




<p>Title: SynalarN Cream Size (mm): 208(height) x 147(width) Date: 17/06/17 Modified: 25/02/24</p>	<p>Colours (Printed)</p>  <p>Colours (NOT Printed)</p>  
<p>Typeface: Helvetica Neue (<i>light, heavy</i>) Type Size: 8pt (<i>minimum</i>)</p>	

Front

Patient Information Leaflet

Synalar[®] N cream

fluocinolone acetonide and neomycin sulfate

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

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

Synalar N cream contains two active ingredients. One is called fluocinolone acetonide which is a corticosteroid (also referred to as a steroid) and reduces inflammation. The other is called neomycin sulfate which is an antibiotic effective against bacterial skin infections. Synalar N cream is used to treat certain inflammatory, itchy or allergic skin conditions such as eczema and dermatitis when infection may be present. 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 N 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 SYNALAR N CREAM

Do not use Synalar N cream:

- If you are allergic to fluocinolone acetonide, neomycin sulfate 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.
 - 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 you have a damaged ear drum do not put any cream into the ears.
 - If it is for a child under the age of one.
 - If breast-feeding, do not apply to the breasts prior to nursing.
- This cream is only for you and must never be used by anyone else. Make sure your doctor knows if any of the above affects you.

Warnings and precautions

- Synalar N cream should be kept away from the eyes.
- Do not use Synalar N cream for longer than 7 days. If using Synalar N 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 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. Excessive use can also damage the kidneys and hearing.

Other medicines and Synalar N 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.

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Reverse

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

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

Important information about some of the ingredients of Synalar N cream

Some of the ingredients in your cream may cause a reaction, such as: Cetostearyl alcohol – may cause local skin reactions (e.g. contact dermatitis). Methyl and propyl parahydroxybenzoates [E218 and E216] - may cause local skin reactions (possibly delayed). Propylene glycol [E1520] – may cause skin irritation.

3. HOW TO USE SYNALAR N CREAM

Always use Synalar N 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, 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 the full period of time (normally 5 days on the face and on children, and 7 days otherwise) unless your doctor tells you to stop earlier.

If you forget to use Synalar N 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 Synalar N 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 and antibiotic rubbed in to the skin, may enter the blood stream. The steroid may cause effects such as roundness of the face, muscle wasting and fluid retention, as sometimes seen when steroids are given as tablets. The antibiotic (neomycin) may damage the kidneys or hearing. The risk of these possible effects is extremely unlikely but is higher in children.
- 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 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 SYNALAR N CREAM

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

Store Synalar N cream below 25°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 Synalar N cream contains

The active substances are fluocinolone acetonide and neomycin sulfate. Synalar N cream contains 0.025% w/w fluocinolone acetonide and 3250 IU/g neomycin sulfate. The other ingredients are cetostearyl alcohol, liquid paraffin, methyl parahydroxybenzoate [E218], polysorbate 60, propylene glycol [E1520], propyl parahydroxybenzoate [E216], purified water and sorbitan monostearate.

What Synalar N cream looks like and contents of the pack

Synalar N cream comes in tubes of 30 grams.

Marketing authorisation holder: Reig Jofre UK Ltd, Unit 9A, Caddsdwn Business Support Centre, Caddsdwn Industrial Park, Bideford, Devon EX39 3DX, UK.

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

'Synalar' is a registered trademark.

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This leaflet was last revised in January 2024

Printed in Sweden BERGSTENS, HBG 100308