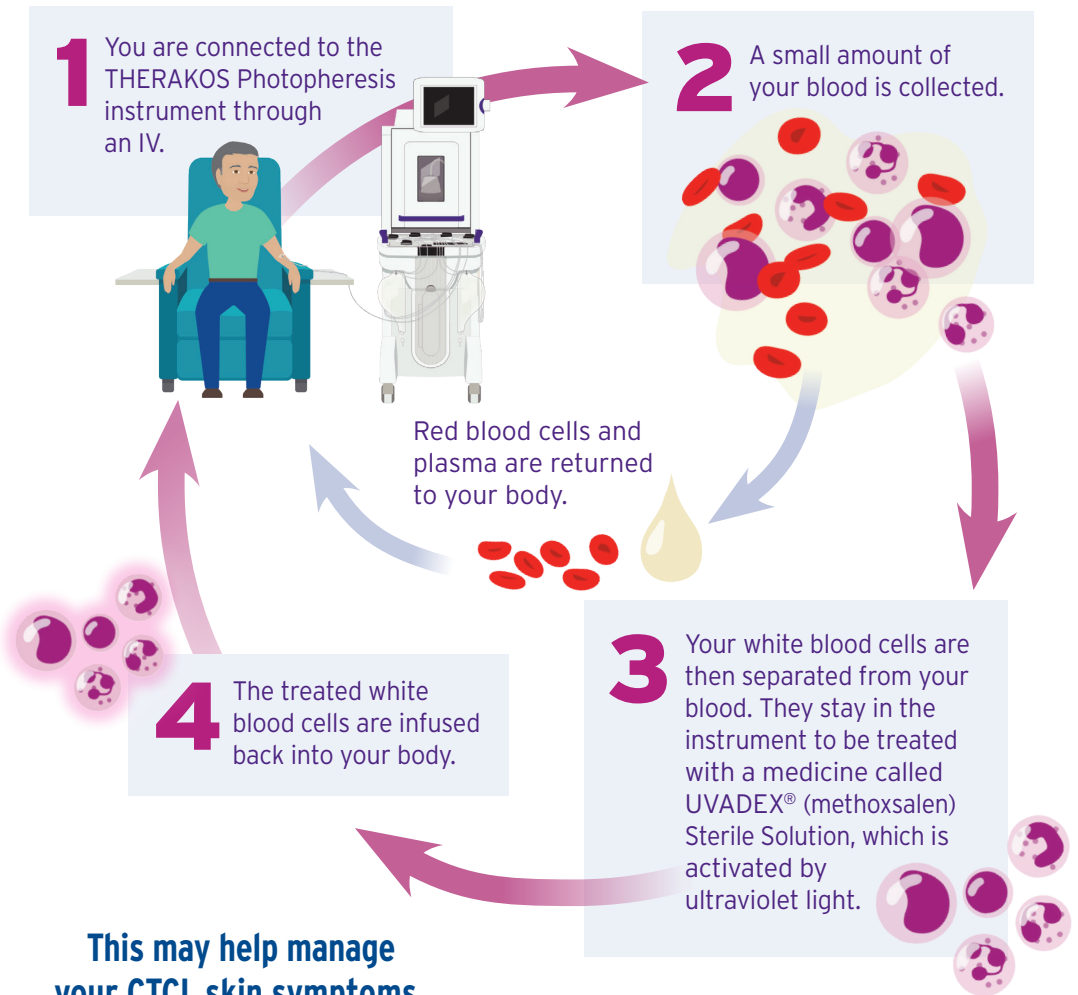
Please see Important Safety Information on pages 6-7 and the [Full Prescribing Information](#), including the **BOXED WARNING, for UVADEX.**

THERAKOS® PHOTOPHERESIS works differently

What is THERAKOS Photopheresis?

THERAKOS Photopheresis is a type of immunotherapy. It can harness the power of your own immune system to help treat your CTCL skin symptoms from the inside out by treating cells in your blood.

What happens during treatment with THERAKOS Photopheresis?



This may help manage your CTCL skin symptoms.

The exact way that THERAKOS Photopheresis works is not known.

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

PREPARING for treatment

WHAT DO I NEED TO KNOW?



For most people*, treatment:

- Happens **2 days** in a row, every 4 weeks
- Lasts about **2 hours** each visit

*Treatment times and duration can vary.

You do not need to bring someone with you for your treatment visits. Each person is different though. You may wish to bring a friend or family member to help pass the time or keep you company.

Following these rules can help the process go as smoothly as possible:

2 Days Before



Drink plenty of fluids such as water or juice



Avoid caffeine and alcohol

The Night Before



Eat a low-fat, healthy meal that may include fruit, vegetables, whole grains (like oatmeal), low-fat or fat-free dairy (like yogurt), and protein (like fish, lean meat and chicken, nuts, beans)



Avoid high-fat foods such as cream, meat, fried food, cheese, and butter

Day of Treatment



Eat a low-fat breakfast and lunch



Visit the restroom right before treatment starts



Consider bringing something to help pass the time, like a book or a laptop. You can also take a nap during treatment



Bring wrap-around sunglasses that protect from UVA light

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS (continued)


- 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.


Please see Important Safety Information on pages 6-7 and the [Full Prescribing Information](#), including the **BOXED WARNING**, for UVADEX.


DURING & AFTER Treatment

WHAT CAN I EXPECT?


During treatment you may feel:


 A slight pulsing from the instrument


 A slight chill or cold feeling where your blood re-enters your body


 Keep your healthcare team informed about how you are feeling throughout treatment.

Be sure to talk to your healthcare team if at any time you feel:

 Dizzy or weak


 Pain at the injection site


 More tired than normal

 Feverish or have redness of your skin

What to expect after treatment:

Once the treatment is done, you are able to go home.

 **Important!** You should avoid sunlight/sun exposure for the first 24 hours after your treatment. Please discuss your skin sensitivity risks with your healthcare professional.

 Keep in mind that results may vary from person to person. Although you may see results sooner, your doctor may suggest that you receive treatment for a minimum of 6 months.

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS (continued)

- 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.

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

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 [meth-ox-sah-len]) 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 the THERAKOS Photopheresis System are mainly related to low blood pressure.

For the THERAKOS CELLEX Photopheresis System procedure:

What is the THERAKOS Photopheresis Systems 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 [Full Prescribing Information](#), including the **BOXED WARNING, for UVADEX.**