

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Avocom-M cream is and what it is used for
2. What you need to know before you use Avocom-M cream
3. How to use Avocom-M cream
4. Possible side effects
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1. What Avocom-M cream is and what it is used for

Avocom-M cream is a medicine which is used to treat inflamed conditions of the skin such as eczema and dermatitis which may be caused by infection with certain fungi and bacteria. The cream contains the following ingredients:

- Miconazole nitrate 2% w/w: Is an antifungal which works by destroying both the fungus that causes the infection and some of the associated bacteria which may also be present.
- Mometasone Furoate 0.1% w/w: Is a topical steroid which reduces inflammation, swelling, redness and itching of the skin.

2. What you need to know before you use Avocom-M cream

Do not use Avocom-M cream if:

- If you are allergic to any ingredient in Avocom-M cream (listed in section 6 below).
- You have any other skin problems such as cold sores, herpes, chicken pox or shingles.

Only use it for the skin problem that you showed the doctor.

Do not use this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before using Avocom-M cream.

Take special care with Avocom-M cream

Check with your doctor or pharmacist before using this medicine if:

- The inflamed skin is on your face. You should not use Avocom-M cream on your face, unless your doctor has told you.

Children:

- The cream should not be used on young children for long periods of time (such as every day for several weeks) unless your doctor has told you.
- The cream should not be used on large areas of a child's body unless your doctor has told you.

Elderly patients

Medicines like Avocom-M cream can cause thinning of the skin when used for a long time without a break. Because thinning of the skin happens naturally in older people, this medicine should be used sparingly for no more than a few weeks in elderly patients.

Only use it for as long as your doctor tells you.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription or herbal medicines.

If you are pregnant or breast-feeding

Ask your doctor for advice before using this medicine if you are pregnant or breast-feeding. Your doctor will decide if you can use Avocom-M cream.

Driving and using machines

Avocom-M cream is not likely to affect you being able to drive or use any tools or machines.

Important information about some of the ingredients of Avocom-M cream

Avocom-M cream contains cetostearyl alcohol, which can cause local skin reactions (e.g. contact dermatitis), chlorocresol and propylene glycol which can cause skin irritation.

3. How to use Avocom-M Cream

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure. Avocom-M cream is for use on your skin only.

How to apply the cream

- Each tube of Avocom-M cream is sealed. Use the cap to pierce the tube.
- Wash the infected area and dry it well.
- As many skin conditions are infectious, you should keep a towel and flannel for your own use. Do not share them so that you do not infect anyone else.
- Apply a small amount of Avocom-M cream to the affected area and rub it in gently until the cream has disappeared.
- Unless the infected skin is on your hands, wash your hands carefully after applying the cream to avoid spreading the infection to other parts of the body or to other people. Clothing which comes into contact with the infected areas should be washed and changed frequently.
- How much to apply-adults and children
- Unless your doctor tells you differently, apply a small amount of Avocom-M cream to the affected area 2 times each day.
- If your skin problem does not improve in 7 days, tell your doctor.

If you have any further questions on the use of this medicine, ask your doctor, nurse, or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using Avocom-M cream and tell your doctor straight away if you notice the following. You may need medical treatment.

Sudden swelling of the face, lips, tongue, wheezing or shortness of breath.

Severe irritation or reddening of the skin where the cream has been used, or other signs of severe allergy.

A few people may find that they suffer from some of the following side effects after using Avocom-M cream:

Allergic skin reactions, bacterial and secondary skin infections, acne, inflammation and/ or infection of the hair follicles, thinning of the skin, red marks with associated prickly heat, loss of skin colour, burning, stinging, itching, tingling, excessive hair growth and softening of the skin and stretch marks. Tell your doctor or pharmacist if you notice or suspect any of the following side effects:

Uncommon side effects (affects fewer than 1 in 100 people)

Skin irritation, burning sensation, itchy skin, hives (also known as nettle rash, or urticaria), irritability.

Frequency not known:

Lighter patches of skin.

Sensitivity reactions (such as rash) at the application site. Inflammation (contact dermatitis). If this occurs stop using the medicine.

Other side effects that may occur with topical corticosteroids are dry skin, skin irritation, dermatitis, dermatitis around the mouth, and small dilated blood vessels.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, nurse, or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Avocom-M Cream

- Keep this medicine out of the sight and reach of children.
- Store below 30°C.
- Shelf life after first opening is 30 days.
- Do not use this medicine after the expiry date which is stated on the carton and label after "EXP".
- The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Further information

What Avocom-M cream contains

The active substance is: -The active substance(s) are (Mometasone Furoate 1 mg, Miconazole Nitrate 20mg in each gram)

-The other ingredients are Methylparaben, Propylparaben, Cetostearyl Alcohol, Cetomacrogol, Disodium EDTA, Paraffin Oil, Vaseline, Disodium Hydrogen Phosphate Anhydrous, Phosphoric Acid 85%, Purified Water.

What Avocom-M cream looks like and contents of the pack

Avocom-M is a white smooth translucent homogenous cream with characteristic odor. The cream is available in a tube containing 30g and 50g.

Manufacturer & Marketing Authorisation Holder:

Middle East Pharmaceutical Industries Co Ltd (Avalon Pharma)

P.O.Box 4180 Riyadh 11491

2nd Industrial City, Riyadh, Kingdom of Saudi Arabia

Tel: +966 (11) 2653948 - 2653427

Fax: +966 (11) 2654723

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To report any side effect(s):

• **Saudi Arabia:**

The National Pharmacovigilance and Drug Safety Centre (NPC)

- Fax: +966-11-205-7602
- SFDA call center: 19999
- Toll free phone: 8002490000
- E-mail: npc_drug@sfd.gov.sa
- Website: <https://ade.sfd.gov.sa>

• **Other GCC States:**

Please contact the relevant competent authority.

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers, Union of Arab Pharmacists