

PATIENT INFORMATION LEAFLET

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

Prednisolone, Cinchocaine hydrochloride

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 you experience any side effect and this becomes serious, tell your doctor or pharmacist.

In this leaflet:

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

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. 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

Take special care with Scheriproct

- 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.

Taking other medicines

- 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 breastfeeding. 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.

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 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 nozzle (applicator) onto the tube.
 - squeeze the tube until the nozzle is full of ointment.
 - insert the nozzle very carefully into the anus until the whole length of the nozzle is inside.
 - then, while squeezing the tube gently, withdraw the nozzle.
 - wash the nozzle carefully in hot soapy water and rinse thoroughly.

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.

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.

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 HPRA 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

Keep out of the sight and reach of children.
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/panel of the carton and on the back of the tube after "EXP".

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. 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: polyethylene glycol 400 monoricinoleate, hydrogenated castor oil, castor oil, 2 octyldodecanol, chypre perfume oil.

What Scheriproct looks like and contents of the pack

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

Manufacturer

Bayer Healthcare Manufacturing S.r.l., Via E. Schering 21, 20090 Segrate, Milan, Italy.

Product procured from within the EU, repackaged and distributed by the parallel product authorisation holder:

PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath.

Product Authorisation Number:

PPA 465/408/1

Scheriproct is a registered trademark of Bayer Pharma AG.

Date of leaflet preparation: April 2018