

# LOCASONE<sup>®</sup> M

Mometasone furoate & Miconazole nitrate Cream

Read all of this leaflet carefully before you start taking this medicine. Keep this leaflet. You may need to read it again. If you have any further questions, ask your physician or pharmacist. This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your physician or pharmacist.

In this leaflet:

- 1- What LOCASONE M is and what it is used for.
- 2- Before you use LOCASONE M.
- 3- How to use LOCASONE M.
- 4- Possible side effects.
- 5- How to store LOCASONE M.
- 6- Further information.

1- What LOCASONE M is and what it is used for.

LOCASONE M cream contains mometasone furoate and miconazole nitrate. Mometasone furoate is one of the potent corticosteroids while miconazole nitrate is a broad-spectrum antifungal against several fungi, yeasts and dermatophytes.

LOCASONE M cream can be used in treatment of skin infections caused by *Candida* spp. or dermatophytes associated with inflammation symptoms.

2- Before you use LOCASONE M:

a- Do not use LOCASONE M:

- If you are hypersensitive to mometasone furoate, miconazole nitrate or any other ingredients of the cream.
- If you are suffering from other skin problem like (rosacea, acne, wounds, Chickenpox, cold sores, genital itching, dermatitis around the mouth, skin atrophy, nappy rash, shingles, warts or ulcerated skin.
- Don't use the cream on your face for more than 5 days.
- Don't apply the cream to children, on any part of their body, for more than 5 days.
- Don't use the cream under your child's nappy to avoid the possibly unwanted effects.
- Don't use a large amount of cream on large areas of the body for a long time.
- Don't use the cream in or around your eyes, including eye-lids.
- Don't use a bandage or plaster to cover the cream on the treated areas without medical advice.

b- Take special care with LOCASONE M:

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

- Your skin becomes irritant or sensitive upon using LOCASONE M cream.

c- Taking other medicines, herbal or dietary supplements:

LOCASONE M cream can interact with anticoagulants such as warfarin.

Please tell your physician or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

d- Taking LOCASONE M with food and drink:

LOCASONE M cream is used topically. Interaction with food and drink not stated.

e. Pregnancy:

Tell your physician if you are pregnant or plan to become pregnant during treatment. Miconazole nitrate is classified into category (c) in the FDA risk pregnancy list. LOCASONE M cream should be used only if the benefits clearly outweigh the risks.

Ask your physician or pharmacist for advice before taking any medicine.

f- Breast-feeding:

No adequate human data but no fetal adverse effects have been reported with topical use in first trimester. LOCASONE M cream should be used only if the benefits clearly outweigh the risks.

Ask your physician or pharmacist for advice before taking any medicine.

g- Driving and using machines:

LOCASONE M cream is used topically. Effect on driving and using machines are not stated.

h- Important information about some of the ingredients of LOCASONE M:

LOCASONE M cream contains E1520 and Cetostearyl alcohol that may cause skin irritation.

3-How to use LOCASONE M:

Always use LOCASONE M cream exactly as your physician has told you. You should check with your physician or pharmacist if you are not sure.

Dosage:

- LOCASONE M cream is not recommended for children below 2 years.
- For Adults & children: apply a thin layer of MOMETASONE-(M) Cream and rub gently the affected area of skin once or twice daily.

a- If you use more LOCASONE M than you should:

Ask your physician or pharmacist. Using of large amount of cream on large areas of the body for a long time may affect some of your hormones or affect growth hormone in children.

b- If you forget to use LOCASONE M:

If you forget to use the cream, use it as soon as you remember then back to the normal schedule.

c- If you stop using LOCASONE M:

Do not stop taking LOCASONE M unless your physician tells you to.

4- Possible side effects:

Like all medicines, LOCASONE M cream can cause side effect although not everybody gets them.

Tell your physician immediately if you experience any of the following symptoms:

Allergic skin reactions, swelling of the face, lips and tongue, acne, bacterial and secondary skin infections, skin discoloration, burning, stinging, itching, tingling, redness, softening of the skin and stretch marks, excessive hair growth, inflammation and infection of the hair follicles.

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

5- How to store LOCASONE M:

Keep out of the reach and sight of children.

Do not store above 30° C.

To be used within one month after first opening.

Do not use LOCASONE M after the expiry date which is stated on the outer carton. The expiry date refers to the last day of that month.

Do not use LOCASONE M if you notice any visible signs of deterioration.

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required.

These measures will help to protect the environment.

6- Further information:

a- What LOCASONE M cream contain:

Each one gram of the cream contains 1.0 mg mometasone furoate and 20 mg miconazole nitrate. The other ingredients are: E1520, E338, glyceryl monostearate, white soft paraffin, light liquid paraffin, cetostearyl alcohol, polyoxyethylene 40 stearate and aqua.

b- What LOCASONE M cream looks like and contents of the pack:

LOCASONE M Cream is: White to off white homogenous smooth cream.

Collapsible Aluminum tube containing 15, 30, 50 and 100 gm cream

Not all pack size marketed.

c- Marketing Authorization Holder and Manufacturer

DEEF Pharmaceutical Industries Co.

Tel. 016 332 3333 Fax: 016 332 4444 E-mail: medrapv@deef.com

For any information about this medicinal product, please contact the local representative of the marketing authorization holder:

DEEF Pharmaceutical Industries Co.

P.O box 6 Badaye 51951, Qassim, Saudi Arabia

Tel. 016 332 3333 E-mail: medrapv@deef.com

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To report any side effects):  
 • National Pharmacovigilance and Drug Safety Center (NPC)  
 Fax: +966-11-205-7662  
 • Calling Vigilance and Crisis Management Executive Directorate.  
 Tel. +966-11-20382222  
 Ext: 2356-2317-2354-2334-2340 -2353  
 • Toll-free: 8002490000  
 • E-mail: npc.drug@sfdca.gov.sa  
 • Web: www.sfdca.gov.sam/pc

This is a medicament

- Medicament is a product which affects your health, and its consumption contrary to instruction 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 experts in medicine, its 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 the medicament out of reach of children

Council of Arab Health Ministers & Union of Arab Pharmacists

Dimensions : 170 x 240 mm

Pantone Color : Black

GSM : N/A

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Market: Domestic

Initiator : Marketing

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Changes :  
New

PRODUCT	LOCASONE M 50 gm Domestic			DRAWING NO.	A10294-00	
ITEM				ITEM CODE	CR250300LEF000	
PREPARED BY				REVIEWED BY	APPROVED BY	
AW Manager	Medical manager	R&D Manager	Marketing Director	Medical & RA Director	Technical director	QA Manager
Sign:						
/ / 2016	/ / 2016	/ / 2016	/ / 2016	/ / 2016	/ / 2016	/ / 2016