PATIENT INFORMATION LEAFLET

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)

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 hexanoate, 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 or elsewhere for which you are not receiving treatment.

Take special care with Scheriproct

• Long-term continuous treatment should be avoided because it increases the possibility of side effects. This is particularly important for infants and small

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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, "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 use a waterproof dressing to cover areas where you have applied the cream.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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.

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.
 - 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. The amount of ointment in the nozzle is one dose.
 - 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 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 accidently 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 product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Scheriproct 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.

If you experience any of these side effects and this becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Scheriproct

• Store Scheriproct out of the reach and sight of children.

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- 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.
- Medicines must 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

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

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

Marketing Authorisation Holder

Bayer plc, Bayer House, Strawberry Hill, Newbury, Berkshire, RG14 1JA, UK.

Manufacturer

The ointment is manufactured by: Bayer HealthCare Manufacturing s.r.l. Via E. Schering 21 20090 Segrate (Milan) Italy

The suppositories are manufactured by: Instituto de Angeli S.r.l., Regello, Italy or Bayer HealthCare Manufacturing s.r.l. Via E. Schering 21 20090 Segrate (Milan) Italy Due to regulatory changes, the content of the following Patient Information Leaflet may vary from the one found in your medicine pack. Please compare the 'Leaflet prepared/revised date' towards the end of the leaflet to establish if there have been any changes.

If you have any doubts or queries about your medication, please contact your doctor or pharmacist.



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This leaflet was last revised in January 2014.

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