Approved patient information leaflet for SCHERIPROCT OINTMENT

SCHEDULING STATUS

S4

SCHERIPROCT OINTMENT

(1,9 mg Prednisolone hexanoate / 5,0 mg cinchocaine hydrochloride per

1 g of ointment)

Read all of this leaflet carefully before you start using SCHERIPROCT OINTMENT

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **SHERIPROCT OINTMENT** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

19 April 2022

Signed: S.R

1. What SCHERIPROCT OINTMENT is and what it is used for

SCHERIPROCT OINTMENT contains a substance called prednisolone, which reduces inflammation and also a local anaesthetic (chinchocaine) which relieves pain.

This medicine is used for the short term (usually 5 – 7 days) symptomatic relief of peri-anal (located around the anus, the opening of the rectum to the outside of the body) discomfort, inflammation and itching caused by thrombosed haemorrhoids (piles), anal fissure (a small tear in the thin, moist tissue (mucosa) that lines the anus) and pruritus ani (irritating, itchy sensation around the anus).

2. What you need to know before you use SCHERIPROCT OINTMENT

Do not use SCHERIPROCT OINTMENT

- if you are hypersensitive (allergic) to (prednisolone heaxanoate or chinchocaine hydrochloride) or any of the other ingredients of **SCHERIPROCT OINTMENT** (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 currently being treated.

Warnings and precautions

Special care should be taken with **SCHERIPROCT OINTMENT**:

- **SCHERIPROCT OINTMENT** should not be used more than 7 days. If symptoms do not improve, discontinue treatment and consult your doctor. Other anal disorders require specific treatment and your doctor might have to do a proctological examination. Tell your doctor immediately, if bleeding occurs.
- Long-term continuous treatment should be avoided because it increases the possibility of side effects. This is particularly important for infants and small children becaue continuous treatment with **SCHERIPROCT OINTMENT** 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 and some of the medicine may be absorbed into the blood stream.
- If the area treated with **SCHERIPROCT OINTMENT** is also infected your doctor should prescribe another medicine, to use with **SCHERIPROCT OINTMENT**, 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 OINTMENT** 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 OINTMENT:

Always tell your healthcare provider if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Please tell your doctor or pharmacist 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 OINTMENT** and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care provider for advice before taking **SCHERIPROCT OINTMENT**.

SCHERIPROCT OINTMENT is contraindicated for use in pregnancy.

Driving and using machines:

It is not always possible to predict to what extent **SCHERIPROCT OINTMENT** may interfere with your daily activities. You should ensure that you do not engage in activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which **SCHERIPROCT OINTMENT** affects you.

3. How to use SCHERIPROCT OINTMENT

Do not share medicines prescribed for you with any other person.

Always use **SCHERIPROCT OINTMENT** exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Do not use **SCHERIPROCT OINTMENT** for more than 7 days.

Always wash your hands before and after applying **SCHERIPROCT OINTMENT.**

1. Before you use the **SCHERIPROCT 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 amount (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 towel paper.

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

Your doctor will tell you how long your treatment with **SCHERIPROCT OINTMENT** will last. Do not stop treatment early even if the symptoms disappear. If you have the impression that the effect of **SCHERIPROCT OINTMENT** is too strong or too weak, tell your doctor or pharmacist.

If you use more SCHERIPROCT OINTMENT than you should:

In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison control centre.

If you missed a dose of SCHERIPROCT OINTMENT:

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. Consult your doctor or pharmacist if you are concerned.

4. Possible side effects

SCHERIPROCT OINTMENT can have side effects.

Not all side effects reported for **SCHERIPROCT OINTMENT** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using **SCHERIPROCT OINTMENT**, please consult your health care provider for advice.

If any of the following happens, stop using **SCHERIPROCT OINTMENT** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- 'swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing',
- 'rash or itching',
- 'fainting'

These are all very serious side effects. If you have them, you may have had a serious reaction to **SCHERIPROCT OINTMENT**. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequency unknown:

- Some thinning of the skin may occur if too much **SCHRIPROCT OINTMENT** 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 notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get 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 to SAHPRA via the **6.04 Adverse Drug Reaction Reporting Form**, found online under SAHPRA"s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **SCHERIPROCT OINTMENT**

5. How to store SCHERIPROCT OINTMENT

Store all medicines out of reach of children.

- Store at or below 25 °C
- Store in the original package
- Keep the container in the outer carton
- Keep the container tightly closed
- Discard the container after three months after first opening.
- Do not store in a bathroom
- Do not use after the expiry date stated on the label / carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

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:

- Castor oil hydrogenated
- Castor oil refined
- Macrogol-400-monoricinoleate

- Octyldodecanol
- Perfume oil chypre

What SCHERIPROCT OINTMENT looks like and contents of the pack

SCHERIPROCT OINTMENT is a colourless to slightly yellowish ointment supplied in white coloured aluminium tubes, sealed with an aluminium membrane, interior wall coated with epoxy resin and closed with a high-density polyethylene (HDPE) white screw cap containing 15 or 30 g.

A rectal polypropylene applicator with a low-density polyethylene cap is provided in addition.

Not all packs and pack sizes may be marketed.

Holder of Certificate of Registration

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19 April 2022 **Signed:** S.R