Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

Dispensing this medicine requires a physician's prescription

Epifoam

Foam for topical treatment

Active ingredients:
Hydrocortisone Acetate 1%
Pramoxine Hydrochloride 1%

For a list of inactive ingredients, see section 'Additional Information'.

Read this entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions about using this medicine, consult your physician or pharmacist.
This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

What is this medicine intended for?

Epifoam is an anti-inflammatory medicine and local anesthetic used for local relief of inflammations and irritation symptoms caused by inflammations that are responsive to corticosteroid treatment.

Therapeutic group:
Hydrocortisone Acetate - topical corticosteroids.
Pramoxine Hydrochloride - local anesthetic.

Before using this medicine

Do not use this medicine if:
- You are sensitive (allergic) or have experienced sensitivity to the active ingredients or to any of the other ingredients that this medicine contains (see section 'Additional Information').

Special warnings regarding the use of this medicine
Before starting treatment with Epifoam, tell your physician:
- If you are pregnant or breastfeeding.
- If you have a bacterial, viral, or fungal infection, consult your physician. You may need to be treated with additional anti-bacterial, anti-viral, or anti-fungal medicines.

- This medicine is for external use only. Avoid contact with the eyes.
- Do not bandage or cover the treated area unless instructed by the physician.
- Do not use tight fitting diapers or plastic pants on a pediatric patient treated in the diaper area, to avoid sealing the treated area.
- Do not use **Epifoam** for a prolonged period.
- If you are sensitive to any food or medicine, tell your physician before you start using this medicine.
- When using **Epifoam**, particularly if you have open wounds, the hydrocortisone may get absorbed in your system.

In some users, systemic absorption of topical steroids can cause a reversible depression of the hypothalamic–pituitary–adrenal axis (HPA), Cushing's syndrome, hyperglycemia, and glycosuria (glucose in the urine).
Prolonged use of corticosteroids, use over large surface areas, and using an occlusive dressing increases absorption into your system. Therefore, your physician will instruct you to undergo a periodic test to measure the amount of free cortisol in your urine and check for ACTH stimulation (ACTH is a hormone produced by the pituitary, which affects the outer layer of the adrenal gland and stimulates the release of corticosteroid hormones by the adrenal gland).

If you are taking or have recently taken other medicines, including nonprescription medications and nutritional supplements, tell your physician or pharmacist.

Pregnancy and breastfeeding
If you are pregnant, think you might be pregnant, or are planning to become pregnant, or are breastfeeding, consult your physician or pharmacist before using **Epifoam**.

How to use this medicine?

Always use according to the physician's instructions. Check with your physician or pharmacist if you are not sure.
The dosage and manner of treatment will be determined only by your physician. The recommended dose is usually:
Apply a thin layer of **Epifoam** to the affected area 3-4 times a day, depending on the severity of your condition.
Do not exceed the recommended dose.
Do not swallow! Epifoam is for **external use only**.
Children: Limit the use of **Epifoam** in children to the least amount compatible with an effective therapeutic regimen. The dosage and manner of treatment will be determined only by your physician. Using corticosteroids for a prolonged period may interfere with the development and growth of children.

Method of medicine administration

Epifoam provided with two parts:
1. An aluminum container
2. A plastic aerosol actuator cap should be placed on top of the container.

Before each use, shake the **Epifoam** container vigorously for 5-10 seconds.
Place the plastic aerosol actuator on top of the aluminum container. Hold the container upright with the cap up, and gently press the cap down several times until foam appears.
Apply a small amount of foam on the affected area 3-4 times a day, or alternatively dispense some foam to a pad and place the pad on the affected area.
After use, the cap and the container should be disassembled and rinsed thorough in warm water.
Note: Do not insert the container into vagina or anus!

Tests and follow-up
If taking this medicine for a prolonged period or if being treated with large doses, you must undergo periodic tests to measure levels of free cortisol in your urine and check ACTH stimulation.

If you have accidentally taken an overdose, or if a child has accidentally swallowed some of this medicine, refer immediately to a physician or a hospital emergency room and bring the medicine package with you.

If you forget to take this medicine at the scheduled time, do not take a double dose. Take the next dose at the usual time and consult your physician.
Persist with the treatment as recommended by the physician.

Do not take medicines in the dark! Check the label and dose each time you take the medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your physician or the pharmacist.

Side effects

Like all medicines, using **Epifoam** may cause side effects in some of the users. Do not be alarmed by this list of side effects. You may not experience any of them.

Consult a physician immediately
If your skin appears reddish, if you have pain, irritation, or swelling that does not go away, stop using the medicine and consult your physician immediately.

The following local side effects have been reported infrequently with topical corticosteroids, but they may occur more frequently with the use of occlusive dressings. These side effects are listed below in an approximately decreasing order of occurrence:
- Burning sensation
- Itching
- Irritation
- Dryness
- Inflammation of the hair follicles in your skin (Folliculitis)
- A genetic illness that expresses in uncontrolled growth of hair over the entire body (Werewolf syndrome)
- Acneiform eruptions
- Loss of skin color (Hypopigmentation)
- Inflammation of the skin around the mouth (Perioral dermatitis)
- Contact dermatitis
- Softening of the skin (Skin maceration)
- Secondary infection
- Thinning of the top layers of the skin (Skin atrophy)
- Stretch marks on the skin (Striae)
- Rash from sweating (Miliaria)

Stop using this medicine if your condition gets worse or if irritation develops.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your physician.

Reporting side effects
You can report side effects to the Ministry of Health (MoH) by following the link 'Reporting Side Effects of Medication' on the MoH home page (www.health.gov.il) which links to an online form for reporting side effects, or by following the link: https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

How to store the medicine?

- Avoid poisoning! This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a physician!
- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- Store below 25˚C.
- This medicine is packaged in a pressurized container, so do not perforate, burn, or expose it to sunlight or temperatures over 49°C, even when it is empty.
- Store the container in an upright position with the cap up.

Additional information

In addition to the active ingredients, this medicine also contains:
Purified Water, Propylene Glycol, Cetyl Alcohol, Glyceryl Monostearate, Ploxyl 40 Stearate, Polyoxethylene 23 Lauryl Ether, Trolamine, Methylparaben, Propylparaben, Hydrocarbon Propellant A-46.

- **What the medicine looks like and what are the contents of the package:** An aluminum container containing 10 grams of white foam and a plastic aerosol actuator cap.
- **Registration holder name and address:** Megapharm Ltd., POB 519, Hod Hasharon 4510501.
- **Manufacturer name and address:** Kremers Urban Pharmaceuticals Inc., Indiana, USA.
- This leaflet was reviewed and approved by the Ministry of Health in August 2017.
- **Medicine registration number in the National Medicines Registry of the Ministry of Health:** 124-11-30345-00.