Vitilen *Lotion*

Methoxsalen USP 1%

Composition :
Each ml of **Vitilen** Lotion contains 10 mg Methoxsalen USP in an inert vehicle containing alcohol (71% v/v), propylene glycol, acetone and purified water.

Indications and usage :
As a topical repigmenting agent in vitiligo in conjunction with controlled doses of ultraviolet A (320-400 nm) or sunlight.

Administration :
Vitilen Lotion is applied to a well-defined area of vitiligo by the physician and the area is then exposed to a suitable source of UVA. Initial exposure time should be conservative and not exceed that which is predicted to be one-half the minimal erythema dose. Treatment intervals should be regulated by the erythema response; generally once a week is recommended or less often depending on results. The hands and fingers of the person applying the medication should be protected by gloves or finger cots to avoid photosensitization and possible burns. Pigmentation may begin after a few weeks but significant repigmentation may require 6 to 9 months of treatment. Periodic retreatment may be necessary to retain all of the new pigment. Idiopathic vitiligo is reversible but not equally reversible in every patient. Treatment must be individualized. Repigmentation will vary in completeness, time of onset and duration. Repigmentation occurs more rapidly in fleshy areas such as face, abdomen, buttocks and less rapidly over less fleshy areas such as the dorsum of the hands or feet.

Adverse Reactions :
Systemic adverse reactions have not been reported. The most common adverse reaction is severe burns of the treated area from overexposure to UVA, including sunlight. Minor blistering of the skin is not a contraindication to further treatment and generally heals without incident. Treatment would be the standard for burn therapy. Since 1953, many studies have demonstrated the safety and effectiveness of topical methoxsalen and UVA for the treatment of vitiligo when used as directed.

Contraindications :
1. Patients exhibiting idiosyncratic reactions to psoralen compounds or a history of sensitivity reactions to them.
2. Patients exhibiting melanoma or with a history of melanoma.
3. Patients exhibiting invasive skin carcinoma generally.
4. Patients with photosensitivity diseases such as porphyria, acute lupus erythematosus, xeroderma pigmentosum, etc.
5. Children under 12 years, since clinical studies to determine the efficacy and safety of treatment in this age group have not been done.

Warnings :
1. SKIN BURNS
Serious skin burns from either UVA or sunlight (even through window glass) can result if recommended exposure schedule is exceeded and/or protective covering or sunscreens are not used. The blistering of the skin sometimes encountered after UV exposure generally heals without complication or scarring.

2. CARCINOGENICITY
None of clinical investigators reported skin cancer as a complication of topical treatment for vitiligo. However, it is recommended that caution be exercised when the patient is fair-skinned, has a history of prior coal tar UV treatment, or has had ionizing radiation or taken arsenical compounds. Such patients who subsequently have oral psoralen – UVA treatment (PUVA) are at increased risk for developing skin cancer.

3. CONCOMITANT THERAPY
Special care should be exercised in treating patients who are receiving concomitant therapy (either topically or systemically) with known photosensitizing agents 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.

Precautions :
Pregnancy Category C
Animal reproduction studies have not been conducted with topical Methoxsalen. It is also not known whether Methoxsalen can cause fetal harm when used topically on a pregnant woman or affect reproductive capacity. It is not known to what degree, if any, topical Methoxsalen is absorbed systemically. Topical methoxsalen should be used in women only when clearly indicated.

Nursing Mothers
It is not known whether topical Methoxsalen is absorbed or excreted in human milk. Caution is advised when topical Methoxsalen is used in a nursing mother.

Pediatric Usage
Safety and effectiveness in children below the age of 12 years have not been established.

Overdosage :
This does not apply to topical usage. In the unlikely event that the lotion is ingested, standard procedures for poisoning should be followed, including gastric lavage. Protection from UVA or daylight for hours or days would also be necessary. The patient should be kept in a darkened room.

Storage :
keep in a cool & dry place, protected from light. Store at 25°C (77°F).

Packaging :
Each bottle contains 30 ml of topical **Vitilen** Lotion containing 1% Methoxsalen USP.

Manufactured by:
ZISKA PHARMA **Ziska Pharmaceuticals Ltd.**
Kaliakoir, Gazipur, Bangladesh