



LOCASONE[®]S

Mometasone furoate & Ointment
Salicylic acid

Read all of this leaflet carefully before you starts using this medicine.

- Keep this leaflet. You might want to read it again.
- If you have any further questions, ask your doctor 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 doctor or pharmacist.

In this leaflet:

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

1- What LOCASONE-S is and what it is used for
Mometasone belongs to a group of medicines corticosteroids or simply called steroids. Mometasone is a potent glucocorticoid with anti-inflammatory and antipruritic effect. Salicylic acid results in the removal of dry and scaly skin. Salicylic acid enhances the absorption of mometasone. LOCASONE-S ointment used to reduce inflammation symptoms (redness and itching), treatment of psoriasis and other corticosteroid-responsive dermatitis.

2- Before you take LOCASONE-S.

A- Do not take LOCASONE-S.

- If you are hypersensitive (allergic) to mometasone furoate, salicylic acid or any of the other ingredients of LOCASONE-S ointment.
- If you have bacterial infections (e.g., as caused by pyogenic skin diseases (pyoderma), syphilis and tuberculosis), viral infections (e.g. as herpes simplex, varicella, herpes zoster, warts, genital warts, molluscum contagiosum), fungal infections (dermatophytes and yeasts) and / or parasitic infections. Unless the causes are treated at the same time.
- For vaccine reactions or even with inflammation of the skin in the facial area (perioral dermatitis), lesions on the face area with redness, scaling and other skin disorders (rosacea), acne vulgaris, and skin thinning (atrophy).
- If you are in the last 3 months of your pregnancy.

B- Take special care with LOCASONE-S

Avoid contact of the ointment with eyes or mucous membranes. LOCASONE-S ointment should not be used without a doctor's prescription in the facial area. A treatment over a prolonged period and on large areas of the skin, on wounds and healthy skin in the armpits and groin should be avoided. The ointment should not be used in closed dressings or similar.

Glucocorticoids can mask, cause or aggravate skin infections. Developing skin infections at the same time, so your doctor will prescribe you an appropriate treatment for fungal or bacterial infections. The treatment does not react, you should stop LOCASONE-S ointment until the infection is adequately controlled. Inform your a doctor if irritation, including excessive dryness of the skin. The treatment may need to be discontinued and appropriate therapy initiated. Salicylic acid can act as a sunscreen cream. When you combine the LOCASONE-S therapy with a UV - Therapy, you should remove the remaining ointment on the skin prior to UV treatment and wash the treated area. In this way, you reduce the risk of burn injury to the adjacent skin that is not protected by the ointment. After UV treatment, the ointment can be applied again.

C- Taking other medicines, herbal or dietary supplements

Please tell your doctor or pharmacist if you are taking any other medicines / using or have recently taken / used, even if it is not prescribed.

D- pregnancy and lactation

Consult before treatment with ointment LOCASONE-S always tell your doctor if you are pregnant.

LOCASONE-S ointment should not be used during the last 3 months of pregnancy and should be avoided during the first 6 months of pregnancy. It is not known whether LOCASONE-S ointment is excreted in human milk. Therefore, you should always consult prior to treatment with LOCASONE-S ointment your doctor if you are breastfeeding.

E- Driving and using machines.

LOCASONE-S ointment does not interfere with the ability to drive and use machines.

F- Important information about some of the ingredients of LOCASONE-S ointment

LOCASONE-S ointment contains Chlorocresol which may cause skin irritation.

3- How to take LOCASONE-S.

Contact LOCASONE-S ointment exactly as your doctor has told you.

You should check with your doctor or pharmacist if you are unsure.

The dose and duration of treatment is determined by your doctor.

The maximum daily dose is 15 g of ointment. Do not treat your skin with a larger amount of ointment or for a longer period than your doctor tells you. Apply carefully a thin layer of ointment to the affected skin morning and evening or as directed. Wash your hands thoroughly with soap afterwards.

Please talk to your doctor if your symptoms do not improve or if it is severe.

If you take more LOCASONE-S than you should

If you use more than prescribed by mistake, please notify your doctor.

If you forget to take LOCASONE-S

Apply. Not take a double dose to make up for a forgotten previous application, get the missed application as soon as possible and then hold back your familiar application rhythm.

If you stop taking LOCASONE-S OINTMENT

Treatment should not be stopped suddenly. It is as with all potent steroids gradual discontinuation of the application is recommended.

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

4- Possible side effects.

Like all medicines, LOCASONE-S ointment can cause side effects, although not everybody gets them.

Common side effects (affects less than 1 in 10 but more than 1 in 100 patients) are weak to moderate: burning at the application site pruritus (itching) and local thinning of the skin (atrophy).

Occur occasionally (less than 1 in 100 but more than 1 in 1,000) Skin banding, infections, rosacea-like inflammation, irregular skin bleeding (bruising) and Folliculitis.

Rarely (less than 1 in 1,000, but more than 1 in 10,000 people), there is a decreased function of the adrenal cortex, increased hair growth, hypopigmentation (decrease in skin pigmentation) and hypersensitivity.

Side effects that occur with unknown frequency.

skin irritation, dry skin, acne, contact dermatitis. Skin changes such as flaking of the skin, better visibility of small blood vessels in the skin, softening of the skin or white dots.

Please tell your doctor or pharmacist if any side effects get serious, or if you notice any side effects not listed in this leaflet.

5- How to store LOCASONE-S.

- Store below 30° C.
- Keep out of reach of children
- To be used within one month after first opening.
- Store in the original container
- Do not use LOCASONE-S after the expiry date which is stated on the box. The expiry date refers to the last day of that month.
- Do not use LOCASONE-S 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-S contains:

Active ingredient:

Each one gram ointment contains:

1 mg mometasone furoate and 50 mg salicylic acid

Inactive ingredients:

Liquid paraffin, white soft paraffin and Chlorocresol

B- What LOCASONE-S looks like and contents of the pack.

LOCASONE-S is a white - pale yellow ointment packed in collapsible aluminum tubes of size 15, 30, 50 and 100 gm.

Not all packs are marketed

C- Marketing Authorization Holder and Manufacturer:

DEEF Pharmaceutical Industries

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

Badaye 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@sda.gov.sa
 • Web: www.sda.gov.sa/npc

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 : 150 X 230 mm
Pantone Color : Black
GSM : N/A
Pharma code : 452
Font Arabic : Winssoft Pro
Font English : Winssoft Pro
Market: Domestic
Initiator : NEW
Last update : 25 / 03 / 2017
Changes : New

PRODUCT	LOCASONE S Domestic			DRAWING NO.	AI0313-00	
ITEM				ITEM CODE	OT070300LEF000	
PREPARED BY				REVIEWED BY	APPROVED BY	
AW Manager	Medical manager	R&D Manager	Marketing Director	Medical & RA Director	Technical director	QA Manager
Sign:						
/ / 2017	/ / 2017	/ / 2017	/ / 2017	/ / 2017	/ / 2017	/ / 2017