

PATIENT INFORMATION ON THE USE OF OXSORALEN-ULTRA[®] CAPSULES (METHOXSALEN, 10 mg) IN THE TREATMENT OF PSORIASIS

This brochure is intended to provide you with information about the treatment of psoriasis. The entire brochure should be read so that you are aware of the requirements on your part to ensure the effectiveness and safety of the therapy. Any additional questions that you may have can be answered by your doctor or pharmacist. In addition, the pharmacist will have a copy of a very technical brochure entitled the "Physician's Package Insert" that you may wish to read.

A. What Is Oxсорalen-Ultra (Methoxsalen)?

Oxсорalen-Ultra (methoxsalen) is a drug which has been shown to be effective in the treatment of psoriasis when combined with exposure to a very specific kind of light. The use of the drug must be combined with exposure to the special light to produce effective therapy. Oxсорalen-Ultra represents a new dose form of methoxsalen. This new dosage form of methoxsalen exhibits significantly greater bioavailability and earlier photosensitization onset time than previous methoxsalen dosage forms.

B. What Is The Special Light?

Light is classified into many different parts. One part is known as ultraviolet light, which is a normal component of sunlight. Artificial or man-made light sources are now available that produce the special part of light (ultraviolet "A") necessary for the most effective therapy.

C. What Is "PUVA"?

"PUVA" is the name of the treatment for psoriasis and stands for the use of Psoralen drug (Oxсорalen-Ultra) in combination with UltraViolet A light.

D. What Is Psoriasis?

Psoriasis is a skin condition associated with red and scaly patches. The cause of psoriasis is not known. PUVA (Oxсорalen-Ultra with ultraviolet A light) is used for the treatment of severe psoriasis that has not been helped by other methods of therapy.

E. What Should The Patient Do Before PUVA Therapy?

Certain other medicines can make you more sensitive to the combination drug and light treatment. In addition, certain other medical conditions can be aggravated by this treatment. Before starting treatment, be sure to tell your doctor if you have experienced any of the following:

- 1) had a severe reaction to Oxсорalen-Ultra in the past
- 2) had recent x-ray treatment or planning any
- 3) have or ever have had skin cancer
- 4) have or ever have had any eye problems such as cataracts or loss of the lens of the eyes
- 5) have or ever have had liver problems
- 6) have or ever have had heart or blood pressure problems
- 7) have any medical condition that requires you to stay out of the sun such as lupus erythematosus
- 8) are taking any drugs (either prescription or nonprescription). Some drugs can increase your sensitivity to ultraviolet light either from the sun or man-made sources. Examples of such drugs include major tranquilizers, sulfa drugs for the treatment of infection or diabetes, tetracycline, antibiotics, griseofulvin products, thiazide-containing diuretics (blood pressure or water elimination drugs), and certain antibacterial or deodorant soaps.

F. How Should The Patient Take Oxsoralen-Ultra?

- 1) The number of capsules recommended by your doctor should be taken with some food or lowfat milk two hours before ultraviolet light treatment.
- 2) Oxsoralen-Ultra is a potent drug. Never take more than is prescribed for you since it may result in burning and/or blistering of your skin after exposure to ultraviolet light.

G. What Precautions Should Be Taken During And After PUVA Therapy?

- 1) Eye Protection — Make sure that you wear special wrap-around sunglasses that totally block or absorb ultraviolet light. Put them on immediately after taking Oxsoralen-Ultra and continue wearing them for 24 hours if any light is present (even if indirect such as reflection or through window glass). Ordinary sunglasses are not adequate.
- 2) Skin & Lip Protection — Do not allow exposure of your skin and lips to sunlight for 8 hours after treatment. In addition, do not expose your skin to either sunlight or sun lamps (regardless of safety claims) within 24 hours of a scheduled treatment. It is advisable to wear protective clothing (hat, gloves) to cover as much of your body as possible after treatment as well as using a sun screen product having a protection factor of at least 15 (only use after treatment).

H. How Long Will The Treatments Last?

May take from six to eight weeks before lesions disappear. Maintenance treatments are usually needed to keep the disease under control.

I. What Are The Problems Associated With Pregnancy Or Breast Feeding?

- 1) Birth control methods should be employed since the effects of PUVA therapy on the unborn child are not known. If you become pregnant, inform your doctor so that he can determine whether it is necessary for you to temporarily stop therapy.
- 2) Since it is not known whether Oxsoralen-Ultra passes into mother's milk, it is safer not to breast feed while taking this drug.

J. What Are The Risks Of PUVA Therapy?

- 1) Premature skin aging may result from prolonged PUVA therapy, especially with those individuals who tan poorly. This problem is similar to excessive exposure to sunlight.
- 2) There is an increased risk of developing both melanoma and non-melanoma skin cancer. This risk is greater for individuals who fall into the following categories:
 - a) fair skin that burns rather than tans
 - b) have had prior treatment with x-rays, grenz rays, or arsenic
 - c) have had coal tar and UltraViolet B (UVB) treatment.Even though your doctor will be examining you, you should routinely and completely examine yourself for small growths on your skin or skin sores that will not heal. Immediately report such observations to your doctor.
- 3) Since studies have shown that animals with unprotected eyes have developed cataracts after PUVA therapy, you should have your eyes examined by an ophthalmologist before starting PUVA therapy, after the first year of therapy and every two years thereafter.

K. What Are The Possible Side Effects?

- 1) The most common side effects of PUVA therapy are nausea, itching, and redness of the skin. The use of lowfat milk or food when ingesting the drug may prevent the nausea.
- 2) Tenderness or blistering of the skin may occur, but these symptoms can be helped by the use of skin products recommended by your doctor or pharmacist.
- 3) Less frequent side effects include depression, dizziness, headache, swelling, rash or leg cramps. Important: Contact your doctor if any side effect continues to bother you after 24-48 hours.

L. What Else Should The Patient Know?

- 1) Remember to take Oxsoralen-Ultra as directed by your doctor. If you forget to take the drug before your scheduled treatment, be sure to call your doctor to determine what he wishes you to do.
- 2) Remember that the drug has been prescribed specifically for you and your diagnosed condition. Do not use the drug for any other conditions nor give the drug to others even if they have similar symptoms.
- 3) If you think that you or anyone else has accidentally taken an overdose, stay out of the sunlight and immediately contact your poison control center, doctor, pharmacist, or nearest hospital emergency room.
- 4) ALWAYS KEEP THIS DRUG AND ALL OTHER DRUGS OUT OF THE REACH OF CHILDREN.
- 5) Store at 25°C (77°F); excursions permitted to 15°C-30°C (59°F-86°F).

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