

Patient information leaflet

Synalar® ointment 0.025% w/w fluocinolone acetonide

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.

Throughout this leaflet this medicine will be referred to as Synalar ointment.

What is in this leaflet:

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

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

Synalar ointment contains fluocinolone acetonide 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. Synalar ointment 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 SYNALAR OINTMENT

Do not use Synalar ointment:

- If you are allergic to fluocinolone acetonide or any of the other ingredients of this medicine (listed in section 6).
- 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.

Warnings and precautions

- Synalar ointment should be kept away from the eyes.
- If using Synalar ointment 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 ointment 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 ointment 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 ointment is used for too long, you may develop stretch marks, thinning of the skin, or visible small veins.

Other medicines and Synalar ointment

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 Synalar ointment.

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

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

Important information about some of the ingredients of Synalar ointment

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

3. HOW TO USE SYNALAR OINTMENT

Always use Synalar ointment 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 ointment onto the affected area, two or three times a day. Rub it gently and thoroughly into the skin.

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

Use the ointment 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 ointment

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

If accidentally swallowed

If you accidentally swallow the ointment, 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 Synalar ointment 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 ointment
- irritation where the ointment 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 ointment 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 treatment 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

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

5. HOW TO STORE SYNALAR OINTMENT

Keep this medicine out of the sight and reach of children. It could harm them. Store Synalar ointment below 25°C. Keep the ointment 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 Synalar ointment contains**

The active substance is fluocinolone acetonide. Synalar ointment contains 0.025% w/w fluocinolone acetonide.

The other ingredients are citric acid, anhydrous lanolin, propylene glycol [E1520], and white soft paraffin.

What Synalar ointment looks like and contents of the pack

Synalar ointment comes in tubes of 30 and 100 grams.

Marketing authorisation holder:

Reig Jofre UK Ltd, 10 The Barns, Farm Road, Caddsdwn Industrial Park,
Bideford, Devon EX39 3BT, UK

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

'Synalar' is a registered trademark.

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