

PATIENT INFORMATION LEAFLET

Scheriproct® 1.5 mg/g + 5 mg/g Rectal Ointment

Scheriproct® 1 mg + 1 mg Suppositories

Prednisolone, Cinchocaine hydrochloride

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not mentioned in this leaflet. See section 4.

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1. What Scheriproct® is and what it is used for

Scheriproct contains a substance which reduces inflammation (prednisolone), and a local anaesthetic (cinchocaine) which relieves pain.

This medicine is used for the relief of the inflammation, swelling, itching and soreness of piles (haemorrhoids) and to relieve itching of the anus (back passage). It is used short-term usually for 5 to 7 days.

2. What you need to know before you use Scheriproct®

Do not use Scheriproct if you:

- are allergic (hypersensitive) to prednisolone caproate, cinchocaine hydrochloride, other local anaesthetics or any of the other ingredients of Scheriproct.
- have a viral infection (e.g. herpes, shingles, chicken-pox)
- have any bacterial or fungal infections of the skin for which you are not receiving treatment

Warnings and precautions

- Talk to your doctor, pharmacist or nurse before using Scheriproct in the following cases: Long-term continuous treatment should be avoided because it can cause the skin to thin and deteriorate in the affected area (see section 4. "Possible Side Effects") and some of the medicine may be absorbed into the blood stream.
- If the area treated with Scheriproct is also infected your doctor should prescribe another medicine to use with Scheriproct, to treat the infection.
- Do not allow Scheriproct to come into contact with the eyes.
- In case latex products such as condoms are used concomitantly in the area of treatment with Scheriproct its ingredients may cause damage to those latex products. Therefore, these may no longer be effective as contraception or as protection against sexually transmitted diseases such as HIV infection. Talk to your doctor or pharmacist, if you require more information.

If symptoms do not improve, consult the doctor again.

Contact your doctor if you experience blurred vision or other visual disturbances.

Other medicines and Scheriproct

- Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
- Some medicines may increase the effects of Scheriproct and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

Pregnancy and breast-feeding

Contact your doctor for advice before using this medicine if you are pregnant or intending to become pregnant or are breast-feeding.

There may be a very small risk to the development of a baby in pregnant women treated with Scheriproct. As with most medicines, this risk is likely to be greatest during the first 3 months of pregnancy.

Driving and using machines:

Scheriproct has no influence on the ability to drive and use machines.

Scheriproct ointment contains castor oil, castor oil hydrogenated and macrogol 400 monoricinoleate that may cause skin reactions.

Scheriproct ointment contains perfume oil, chypre fragrance with 3-methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one, benzyl alcohol, benzyl benzoate, benzyl cinnamate, benzyl salicylate, cinnamal, cinnamyl alcohol, citral, citronellol, coumarin, eugenol, farnesol, geraniol, hydroxycitronella, isoeugenol, linalool, limonene (d- and l-limonene), oak moss. These allergens may cause allergic reactions.

3. How to use Scheriproct®

Always use Scheriproct exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Do not use Scheriproct for more than 7 days.

Always wash your hands before and after applying Scheriproct.

How to use Scheriproct Ointment:

1. Before you use the ointment, gently but thoroughly wash and dry the anus (back passage) and the skin around it.
2. If the ointment is to be used for the area **around** the anus:
 - squeeze a small quantity (about the size of a pea) on to the top of your finger. The amount of ointment in the applicator (nozzle) is one dose.
 - spread it gently over the skin and just inside the anus.
 - do not rub it in.
3. If the ointment is to be used **inside** the anus:
 - put the separate applicator (nozzle) onto the tube.
 - squeeze the tube until the applicator is full of ointment.
 - insert the applicator very carefully into the anus until the whole length of the applicator is inside.
 - then, while squeezing the tube gently, withdraw the applicator.
 - wash the applicator carefully in hot soapy water and rinse thoroughly.
 - After each use, clean the applicator with a paper towel, remove the remaining product in the applicator with a cotton swab and clean it again with a paper towel. Rinse the applicator under warm water for about 1 minute and dry the applicator with a paper towel. Do not use the applicator if damaged.

Generally, the ointment should be applied thinly twice a day, but it may be applied three or four times on the first day, to obtain quick relief.

How to use Scheriproct Suppositories:

1. Before you insert a suppository find the small tear in the foil packet and remove the covering foil by tearing it in half.
2. If the suppositories have become softened, owing to warm temperature, they can be hardened by putting them into cold water before you remove the covering foil.
3. Insert the whole suppository into the anus.
4. To make insertion easier, either stand with one foot raised on a chair or squat down.

The usual treatment is one suppository a day, to be inserted preferably after a bowel movement.

However, if your discomfort is severe, you should insert one suppository two or three times a day at the start of treatment.

If you use more Scheriproct than you should

If you accidentally swallow Scheriproct it is unlikely to be dangerous but contact your doctor or pharmacist if you are worried.

If you forget to use Scheriproct

Do not use or take a double dose to make up for a forgotten dose. When you remember, use/take the next prescribed dose and continue with the treatment. See your doctor or pharmacist if you are worried.

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

4. Possible side effects

Like all medicines, Scheriproct can cause side effects, though not everybody gets them.

Some thinning of the skin may occur if too much Scheriproct is applied for long periods of time (much longer than 5 - 7 days).

Allergic skin reactions may occur in rare cases.

Blurred vision may occur, however, the frequency is not known.

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 HPRÁ Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Scheriproct®

Store Scheriproct out of the sight and reach of children.

Scheriproct Ointment:

Do not store above 25°C. Once opened, use within 3 months. Replace the cap tightly after use. The expiry date is printed on one flap of the carton and on the back of the tube after "EXP".

Scheriproct Suppositories:

Store at 2 - 8°C

The expiry date is printed on one flap of the carton after "EXP" and on the foil.

Do not use Scheriproct after the expiry date. The expiry date refers to the last day of that month.

Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and further information

What Scheriproct Ointment contains

- The active substances are prednisolone caproate and cinchocaine hydrochloride. 1g of Scheriproct Ointment contains prednisolone caproate equivalent to 1.5 mg of prednisolone and 5 mg cinchocaine hydrochloride.
- The other ingredients are: Octyldodecanol
Castor oil, refined
Castor oil, hydrogenated
Macrogol- 400-monoricinoleate
Perfume oil, chypre (contains 3-methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one, benzyl alcohol, benzyl benzoate, benzyl cinnamate, benzyl salicylate, cinnamal, cinnamyl alcohol, citral, citronellol, coumarin, eugenol, farnesol, geraniol, hydroxycitronella, isoeugenol, linalool, limonene (d- and l-limonene), oak moss (see section 2)).

What Scheriproct Suppositories contain

- The active substances are prednisolone caproate and cinchocaine hydrochloride. Each suppository contains prednisolone caproate equivalent to 1 mg prednisolone and 1 mg cinchocaine hydrochloride.
- The other ingredient is hard fat.

What Scheriproct looks like and contents of the pack

Scheriproct Ointment is a colourless to slightly yellowish ointment supplied in tubes of 30 g.

Scheriproct suppositories are white to yellowish and are supplied in packs of 12 suppositories.

Marketing Authorisation Holder

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