

## Approved patient information leaflet for [SCHERIPROCT SUPPOSITORIES]

### SCHEDULING STATUS

S4

### SCHERIPROCT SUPPOSITORIES

(1,3 mg Prednisolone hexanoate / 1,0 mg cinchocaine hydrochloride per  
1 g)

**Read all of this leaflet carefully before you start using SCHERIPROCT  
SUPPOSITORIES**

- 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.
- **SCHERIPROCT SUPPOSITORIES** 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

1. What **SCHERIPROCT SUPPOSITORIES** is and what it is used for
2. What you need to know before you use **SCHERIPROCT SUPPOSITORIES**
3. How to use **SCHERIPROCT SUPPOSITORIES**
4. Possible side effects
5. How to store **SCHERIPROCT SUPPOSITORIES**
6. Contents of the pack and other information

## **1. What SCHERIPROCT SUPPOSITORIES is and what it is used for**

**SCHERIPROCT SUPPOSITORIES** 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 SUPPOSITORIES**

### **Do not use SCHERIPROCT SUPPOSITORIES**

- if you are hypersensitive (allergic) to (prednisolone heaxanoate or chinchocaine hydrochloride) or any of the other ingredients of **SCHERIPROCT SUPPOSITORIES** (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 SUPPOSITORIES**:

- **SCHERIPROCT SUPPOSITORIES** 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 because continuous treatment with **SCHERIPROCT SUPPOSITORIES** 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 SUPPOSITORIES** is also infected your doctor should prescribe another medicine, to use with **SCHERIPROCT SUPPOSITORIES**, 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 SUPPOSITORIES** 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 SUPPOSITORIES:**

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 SUPPOSITORIES** 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 SUPPOSITORIES**.

**SCHERIPROCT SUPPOSITORIES** is contraindicated for use in pregnancy.

**Driving and using machines:**

It is not always possible to predict to what extent **SCHERIPROCT SUPPOSITORIES** 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 SUPPOSITORIES** affects you.

**3. How to use SCHERIPROCT SUPPOSITORIES**

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

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

Always wash your hands before and after inserting **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.

Your doctor will tell you how long your treatment with **SCHERIPROCT SUPPOSITORIES** will last.

Do not stop treatment early even if the symptoms disappear. If you have the impression that the effect of **SCHERIPROCT SUPPOSITORIES** is too strong or too weak, tell your doctor or pharmacist.

**If you use more SCHERIPROCT SUPPOSITORIES 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 SUPPOSITORIES:**

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 SUPPOSITORIES can have side effects.**

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

If any of the following happens, stop using **SCHERIPROCT SUPPOSITORIES** 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 SUPPOSITORIES**. 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 **SCHERIPROCT SUPPOSITORIES** is inserted 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 SUPPOSITORIES** 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 SUPPOSITORIES**

## **5. How to store SCHERIPROCT SUPPOSITORIES**

Store all medicines out of reach of children.

- Store in a refrigerator between 2 to 8 °C.
- Do not freeze.
- Store in the original packaging.
- Keep the packaging in the outer carton.
- 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 SUPPOSITORIES contains**

The active substances are prednisolone hexanoate and cinchocaine hydrochloride. One of the **SCHERIPROCT SUPPOSITORIES** contains 1,3 mg prednisolone hexanoate and 1,0 mg cinchocaine hydrochloride.

The other ingredient is:

- Hard fat

### **What SCHERIPROCT SUPPOSITORIES looks like and contents of the pack**

**SCHERIPROCT SUPPOSITORIES** are yellowish-white suppositories without cosmetic defects supplied in cardboard boxes containing 12 suppositories packed in strips made of aluminium, soft tempered with thickness of 50 µm and laminated with low-density polyethylene as inner layer.

Not all packs and pack sizes may be marketed.

### **Holder of Certificate of Registration**

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