

Package leaflet: Information for the patient

EMI CREAM (Betamethasone, Gentamicin, Tolnaftate and Idochlorhydroxyquinolin cream)

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.

What is in this leaflet

1. What EMI CREAM is and what it is used for
2. What you need to know before you take EMI CREAM
3. How to take EMI CREAM
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1. What EMI CREAM is and what it is used for

EMI CREAM contains a medicine Betamethasone, Gentamicin, Tolnaftate and Idochlorhydroxyquinolin.

EMI CREAM can be used for the following disorders:

- To treat inguinal dermatosis, chronic dermatitis of the extremities.
- To treat erythrasma, balanoposthitis, herpes zoster.
- To treat eczematoid dermatitis, contact dermatitis, follicular dermatitis
- To treat dyshidrosis, paronychia, anal pruritus, seborrheic eczema, intertrigo, seborrheic dermatitis
- To treat pustular acne, impetigo, neurodermatitis, angular stomatitis, photosensitivity dermatitis
- To treat lichenified inguinal dermatophytosis and tinea infections such as tinea pedis, tinea cruris and tinea corporis.

EMI Cream is used for the relief of the inflammatory manifestations of corticosteroid-responsive dermatoses when complicated by secondary infection caused by organisms sensitive to the components of this dermatologic preparation or when the possibility of such infection is suspected.

2. What you need to know before you take EMI CREAM

Do not take EMI CREAM:

- if you Any of the side effects that are reported following systemic use of corticosteroids, including adrenal suppression, may also occur with topical corticosteroids.
- on especially in infants and children.

Do not uses if any of the above apply to you? If you are not sure, talk to your doctor or pharmacist before using this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking EMI CREAM:

- if you use for particularly in infants and children.
- Topical antibiotics occasionally may result in overgrowth of non-susceptible organisms. If this occurs or if irritation, sensitization or superinfection develops, treatment with EMI Cream should be discontinued and appropriate therapy instituted.
- If you have thyroid test Systemic absorption of Iodochlorhydroxyquinolin may interfere with thyroid function tests.
- If you have ferric chloride test for phenylketonuria can yield a false-positive result if Iodochlorhydroxyquinolin is present in the urine.
- if you have a narrowing (stenosis) of the kidney artery.
- if you have an increase in the thickness of the heart muscle (known as hypertrophic cardiomyopathy).
- if EMI cream use in Pediatric patients greater susceptibility to topical corticosteroid-induced hypothalamic-pituitary-adrenal (HPA) axis suppression and to exogenous corticosteroid effects than mature patients because of greater absorption due to a large skin surface area to body weight ratio.
- if in children receiving topical corticosteroids, HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported

Other medicines and EMI CREAM

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This is because EMI CREAM can affect the way some medicines work and some medicines can have an effect on EMI CREAM. Your doctor may need to change your dose and/or to take other precautions.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

CYP3A4 inhibitors: Co-administered drugs that can inhibit CYP3A4 (e.g. ritonavir and itraconazole) have been shown to inhibit the metabolism of corticosteroids leading to increased systemic exposure. The extent to which this interaction is clinically relevant depends on the dose and route of administration of the corticosteroids and the potency of the CYP3A4 inhibitor.

Systemic aminoglycoside therapy: Possibility of cumulative toxicity should be considered when gentamicin sulphate is applied topically in combination with systemic aminoglycoside therapy.

Pregnancy and breast-feeding

Pregnancy:

You must tell your doctor if you think you are (or might become) pregnant or are breast-feeding.

Driving and using machines

A detrimental effect on such activities would not be anticipated from the adverse reaction profile of EMI Cream.

3. How to take EMI CREAM

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

You usually apply thin film of EMI Cream should be applied to cover completely the affected area two or three times daily

- This cream is for use on your skin only.
- Do not use more than the amount prescribed for you.
- Frequency of application should be determined according to severity of the condition.
- Duration of therapy should be determined by patient response.
- In cases of tinea pedis, longer therapy (2-4 weeks) may be necessary.

If you take more EMI CREAM than you should

If, by mistake on a few occasions you use more than you should, do not worry. If you apply a lot or if a lot is accidentally swallowed, it could make you ill.

Talk to your doctor or go to the hospital as soon as possible.

If you forget to take EMI CREAM

If you forget to apply your cream, apply it as soon as you remember.

If it is close to the time you are next meant to apply it, wait until this time.

If you stop taking EMI CREAM

If you use this medicine regularly make sure you talk to your doctor before you stop using it.

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

4. Possible side effects

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

If you experience any of the following reactions, **stop taking EMI CREAM and see your doctor immediately:**

Other side effects you may notice when using EMI CREAM include:

- a feeling of burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae and miliaria. where the cream is applied
- if you have Rash, irritation and hypersensitivity have been reported with the topical usage of gentamicin sulfate, Iodochlorhydroxyquinolin and rarely with tolnaftate.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store EMI CREAM

Store at temperatures not exceeding 30°C. Protect from moisture.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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. Contents of the pack and other information

What EMI CREAM contains –

-The active substance is Betamethasone Dipropionate USP, Gentamicin Sulphate BP, Tolnaftate USP & Iodochlorhydroxyquinolin.

Each gram contains:

Betamethasone Dipropionate USP...0.643 mg, Gentamicin Sulphate BP equivalent to Gentamicin...1 mg, Tolnaftate USP...10 mg, Iodochlorhydroxyquinolin ...10 mg

Chlorocresol BP (as preservative)... 1 mg

- The other ingredients are Liquid Paraffin, White Soft Paraffin, Cetostearyl Alcohol, Cetomacrogol 1000, Disodium EDTA, Sodium Methyl Hydroxybenzoate, Sodium Propyl Hydroxybenzoate, Chlorocresol, Propylene glycol, Rose oil perfumed & Purified Water

What EMI CREAM looks like and contents of the pack

EMI CREAM is Creamy white homogenous cream.

EMI CREAM is available in Lami Tube. A lami tube containing 30 gm cream packed in a Primary Carton along with the Pack Insert.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder

MVC Pharmaceuticals
Shop No.1Ground Floor,
Parasmani Apt., Daheli.Bhilad,
Tal-Umergam, Dist.-Valsad-396105
Gujarat

Manufacturer:

MVC Pharmaceuticals
Shop No.1Ground Floor,
Parasmani Apt., Daheli.Bhilad,
Tal-Umergam, Dist.-Valsad-396105
Gujarat

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