

REGISTERED PACKAGE INSERT

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

SCHERIPROCT OINTMENT

COMPOSITION

1 g ointment contains prednisolone caproate (1,4-pregnadiene-3,20-dione-11 β -17 α ,21-triol-21-caproate) 1,9 mg and cinchocaine hydrochloride as the hydrochloride of (2-butoxy-N-(2-diethylaminoethyl)cinchonamide) 5 mg.

PHARMACOLOGICAL CLASSIFICATION

A. 11.8 Anal suppositories and ointments.

PHARMACOLOGICAL ACTION

Prednisolone exerts an antiinflammatory and antipruritic effect. Capillary dilatation, intercellular oedema and tissue infiltration regress; capillary proliferation is suppressed.

As a local anaesthetic, cinchocaine eases the pain.

INDICATIONS

Short term symptomatic relief of perianal discomfort, inflammation and itching caused by thrombosed haemorrhoids, anal fissure and pruritus ani.

CONTRA-INDICATIONS

Hypersensitivity to any of the ingredients.

Viral infections, primary bacterial or fungal infections in the treatment area. Secondary infections of the skin in the absence of appropriate antiinfective therapy. Known sensitivity to local anaesthetics.

Corticosteroids have been shown to be teratogenic in animals following dermal application. As these agents are absorbed percutaneously, teratogenicity following topical application cannot be excluded. Therefore, Scheriproct should not be used during pregnancy.

The excretion of effective amounts of glucocorticoid with the breast milk is improbable.

WARNINGS

This product should not be used continuously for more than 7 days. If symptoms do not disappear quickly, discontinue treatment and consult your doctor. Certain anal disorders require specific treatment and a proctological examination. In case of bleeding, consult a doctor promptly.

DOSAGE AND DIRECTIONS FOR USE

The anal region should be cleaned thoroughly before using Scheriproct, which is best applied after defaecation.

Unless otherwise prescribed by the doctor, generally apply twice daily. On the first day, for faster symptomatic relief, up to four times. Smear a little ointment (about the size of a pea) around the anus and in the anal ring with a finger and use the finger-tip to overcome the resistance of the sphincter. Before applying within the rectum, the enclosed nozzle should be screwed on to the tube. However, for very inflamed and hence painful lesions it is advisable initially to apply the ointment internally with the finger.

Protruding lumps should be thickly smeared and carefully pressed back with the finger.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS

In infants, long-term continuous therapy with topical corticosteroids should be avoided. Occlusion is not appropriate on the perineum. Adrenal suppression can occur, even without occlusion. There is a risk of developing skin atrophy following extensive therapy. The application of unusually large quantities of topical corticoids may result in the absorption of systemically active amounts of corticoid. Infections or secondarily infected dermatoses definitely require additional therapy with antibiotics or chemotherapeutic agents. This treatment can often be topical, but for heavy infections systemic antibacterial therapy may be necessary. If fungal infections are present, a topically active antimycotic should be applied. Allergic skin reactions may occur.

Inadvertent contact of the preparation with the eyes should be avoided. Careful handwashing after use is recommended.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

In the case of accidental oral intake of the preparation (eg by swallowing a few grams of the ointment) mainly systemic effects of the local anaesthetic cinchocaine hydrochloride are to be expected, which, according to the dose, may manifest themselves as severe cardiovascular (depression to cessation of cardiac function) and CNS symptoms (convulsions; inhibition to arrest of respiratory function).

IDENTIFICATION

Colourless to slightly yellowish translucent ointment.

PRESENTATION

White coloured aluminium tubes, interior wall coated with epoxy resin, containing 15 or 30 g.

STORAGE INSTRUCTIONS

Store at or below 25°C. For shelf-life, please refer to the imprint on the pack. After first opening of container (in-use stability), shelf-life allocated is 3 months.
Keep out of reach of children.

REGISTRATION NUMBER

E/11.8/0667

REGISTERED PACKAGE INSERT

-3-

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Bayer (Pty) Ltd
(Reg No: 1968/011192/07)
27 Wrench Road
ISANDO
1609

DATE OF PUBLICATION OF THE PACKAGE INSERT

3 August 2000