

J. Iverson Riddle Developmental Center

Patient Education Monograph

IMPORTANT NOTE: THE FOLLOWING INFORMATION IS INTENDED TO SUPPLEMENT, NOT SUBSTITUTE FOR, THE EXPERTISE AND JUDGEMENT OF YOUR PHYSICIAN, PHARMACIST OR OTHER HEALTHCARE PROFESSIONAL. IT SHOULD NOT BE CONSTRUED TO INDICATE THAT USE OF THE DRUG IS SAFE, APPROPRIATE, OR EFFECTIVE FOR YOU. CONSULT YOUR HEALTHCARE PROFESSIONAL BEFORE USING THIS DRUG.

METHOXSALEN - ORAL

USES: This medication is used along with controlled ultraviolet light (UVA) to help control severe psoriasis. It may also be used for other skin conditions (vitiligo, cutaneous T-cell lymphoma-CTCL). Methoxsalen works by making the skin more sensitive to UVA light. For the treatment of psoriasis, this combination helps to slow the overgrowth of skin cells. For the treatment of vitiligo, this combination helps to increase the number of pigment-producing cells (melanocytes) in the skin.

- This medication is not recommended for use in children younger than 12 years.

HOW TO USE: Read the Patient Information Leaflet if available from your pharmacist before you start taking methoxsalen and each time you get a refill. If you have any questions, ask your doctor or pharmacist.

- Do not sunbathe for 24 hours before taking methoxsalen and having the UVA light treatment.
- Take this medication by mouth with food or milk, usually 2 to 4 hours before your UVA light treatment or as directed by your doctor. Taking methoxsalen with food helps to increase absorption of the medication and also decreases nausea.
- The dosage of methoxsalen is based on your weight, medical condition, and response to treatment. The amount and time of UVA light for each treatment is based on your skin type and response to treatment. You may have UVA light treatments 2 to 4 times a week when you first start and then less frequently as your condition improves.
- For 24 hours after taking the capsule, during daylight hours wear wrap-around sunglasses which block out UVA light. This will prevent UVA rays from entering the eyes. UVA light can cause methoxsalen to bind to the lenses of the eyes, causing cataracts. Also, avoid sunlight (including sunlight through windows) on your skin or lips for at least 8 hours after taking methoxsalen. This will prevent the body from getting too much UVA rays which could lead to sunburns. If you cannot avoid sunlight, wear protective clothing (such as hat, gloves, long-sleeved shirt, pants) and/or sunscreen which blocks out UVA light. Consult your doctor or pharmacist for information on which sunscreen to use. Do not apply the sunscreen to areas of the skin affected by psoriasis/vitiligo until after the UVA light treatment.
- During the UVA light treatment, follow all instructions given by the healthcare professional. After the UVA light treatment, do not sunbathe for at least 48 hours. Doing so may increase the risk of severe burns. Consult your doctor for more details.
- Tell your doctor if your condition does not improve or if it worsens.

MISSED DOSE: This medication is taken only before a UVA light treatment. If you forget to take your dose as scheduled or miss a treatment, contact your doctor immediately to reschedule your treatment.

STORAGE: Store at room temperature at 77 degrees F (25 degrees C) away from light and moisture. Brief storage between 59-86 degrees F (15-30 degrees C) is permitted. Do not store in the bathroom. Keep all medicines away from children and pets.

- Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company for more details about how to safely discard your product.

SIDE EFFECTS: Nausea or trouble sleeping may occur with methoxsalen. Mild itching/drying/reddening/darkening of skin may occur when methoxsalen is used along with UVA light treatment. If any of these effects persist or worsen, tell your doctor or pharmacist promptly.

- If needed, consult your doctor or pharmacist about which products (such as a moisturizer) to use to help treat dry/itchy skin.

- Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.
- Tell your doctor immediately if any of these unlikely but serious side effects occur: severe reddening of skin, blistering/peeling/burning of skin, thinning/wrinkling skin, painful browning/whitening/yellowing of nails, swelling ankles, mental/mood changes (such as depression, nervousness).
- Tell your doctor immediately if any of these rare but serious side effects occur: unusual growths/moles/skin sores, decreased/blurred vision.
- A very serious allergic reaction to this drug is rare. However, seek immediate medical attention if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.
- This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.
- In the US -
- Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.
- In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

PRECAUTIONS: Before taking methoxsalen, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

- Before using this medication, tell your doctor or pharmacist your medical history, especially of: conditions that make you sensitive to light (such as lupus, certain porphyrias, xeroderma pigmentosum, albinism), skin cancer (melanoma, basal cell or squamous cell carcinomas), removal of natural lens in the eye, coal tar/UVB treatment, radiation treatment, arsenic treatment, cataracts, liver disease, heart disease, kidney disease.
- Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products).
- This medication is not recommended for use during pregnancy. It may harm an unborn baby. Consult your doctor for more details.
- It is unknown if this medication passes into breast milk. Because of the possible risk to the infant, breast-feeding while using this drug is not recommended. Consult your doctor before breast-feeding.

DRUG INTERACTIONS: The effects of some drugs can change if you take other drugs or herbal products at the same time. This can increase your risk for serious side effects or may cause your medications not to work correctly. These drug interactions are possible, but do not always occur. Your doctor or pharmacist can often prevent or manage interactions by changing how you use your medications or by close monitoring.

- To help your doctor and pharmacist give you the best care, be sure to tell your doctor and pharmacist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products) before starting treatment with this product. While using this product, do not start, stop, or change the dosage of any other medicines you are using without your doctor's approval.
- Some products that may interact with this drug include: other medications that may make your skin sensitive to light (such as anthralin, coal tar, griseofulvin, phenothiazines including promethazine, sulfa antibiotics including sulfamethoxazole, fluoroquinolone antibiotics including ciprofloxacin, thiazide diuretics including hydrochlorothiazide, tetracycline antibiotics including doxycycline).
- This document does not contain all possible drug interactions. Keep a list of all the products you use. Share this list with your doctor and pharmacist to lessen your risk for serious medication problems.

NOTES: Do not share this medication with others.

- Laboratory and/or medical tests (such as eye exams, complete blood count, kidney/liver function) should be performed periodically to monitor your progress or check for side effects. Consult your doctor for more details.

OVERDOSE: If overdose is suspected, contact a poison control center or emergency room immediately. US residents can call the US National Poison Hotline at 1-800-222-1222. Canada residents can call a provincial poison control center. Symptoms of overdose include: severe reddening of skin, blistering/burning/peeling of skin.

WARNING: For the treatment of psoriasis, this medication should only be used for severe psoriasis that has not responded well to other treatments since this medication may cause serious side effects (such as cataracts, skin cancer/aging). Consult your doctor for more details.

- This medication comes in different dosage forms which do not have the same effects. Do not switch between different dosage forms without talking to your doctor. Each time you get a refill, make sure that you receive the correct form of this medication that your doctor prescribed.