REGISTERED PACKAGE INSERT

SCHEDULING STATUS S4

PROPRIETARY NAME AND DOSAGE FORM

SCHERIPROCT SUPPOSITORIES

COMPOSITION

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

PHARMACOLOGICAL CLASSIFICATION

A. 11.8 Suppositories.

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.

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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 insert one suppository daily high into the rectum. If symptoms are severe, insert one suppository two to three times on the first day.

The consistency of suppositories that have become softened by warmth should be restored by immersion in cold water before the covering is removed.

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 several suppositories) 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

Yellowish-white suppositories without cosmetic defects.

PRESENTATION

Boxes containing 12 suppositories packed in aluminium foil strips.

STORAGE INSTRUCTIONS

Store in refrigerator between 2 to 8 °C.
Do not freeze.
For shelf-life, please refer to the imprint on the pack. Keep out of reach of children.

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REGISTRATION NUMBER

E/11.8/0668

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

Bayer (Pty) Ltd
(Reg No: 1968/011192/07)
27 Wrench Road
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DATE OF PUBLICATION OF THE PACKAGE INSERT

3 August 2000