

Package leaflet: Information for the user

2001214_3

Scheriproct® Ointment

(1.9 mg prednisolone hexanoate / 5.0 mg cinchocaine hydrochloride per 1 g)

Scheriproct® Suppositories

(1.3 mg prednisolone hexanoate / 1.0 mg cinchocaine hydrochloride per suppository)

xxxxxx

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 listed in this leaflet. See section 4.

What is in this leaflet

1. What Scheriproct® is and what it is used for
2. What you need to know before you use Scheriproct®
3. How to use Scheriproct®
4. Possible side effects
5. How to store Scheriproct®
6. Contents of the pack and other 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 shortterm usually for 5 to 7 days.

2. What you need to know before you use Scheriproct®**Do not use Scheriproct**

- if you are allergic to prednisolone hexanoate, cinchocaine hydrochloride, other local anaesthetics or any of the other ingredients of this medicine (listed in section 6).
- if you have a viral infection (e.g. herpes, shingles, chicken-pox)
- if you have any bacterial or fungal infections of the skin or elsewhere for which you are not receiving treatment.

Warnings and precautions

Talk to your doctor or pharmacist before using Scheriproct

- Long-term continuous treatment should be avoided because it increases the possibility of side effects. This is particularly important for infants and small children because continuous treatment with Scheriproct for long periods may reduce the activity of the adrenal glands and so lower resistance to disease. Also, long-term treatment can cause the skin to thin and deteriorate in the affected area (see section 4) 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 use a waterproof dressing to cover areas where you have applied the ointment.
- In case latex products such as condoms are used concomitantly in the area of treatment with Scheriproct its ingredient(s) 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.

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

Other medicines and Scheriproct

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

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 taking this medicine. 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 fragrance (perfume oil, chypre) with allergens that may cause allergic reactions. For the complete allergen's composition, see section 6.

3. How to use Scheriproct®

Always use this medicine exactly as your doctor has told you. 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.
 - 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:
 - Screw the separate applicator completely onto the tube. Do not use the applicator if damaged.
 - Squeeze the tube until the applicator is full of ointment. The amount of ointment in the applicator is one dose.
 - 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.
 - After each use, clean externally the applicator with a paper towel, then 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 externally the applicator with a paper towel.

Generally, the ointment should be applied 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 or if you accidentally swallow some Scheriproct

If you use too much Scheriproct or 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 a double dose to make up for a forgotten dose. When you remember, use 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 medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although 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 to 7 days).

Allergic skin reactions may occur in rare cases. Castor oil, one of the ingredients of Scheriproct Ointment may cause a skin reaction.

You must get urgent medical help if you have any of the following symptoms. You may be having an allergic reaction. This is rare and may affect up to 1 in 1,000 people:

- **Angioedema (rapid swelling under the skin)**
- **Eye swelling**
- **Swelling face**
- **Dyspnoea (shortness of breath)**

Not known (frequency cannot be estimated from the available data): Blurred vision.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 Scheriproct®

- Keep this medicine out of the sight and reach of children.
- Do not store Scheriproct Ointment above 25°C.
- Store Scheriproct Suppositories in a refrigerator (2°C to 8°C).
- Do not use Scheriproct after the expiry date which is stated on the pack after EXP. The expiry date refers to the last day of that month.
- Do not throw away any medicines via waste water 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 Scheriproct Ointment contains

- The active substances are prednisolone hexanoate and cinchocaine hydrochloride. 1 g of Scheriproct Ointment contains 1.9 mg prednisolone hexanoate and 5.0 mg cinchocaine hydrochloride
- The other ingredients are macrogol-400-monicinoleate, castor oil, hydrogenated, castor oil, refined, 2 octyldodecanol, perfume oil, Chypre.

Perfume oil, chypre contains the following allergens: 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 hexanoate and cinchocaine hydrochloride. Each suppository contains 1.3 mg prednisolone hexanoate and 1.0 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 with a separate applicator.
- **Scheriproct Suppositories** are yellowish-white and are supplied in packs of 12 suppositories.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Karo Pharma AB
Box 16184
103 24 Stockholm
Sweden

Manufacturer

The ointment is manufactured by:
LEO Pharma Manufacturing Italy S.r.l.
Via E. Schering 21
20054 Segrate (Milan), Italy

The suppositories are manufactured by:
Istituto de Angeli S.r.l., Reggello, Italy
or LEO Pharma Manufacturing Italy S.r.l.
Via E. Schering 21
20054 Segrate (Milan), Italy

This leaflet was last revised in May 2021.

® Registered Trade Mark

karo
pharma

2001214_3
xxxxxx