

Vitilen

Methoxsalen USP 10 mg



COMPOSITION

Vitilen capsule: Each capsule contains Methoxsalen USP 10 mg.

CLINICAL PHARMACOLOGY

The combination treatment regimen of Psoralen (P) and UVA (Ultraviolet radiation of 320-400 nm wavelength) is commonly known as PUVA. Skin reactivity to UVA radiation is enhanced by the ingestion of Methoxsalen. The drug reaches its maximum bioavailability 1-3 hours after oral administration and may last for up to 8 hours. Methoxsalen is reversibly bound to serum albumin and is also preferentially taken up by epidermal cells. In both mice and man, Methoxsalen is rapidly metabolized. Approximately 95% of the drug is excreted as a series of metabolites in the urine within 24 hours.

MECHANISM OF ACTION

The exact mechanism of action of Methoxsalen with the epidermal melanocytes and keratinocytes is not known. The best known biochemical reaction of Methoxsalen is with DNA. Methoxsalen, upon photoactivation, conjugates and forms covalent bonds with DNA (both monofunctional and bifunctional). Reactions with proteins have also been described.

INDICATIONS AND USAGE

It is indicated for the repigmentation of idiopathic vitiligo. It is also indicated for the symptomatic control of severe, recalcitrant, disabling psoriasis not adequately responsive to other forms of therapy and when the diagnosis has been supported by biopsy.

CONTRAINDICATIONS

- Patient with idiosyncratic reactions to psoralen compounds
- Patient possessing light sensitive disease including lupus erythematosus, porphyria,
- erythropoietic protoporphyria, variegate porphyria, xeroderma pigmentosum and albinism
- Patient with melanoma or possessing a history of melanoma
- Patient with invasive squamous cell carcinomas
- Patient with aphakia

WARNINGS & PRECAUTIONS

- **SKIN BURNING:** Serious burns from either UVA or sunlight (even through window glass) can result if the recommended dosage of the drug and/or exposure schedules are not maintained.
- **CARCINOGENICITY:** The increasing risk of carcinoma appears great among patients who are fair skinned or had pre-PUVA exposure or prolong treatment with tar UVB, ionizing radiation or arsenic.
- **CATARACTOGENICITY:** Among patients using proper eye protection, there is no evidence for a significantly increased risk of cataracts in association with PUVA therapy.

Patients must not sunbathe during the 24 hours prior to Methoxsalen ingestion and UV exposure.

PREGNANCY & LACTATION

Pregnancy Category C. Methoxsalen should be given to a woman only if clearly needed. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Methoxsalen is administered to a nursing woman.

PEDIATRIC USE

Safety in children has not been established.

ADVERSE REACTIONS

The most commonly reported side effect of Methoxsalen alone is nausea, which occurs with approximately 10% of all patients. This effect may be minimized or avoided by instructing the patient to take Methoxsalen with milk or food, or to divide the dose into two portions, taken approximately one-half hour apart. Other effects include nervousness, insomnia and psychological depression.

OVERDOSAGE

In the event of Methoxsalen overdosage, induce emesis and keep the patient in a darkened room for at least 24 hours. Emesis is beneficial only within the first 2 to 3 hours after ingestion of Methoxsalen, since maximum blood levels are reached by this time.

DOSAGE & ADMINISTRATION

VITILIGO THERAPY: Two **Vitilen** capsules (10 mg each) in one dose taken with milk or food two to four hours before ultraviolet light exposure.

LIGHT EXPOSURE: The exposure time to sunlight should comply with the following guide:

Skin color	Light	Medium	Dark
Initial exposure	15 min	20 min	25 min
Second exposure	20 min	25 min	30 min
Third exposure	25 min	30 min	35 min
Fourth exposure	30 min	35 min	40 min

SUBSEQUENT EXPOSURE: Gradually increase exposure based on erythema and tenderness of the amelanotic skin. Therapy should be on alternate days and never two consecutive days.

PSORIASIS THERAPY: The **Vitilen** capsules should be taken 2 hours before UVA exposure with some food or milk, according to the following table:

Patient's Weight		Dose (mg)
(kg)	(lbs)	
<30	<66	10
30-50	66-110	20
51-65	112-143	30
66-80	146-176	40
81-90	179-198	50
91-115	201-254	60
>115	>254	70

STORAGE

Do not store above 25°C. Protect from light. Keep out of reach of children.

PRESENTATION

Vitilen Capsules: Each box contains 5 x 10's capsules in blister pack.

Manufactured by:

ZISKA Ziska Pharmaceuticals Ltd.
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