

Patient information leaflet

Metosyn[®] FAPG cream

fluocinonide

Read all of this leaflet carefully before you start using 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. See section 4.

What is in this leaflet:

1. What Metosyn FAPG cream is and what it is used for
2. What you need to know before you use Metosyn FAPG cream
3. How to use Metosyn FAPG cream
4. Possible side effects
5. How to store Metosyn FAPG cream
6. Contents of the pack and other information

1. WHAT METOSYN FAPG CREAM IS AND WHAT IT IS USED FOR

Metosyn FAPG cream contains fluocinonide which is a corticosteroid (also referred to as a steroid) and reduces inflammation.

It is used to treat certain inflammatory, itchy or allergic skin conditions such as eczema, dermatitis, prurigo, psoriasis, lichen planus and discoid lupus erythematosus.

It is not normally used to treat large areas of psoriasis because the likelihood of side effects is greater.

Corticosteroid creams, ointments and other topical preparations come in four different potencies or strengths. These are known as mild, moderately potent, potent or very potent. Healthcare professionals will usually refer to topical corticosteroid potency rather than strength. A potent or strong corticosteroid has a much stronger effect than a mild corticosteroid when using the same amount. The percentage of active ingredient that is sometimes included on product packaging does not indicate potency. Metosyn FAPG cream is classed as a strong corticosteroid.

Your healthcare professional will prescribe or advise a steroid of the appropriate potency for your condition.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE METOSYN FAPG CREAM

Do not use Metosyn FAPG cream:

- If you are allergic to fluocinonide or any of the other ingredients of this medicine (listed in section 6).
- Where infection is the main cause of the skin problem, particularly if it is caused by TB, syphilis, a fungus or a virus.
- For acne.
- For nappy rash or itchiness around the genital area.
- If you have a skin condition called rosacea which is red rash, sometimes with spots and pustules, on the cheeks of the face.
- If you have a skin condition called perioral dermatitis which is a dry sore red rash around the

mouth

- If it is for a child under the age of one.
- If breast-feeding, do not apply to the breasts prior to nursing.

Make sure your doctor knows if any of the above affects you.

Warnings and precautions

- Metosyn FAPG cream should not normally be used on the face. If it is, keep away from the eyes and do not use for more than 5 days.
- Waterproof dressings should not be used for children, or the face, and only in adults if your doctor tells you. The affected area should be thoroughly cleaned before putting on a waterproof dressing. Ask your doctor for instructions.
- Do not use more cream than the doctor tells you, especially if you are pregnant or breast-feeding.
- If there is a worsening of your condition during use consult your prescriber – you may be experiencing an allergic reaction, have an infection or your condition requires a different treatment. If you experience a recurrence of your condition shortly after stopping treatment, within 2 weeks, do not restart using the cream without consulting your prescriber unless your prescriber has previously advised you to do so. If your condition has resolved and on recurrence the redness extends beyond the initial treatment area and you experience a burning sensation, please seek medical advice before restarting treatment.
- If too much cream is used for too long, you may develop stretch marks, thinning of the skin, or visible small veins.

Other medicines and Metosyn FAPG cream

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

If you go into hospital, let the medical staff know that you are using Metosyn FAPG cream.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Driving and using machines

Metosyn FAPG cream should not affect your ability to drive or use machinery.

Important information about some of the ingredients of Metosyn FAPG cream

Some of the ingredients in your cream may cause a reaction, such as: stearyl alcohol – may cause local skin reactions (e.g. contact dermatitis). Propylene glycol [E1520] – may cause skin irritation.

3. HOW TO USE METOSYN FAPG CREAM

Always use Metosyn FAPG cream exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Unless your doctor tells you differently, put a small amount of cream onto the affected area, three or four times a day. Rub it gently and thoroughly into the skin. Once the condition starts to improve it may be possible to reduce the dose to once or twice a day.

Try to apply your cream at the same times each day.

Use the cream for as long as directed by your doctor.

If you forget to use Metosyn FAPG cream

If you forget to apply the cream at the correct time, do so as soon as you remember.

If accidentally swallowed

If you accidentally swallow the cream, contact your nearest doctor or hospital.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines Metosyn FAPG cream can cause side effects, although not everybody gets them. The following side effects have been reported but how often they occur is unknown:

- an allergic (itchy) reaction to the cream
- irritation where the cream has been applied
- a worsening of acne, rosacea and dermatitis around the mouth (see section 2)
- patches of pale skin (depigmentation)
- localised increased hair growth
- if too much cream is used for too long, you may develop stretch marks, thinning of the skin or visible small veins. In addition some of the steroid rubbed in to the skin may enter the blood stream. Effects such as roundness of the face, muscle wasting and fluid retention, as sometimes seen when steroids are given as tablets, may occur. The risk of these possible effects is higher in children. If this happens, your doctor may decide to stop treatment.
- Steroid withdrawal reaction: if used over prolonged periods a withdrawal reaction, which might appear to be different from the previous condition, may occur in some patients during or within days to weeks after stopping treatment, with some or all of the following features: redness of the skin which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.

Do not be alarmed by this list of possible side effects. You may not have any of them.

Reporting of side effects

If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE METOSYN FAPG CREAM

Keep this medicine out of the sight and reach of children. It could harm them.

Store Metosyn FAPG cream below 30°C. Keep the cream in the tube it came in. Do not use this medicine after the expiry date which is stated on the tube and carton. The expiry date refers to the last day of that month.

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 Metosyn FAPG cream contains**

The active substance is fluocinonide. Metosyn FAPG cream contains 0.05% w/w fluocinonide. The other ingredients are hexanetriol, stearyl alcohol, citric acid, polyethylene glycol, propylene glycol [E1520].

What Metosyn FAPG cream looks like and contents of the pack

Metosyn FAPG cream comes in tubes of 25 and 100 grams.

Marketing authorisation holder

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Bideford, Devon EX39 3DX, UK

Manufacturer: Bioglan AB, PO Box 50310, S-202 13 Malmö, Sweden.

'Metosyn' is a registered trademark.

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