

# Synalar<sup>®</sup> N Ointment



**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:**

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

Synalar N ointment contains two active ingredients. One is called fluocinolone acetonide which is a steroid and reduces inflammation. The other is called neomycin sulphate which is an antibiotic effective against bacterial skin infections.

Synalar N ointment is used to treat certain inflammatory, itchy or allergic skin conditions such as eczema and dermatitis when infection may be present.

**2. BEFORE YOU USE SYNALAR N OINTMENT**

**Do not use Synalar N ointment:**

- 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.
- 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.

**Take special care with Synalar N ointment:**

- Synalar N ointment should be kept away from the eyes.
- Do not use Synalar N ointment for longer than 7 days. If using Synalar N 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 too much ointment 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

**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 N ointment.

**Pregnancy and breast feeding**

Do not use more ointment 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 N ointment should not affect your ability to drive or use machinery.

### **Important information about some of the ingredients of Synalar N ointment**

Some of the ingredients in your cream may cause a reaction, such as: Propylene glycol – may cause skin irritation.

### **3. HOW TO USE SYNALAR N OINTMENT**

Always use Synalar N ointment 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 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 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 ointment**

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

#### **What to do in case of overdose**

If you accidentally swallow the ointment, 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 N ointment 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 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 and antibiotic rubbed in to the skin, may enter the bloodstream. 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.

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.

#### **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](http://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 N OINTMENT**

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

You should store your ointment below 25°C. Keep your ointment in the tube it came in. Do not use your ointment 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 ingredients are 0.025% w/w Fluocinolone Acetonide and neomycin sulphate 0.5% w/w.

The other ingredients are lanolin, liquid paraffin, propylene glycol, and white soft paraffin.

#### **What Synalar N ointment looks like and contents of the pack**

Synalar N ointment comes in tubes of 30 grams.

#### **Marketing authorisation holder:**

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

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

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