

Only for the use of Registered Medical Practitioners or a Hospital or a Laboratory.

METHOXSALEN TABLETS
METHOXSALEN TOPICAL SOLUTION U.S.P.
METHOXSALEN & AMINOBENZOIC ACID OINTMENT
MELANOCYL®

मेलानोसिल

VITILIGO: The term vitiligo which for the Latin people meant the spotted skin of the calf-vitellus has been often used for a very long time to indicate different types of Leukoderma.

Vitiligo is an acquired amelanosis of unknown cause that affects all races and is the term referred to an acquired idiopathic, macular, total loss of pigmentation.

Vitiligo is a great social and aesthetic problem. In India, vitiligo is widespread and the percentage is higher than in Western countries.

What is **MELANOCYL®**? **MELANOCYL®** contains Methoxsalen (also called Ammoidine, Xanthotoxine or 8-Methoxypsoralen) and is marketed in the form of tablets, ointment and solution.

Oral Treatment: The recommended dose is 0.7 mg per kilogram body weight, to be taken on alternate days on an empty stomach preferably with a glass of milk or bland diet in a single dose to be followed two hours later by exposure to sunlight as peak blood levels of 8-MOP are 3 hours after digestion.

We recommend for

Men	: between 51 to 65 Kgs	30 mgs or 3 tablets
	between 66 to 80 Kgs	40 mgs or 4 tablets
Women	: between 30 to 50 Kgs	20 mgs or 2 tablets
	between 51 to 65 Kgs	30 mgs or 3 tablets
Children	: upto 30 Kgs	10 mgs or 1 tablet
	between 30 to 50 Kgs	20 mgs or 2 tablets

IRRADIATION OR SOLAR EXPOSURE :

In case of oral treatment only, the following exposure schedules are recommended for treatment and maintenance of Psoriasis and Vitiligo.

PSORIASIS

No. of Exposures	Day	Exposure to sunlight In minutes
1	1	5 mins.
2	4	10 mins.
3	6	15 mins.

4	8	20 mins.
5	10	25 mins.
6	12	30 mins.
7	14	30 mins.
8	16	30 mins.
9	18	30 mins.
10	20	30 mins.
11	22	30 mins.
12	24	30 mins.
Upto the recommended number of exposures or remission.		

MAINTENANCE THERAPY FOR PSORIASIS.

Psoriatic patients should be given one exposure per week and gradually frequency of exposure should be reduced. Those patients who develop moderate or gross recurrence during the maintenance treatment should be put on initial treatment again.

VITILIGO

No. of Exposures	Day	Light Dose in minutes
1	1	5 mins.
2	4	5 mins.
3	6	5 mins.
4	8	7 mins.
5	10	7 mins.
6	12	7 mins.
7	14	10 mins.
8	16	10 mins.
9	18	10 mins.
10	20	12 mins.
11	22	12 mins.
12	24	12 mins.
13	26	15 mins.
14	28	15 mins.
15	30	15 mins.
16	32	20 mins.
17	34	22 mins.
Upto the recommended exposures		

MAINTENANCE THERAPY FOR VITILIGO

Patients with VITILIGO are given 3 exposures per week in the initial period and depending upon the response, the duration of exposure is to be adjusted.

The best exposure time is when the sun is at its zenith. We would suggest between 11.00 a.m. and 3.00 p.m. The position of the patient must be lying down. If the patient has a tendency to sleep, someone must wake him or the patient must use an alarm clock. It should be noted that leukodermic patches over the face, eyelids, nasal or buccal orifices or scrotum are treated only with tablets. For leukodermic patches on the hands, tablets only are advised; but if gloves can be worn, local/topical treatment can be advised simultaneously. Oral treatment for the above areas of the body is recommended because these areas are normally exposed to sunrays throughout the day or are very sensitive. The over-exposure may give rise to severe erythema if local treatment is used.

Use of PARAMINOL[®]: PARAMINOL[®] should be applied on the periphery of the vitiliginous patch to protect the area of normal skin.

RESULTS :

With such regimen, repigmentary response in most cases and cosmetically acceptable repigmentation is achieved in 75% of cases. Repigmentation may begin after a few weeks; however, significant results may take as long as six to nine months and repigmentation, at the optimum level, may, in some cases, require maintenance dosage to retain the new pigment.

TOXICITY :

Extensive clinical experience has shown that orally administered Methoxsalen is virtually non-toxic; there are no reported cases of an adverse effect.

Side effects may occur in a few patients. If symptoms like nausea, vomiting, etc. occur half the dose should be given 2½ hours before exposure to sunrays and the remaining half dose should be given 2 hours before exposure to sunrays. Thus, two oral doses can be given at an interval of half an hour.

PRECAUTIONS :

The patients should wear optical dark glasses during sun exposure to be kept on for 4 to 5 hours thereafter.

Specific instruction for only local/topical treatment:

To be used strictly under medical supervision

Local/topical treatment with MELANOCYL[®] SOLUTION or OINTMENT can be used in serious renal or hepatic diseases, diabetes, blood dyscrasias or if oral treatment has not been well tolerated. Sleeplessness or irritability may be indications of intolerance to the drug.

The schedule of exposure to be followed very accurately is as follows:

- Half a minute per day for the first week.
- One minute per day for the second week.
- Two minutes per day for the third week.

This exposure provokes usually a slight erythema (irritation blister). The exposure could be increased in duration according to the patient's tolerance. Within a few months, the threshold of erythema (irritation blister) can be reached in 5-6 minutes. After every exposure, the patient should cover all the treated leukodermic patches or apply over them **PARAMINOL[®] OINTMENT**. These protective measures are essential as most of the local reactions are due to inadvertent exposure and additional solar radiation.

MELANOCYL[®] SOLUTION:

Should be applied one hour before exposure very gently with the brush provided. Rubbing is not necessary. For the first 15 days, it is advisable to use a weaker solution by diluting upto 1:10 with eau de Cologne.

MELANOCYL[®] OINTMENT:

MELANOCYL[®] OINTMENT is as effective as **MELANOCYL[®] SOLUTION** and may be used especially for tender skins.

SYMPTOMS AND REACTIONS:

In case an inflammatory reaction occurs, the application of **MELONOCYL[®]** should be interrupted. The inflammation can be treated in the same way as an ordinary burn of the first degree. Usually, application of Calamine lotion is sufficient.

PRESENTATION:

MELANOCYL[®] TABLETS - Blister pack of 40 tabs. containing 10 mg of Methoxsalen U.S.P. per tablet.

MELANOCYL[®] SOLUTION - Bottle of 25 ml containing 1.0% w/v Methoxsalen U.S.P.

MELANOCYL[®] OINTMENT - Tube of 25 g containing 0.75% w/w Methoxsalen U.S.P. and 2% w/w Aminobenzoic Acid B.P.

Kindly note that when going out, you are exposed to ultra-violet radiation and you may get burnt when local/topical application with Solution or Ointment is made. After every exposure, the patient should cover all the treated leukodermic patches or apply over them **PARAMINOL[®] OINTMENT**.

Manufactured by :

WARDEX PHARMACEUTICALS PVT. LTD.

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