

MELADININE® TABLET

Methoxsalen (10mg)

What is in this leaflet

1. What MELADININE is used for
2. How MELADININE works.
3. Before you use MELADININE
4. How to use MELADININE
5. While you are using it
6. Side effects
7. Storage and Disposal of MELADININE
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What MELADININE is used for

Meladinine is used for the treatment of vitiligo (disease that causes the loss of skin colour in smooth, white patches), psoriasis (skin condition that causes the skin cells to grow too quickly, resulting in red patches of skin covered with thick, white, silvery scales) and idiopathic alopecia (baldness).

How MELADININE works

Methoxsalen is a naturally occurring substance that is reactive to light. It works by enhancing the body's sensitivity to ultraviolet light A (UVA).

Before you use MELADININE

- When you must not use it

This medication is not recommended to be used for conditions:

- cosmetic purposes eg. tanning
- skin disease can be aggravated by sunshine
- high blood pressure
- heart failure
- history of skin cancer
- cataract
- liver or kidney failure
- previous treatment with arsenic, ionizing radiation
- children.

- Before you start to use it

Before taking Meladinine, 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.

- Taking other medicines

The effects of some medicines can change if you take other medicines 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 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 medicines, nonprescription medicines, 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 medicine include: other medications that may make your skin sensitive to light (such as phenothiazines including promethazine, sulfa antibiotics including sulfamethoxazole, tetracycline antibiotics including doxycycline).

How to use MELADININE

- How much to use

Oral treatment. The dose of Meladinine tablets varies according to

the age, weight and resistance of the people. The average dose for an adult is 2-4 tablets daily. This is continued during the whole course of treatment provided no untoward effects appear. If you show any intolerance, your doctor may reduce the dose or withhold the treatment every fourth day or every fourth week according to condition.

The treatment should be conducted under the supervision of the skin specialist.

It has been observed clinically in the treatment of leucoderma (vitiligo) that the best results are obtained by combining both oral and topical treatment together with solar or ultra-violet irradiation.

- When to use it

Take exactly as prescribed by your doctor. Do not take in larger or smaller amounts or for longer than recommended. Follow the directions on your prescription label. Taking too much Meladinine can cause your skin to be overly sensitive to light, and severe sunburn may result.

- How long to use it

Take this medication with food or milk if it upsets your stomach.

- If you forget to use it

Call your doctor for instructions if you miss your Meladinine dose or forget to take the medicine.

The timing of when you take Meladinine is very important in relation to UVA treatment. Therefore, you may need to reschedule your light therapy appointment if you have not taken Meladinine at the proper time beforehand.

- If you use too much (overdose)

Seek emergency medical attention if overdose suspected. You will be extremely sensitive to light after an overdose

MELADININE® TABLET

Methoxsalen (10mg)

While you are using it

- Things you must do

Tell your doctor about all medications you use now or have used in the past (including those applied to the skin), Follow your doctor's instructions about applying topical medications or any moisturizing lotions after your Meladinine and UVA treatment.

While taking Meladinine, check your skin regularly for signs of skin cancer. Methoxsalen is devoid of teratogenic effect in animals. The available clinical data for small populations of human subjects shown no indication of specific malformation effects. However, due to the absence of adequate quantities of data, the treatment should be avoided during pregnancy.

It is unknown if this medication passes into breast milk. Because of the possible risk to the infant, breast-feeding while using this medicine is not recommended. Consult your doctor before breast-feeding.

- Things you must not do

- Avoid exposure to sunlight or tanning beds.
- Even sunlight shining through clouds or through a glass window can expose you to harmful UV rays.
- Wear protective clothing and use sunscreen (SPF 15 or higher) when you are outdoors or near a window.
- Do not apply sunscreen to areas of active psoriasis that will be treated with UVA therapy.
- You must protect your skin and eyes from natural sunlight (even sun shining through a window).
- Wear sunglasses for at least 24 hours after treatment.
- For utmost protection, wear a pair of wraparound UVA-absorbing sunglasses, even while you are indoors near a window.

- Do not expose your skin to sunlight or tanning beds for at least 48 hours.
- Wear protective clothing including a hat and gloves.
- Use a sunscreen with a minimum SPF of 15, and apply it to all uncovered skin areas exposed to light.
- In women of child-bearing age, use of an effective form of contraception should be recommended during treatment.

- Things to be careful of

Driving and using machines:

Meladinine may affect your ability to drive or use machines. If Meladinine make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Meladinine in therapeutic doses is completely free from toxicity. Occasionally there may occur gastric discomforts, nausea, nervousness, insomnia or depressed mood. To minimize gastric effects, the tablets may be taken with milk or a meal. You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

Storage and Disposal of MELADININE

- Storage

Store at below 25°C
Keep all medicines away from children and pets.

- Disposal

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

Product Description

- What it looks like

Odourless, cylindrical white tablets with convex faces bearing the letter M on one face.

- Ingredients

Active ingredient: Methoxsalen 10mg.
Inactive ingredients: Maize starch, talc, sucrose, spray-dried acacia, magnesium stearate, purified water and acetone.

- MAL number

MAL05090015AC.

Manufacturer

Laboratoires Macors
Rue Des Caillottes, 89000,
Zone Industrielle Plaine Des Isles,
Auxerre, France.

Product registration holder

Antah Pharma Sdn Bhd
No. 3, Jalan 19/1, 46300,
Petaling Jaya, Selangor.

Date of revision:

29/10/2015.

Serial Number:

BPFK(R4/1)201015/00377.