

Dexalocal® cream and solution Dexalocal-F® cream

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 instruction 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.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

What is Dexalocal/Dexalocal-F and when are they used?

Dexalocal and Dexalocal-F are indicated for external application in the treatment of inflammatory, allergic and eczematous skin conditions.

All the preparations contain the active substance, dexamethasone, which has anti-inflammatory and anti-allergic properties and alleviates itching.

Dexalocal-F also contains the antibiotic, framycetin (Neomycin B) and is used when a bacterial infection is present at the same time.

Dexalocal is available as a cream and a solution, Dexalocal-F is available as a cream:

- The cream has a cooling effect and is indicated in both the acute and weeping stages of the disorder and in cases where the patient is sensitive to fat.
- The solution is an aqueous solution of alcohol. It is suitable for the treatment of body regions that are covered in hair. It does not adhere to the hair and leaves no visible residues after application.

Dexalocal and Dexalocal-F are available only on prescription.

When must Dexalocal/Dexalocal-F not be used?

Dexalocal/Dexalocal-F must not be given to patients presenting with the following: skin tuberculosis, syphilis, viral infections of the skin (herpes simplex, chickenpox [smallpox], shingles), fungal infections, recent reactions to vaccines, open wounds, purulent inflammation such as furuncles, abscesses and acne, and in cases of known hypersensitivity to one of the ingredients of the preparation.

Dexalocal-F must not be used to treat allergies to Neomycin or other aminoglycoside antibiotics.

When is caution advised during the application of Dexalocal/Dexalocal-F?

Dexalocal/Dexalocal-F are highly potent agents. Do not exceed the treatment period (usually 2 – 3 weeks) advised by your doctor, otherwise skin damage may occur.

Consult your doctor if a skin condition does not respond to the treatment within a few days, or if it gets worse. Your doctor should also be informed of itching and redness, blisters or intense thinning of and damage to the skin. Application to large areas (more than 10 % of the body surface) and to highly absorbent regions (open wounds, abraded skin, between folds of skin in the joints as well as between the fingers and toes, skin/mucous membrane layers, around the eyes) should be avoided.

Dexalocal/Dexalocal-F should, at most, be applied only for short periods and only to small regions of problem areas such as the face and genitals. Dexalocal/Dexalocal-F should be used with caution in infants, although not for long periods and not to large areas. Do not apply Dexalocal/Dexalocal-F for longer periods or to areas larger than those advised by your doctor.

Use Dexalocal/Dexalocal-F only for the current skin condition for which this medicinal product has been prescribed. Do not give Dexalocal/Dexalocal-F to other persons.

Inform your doctor or pharmacist if you

- suffer from other illnesses
- or have allergies
- are using any other medicines (including non-prescription medicines (over-the-counter) medicines) either externally or internally.

Can Dexalocal/Dexalocal-F be applied during pregnancy or whilst breast-feeding?

Although no adverse events of Dexalocal/Dexalocal-F have been observed in unborn children following application of this medicinal product during pregnancy, laboratory animal tests indicate a risk of deformity following administration of very high dose levels. For this reason Dexalocal/Dexalocal-F should not, where possible, be used in pregnancy, especially during the first trimester. Nursing mothers should only apply the preparations for short periods and to small areas. In all cases, seek medical advice and inform your doctor if you become pregnant before/during treatment.

How should Dexalocal/Dexalocal-F be applied?

Unless otherwise prescribed, apply Dexalocal and Dexalocal-F thinly to the affected area 1 to 2 times a day. Your doctor will select the optimum form of application for your particular skin condition. Always use strictly as directed. Talk to your doctor or pharmacist if you think that the medication is too strong or too weak.

What are the possible side effects of Dexalocal/Dexalocal-F?

Local side effects such as skin irritation, a burning sensation, itching and dryness as well as hypersensitivity reactions may occur.

After prolonged application, the skin in the treated area may become thin, the smaller superficial blood vessels may become dilated and blue-red striae may form.

In children, particularly infants and young children, it should be noted that the active substance is increasingly absorbed by the circulation such that, amongst other things, long-term application may lead to growth disorders.

A transient burning sensation may be experienced upon administration of the solution to irritated skin; this is due to the alcohol content of the preparation.

Other points to note

Keep all medicines out of the reach of children!

Dexalocal/Dexalocal-F, cream: Do not store above 30 °C.

Dexalocal solution: Store in a refrigerator (2 °C – 8 °C). Use Dexalocal/Dexalocal-F only up to the date indicated by "EXP" on the container.

Further information is available from your doctor or pharmacist, both of whom have detailed product information (Summary of Product Characteristics) at their disposal.

What does Dexalocal/Dexalocal-F contain?

- 1 g of Dexalocal cream contains: 1 mg dexamethasone, preservatives: methyl-propyl p-hydroxybenzoate (E 216, E 218), antioxidant: butylhydroxyanisole (E 320) and other excipients.
- 1 g of Dexalocal solution contains 1 mg dexamethasone and excipients.
- 1 g of Dexalocal-F cream contains: 1 mg dexamethasone, 5 mg framycetin sulphate, preservatives: methyl-propyl p-hydroxybenzoate (E 216, E 218), antioxidant: butyl-hydroxyanisole (E 320) and other excipients.

Where can you obtain Dexalocal/Dexalocal-F?

What pack sizes are available?

Dexalocal and Dexalocal-F are available from pharmacies only on prescription.

Dexalocal: cream 20 g

Dexalocal: solution 30 ml

Dexalocal-F: cream 20 g



Distribution Company:

Medinova Ltd., CH-8052 Zurich, Switzerland