CTCL Skin Symptoms Chat: Appointment Prep 101



You've been told that your skin symptoms are from CTCL— Cutaneous T-Cell Lymphoma. A good step in managingthe symptoms is partnering with your doctor to discuss your care plan.

You can use this discussion guide to help you prep for your next appointment and make the most of your conversation with your doctor. See if photopheresis may be right for you.



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.

Please see additional Important Safety Information on pages 4-5 and click here for the full <u>Prescribing</u> <u>Information</u>, including the BOXED WARNING, for UVADEX. It is recommended that you discuss the therapy and your conditions with your doctor.

Things to tell your do	ctor			
Fill out this section to give your c you and what you have done to m		a of how your CTCL skin sy	mptoms affect	
1. What CTCL skin symptoms are	e you experiencir	ıg?		
Red rash	Pain		Other:	
Dry, red, scaly patches	Skin-thick	ening on palms and soles		
Itchiness			_	
2. Where are you having sympto	ms?			
Scalp	Back		Feet	
Face	Hands		Groin	
Neck	Arms		Other:	
Chest	Legs			
Stomach				
3. How often are you experienci	ng CTCL skin syn	nptoms?		
Constant	Other:			
Weekly				
Monthly				
4. What treatments have you be	_			
Skin-directed therapy (for ex Please list all treatments that yo				,
Please list all treatments that yo	u nave been presch	ieu and chcle those nom your	nst that you are <u>cu</u>	<u>nentiy</u> taking.
Systemic therapy (for examp	le, photopheresis,	biologics, chemotherapy)		
Please list all treatments that yo	u have been prescrib	ped and circle those from your	list that you are <u>cu</u>	<u>rrently</u> taking.
Other				
Please list any other treatments	that you have been	prescribed and circle those from	m your list that you	ı are <u>currently</u> taking.

Things to ask your doctor

Not sure what to ask? Use these questions to help you talk with your doctor about your CTCL skin symptoms and, if you have been unresponsive to other treatments, discuss if photopheresis may be a possible option for you.



About CTCL Skin Symptoms:

- What is CTCL?
- What causes CTCL skin symptoms?
- Is CTCL common?
- Is there a cure for CTCL skin symptoms?
- What percentage of your patients have CTCL skin symptoms?
- How should I care for my skin day-to-day?
- What should I look for/avoid in skincare products?

About Photopheresis Treatment:

- Am I a candidate for photopheresis?
- How would I prepare for photopheresis treatment?
- What does the procedure feel like? Is it painful?
- What happens to the blood during the photopheresis process?
- How long would I be on photopheresis?
- What is the treatment schedule? How long does each treatment take?
- What are the possible side effects of photopheresis?
- How soon could I expect to see a response in my skin symptoms?
- Would the cost of photopheresis be covered by my insurance?

Other questions:

To learn more about CTCL skin symptoms or for more information on THERAKOS® CELLEX® Photopheresis System, please talk to your doctor and visit www.therakos.com.

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What is UVADEX (methoxsalen) Sterile Solution?

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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.

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.

IMPORTANT SAFETY INFORMATION (continued)

For the THERAKOS CELLEX Photopheresis Systems 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 SYSTEMS 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 SYSTEMS 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 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 1-800-844-2830.

Please click for the full <u>Prescribing Information</u>.



