

Patient Information Leaflet

Fluocinolone Acetonide Ph. Eur. 0.025% w/w

Synalar[®] Cream

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

- Keep this leaflet. You may need 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 become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Synalar cream is and what it is used for
2. Before you use Synalar cream
3. How to use Synalar cream
4. Possible side effects
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6. Further information

1. WHAT SYNALAR CREAM IS AND WHAT IT IS USED FOR

Synalar cream contains fluocinolone acetonide which is 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.

2. BEFORE YOU USE SYNALAR CREAM

Do not use Synalar cream:

- If you know you are allergic to any of the ingredients.
- Where infection is the main cause of the skin problem.
- 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.

Take special care with Synalar cream:

- Synalar cream should be kept away from the eyes.
- If using Synalar cream on the face or on children (over the age of 1 year), do not use for more than 5 days. Your doctor will tell you if your treatment should be longer than this.
- 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 too much cream is used for too long, you may develop stretch marks, thinning of the skin, or visible small veins.

Taking or using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken or used any other medicines, including medicines obtained without a prescription.

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

Pregnancy and breast feeding

Do not use more cream than the doctor tells you to.

Ask your doctor or pharmacist for advice before taking this, or any other medicine when you are pregnant, think you may be pregnant, are planning to become pregnant, or are breast-feeding.

Driving and using machines

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

Important information about some of the ingredients of Synalar cream

Some of the ingredients in your cream may cause a reaction, such as: Cetostearyl alcohol – may cause local skin reactions (eg. contact dermatitis). Propylene glycol – may cause skin irritation.

3. HOW TO USE SYNALAR CREAM

Always use Synalar cream exactly as your doctor has told you. Please read the label on the tube.

You should 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, two or three times a day. Rub it gently and thoroughly into the skin.

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

Use the cream for as long as directed by your doctor (normally 5 days on the face and on children, and 7 days otherwise)

If you forget to use Synalar cream

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

What to do in case of overdose

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

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

4. POSSIBLE SIDE EFFECTS

Like all medicines Synalar cream can sometimes cause side effects, although not everybody has them.

The following side effects have also 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.

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

If any of the side effects become serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE SYNALAR CREAM

Keep out of the reach and sight of children. Your cream could harm them.

You should store your cream below 25°C. Keep your cream in the tube it came in. Do not use your cream after the expiry date on the tube. The expiry date refers to the last day of that month.

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

The active ingredient is 0.025% w/w Fluocinolone Acetonide.

The other ingredients are benzyl alcohol, cetostearyl alcohol, citric acid, liquid paraffin, polysorbate 60, propylene glycol, purified water and sorbitan monostearate.

What Synalar cream looks like and contents of the pack

Synalar cream comes in tubes of 30 and 100 grams.

Marketing authorization holder

GP Pharma Ltd, Finch House, 28-30 Wolverhampton Street, Dudley DY1 1DB, UK.

Manufacturer

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

'Synalar' is a registered trademark.

This leaflet was last approved in July 2010