PROFESSIONAL INFORMATION FOR HUMAN USE

SCHEDULING STATUS

S1

PROPRIETARY NAME (AND DOSAGE FORM)

NYSTACID OINTMENT

COMPOSITION

NYSTACID OINTMENT contains 100 000 units of nystatin per gram.

Excipients:

Plastibase

PHARMACOLOGICAL CLASSIFICATION

A 20.1.7 Antifungal Antibiotics

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Nystatin is an tetraene macrolide fungistatic and fungicidal antibiotic but exhibits no appreciable activity against bacteria.

It exhibits antifungal activity against *Candida albicans*.

The antifungal activity of polyene nystatin depends principally on its binding to a sterol moiety, primarily ergosterol in the membrane of sensitive fungi. By virtue of their interaction with these sterols, polyenes appear to form pores or channels that increase the permeability of the membrane, allowing leakage of intracellular components.

Pharmacokinetic properties

Nystatin is poorly absorbed from the gastrointestinal tract. It is not absorbed through the skin or mucous membranes when applied topically.

INDICATIONS

NYSTACID OINTMENT is indicated for the treatment of local cutaneous mycotic infections, caused by *Candida albicans* (monilia). Conditions such as athlete's foot (dermatophytosis), perleche, paronychia, intertrigo, nappy rash and other cutaneous lesions can be expected to respond.

NYSTACID OINTMENT is contraindicated in:

- Patients with hypersensitivity to the nystatin or to any of the excipients in NYSTACID OINTMENT (see COMPOSITION).

WARNINGS AND SPECIAL PRECAUTIONS

Local irritation and sensitisation (including rash, dermatitis, pruritis and burning) have been reported (see SIDE EFFECTS).

If local sensitisation develops, treatment should be discontinued.

NYSTACID OINTMENT should not be used for the treatment of systemic or ophthalmic infections.

Nystatin is virtually non-toxic and non-sensitising and is well tolerated by all age groups including debilitated infants, even on prolonged administration.

INTERACTIONS

Interactions are not observed.

PREGNANCY AND LACTATION

Pregnancy

The safety of NYSTACID OINTMENT in pregnancy has not been established.

Lactation

The safety of NYSTACID OINTMENT in lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE

Apply twice daily to the affected areas or as directed by the doctor or pharmacist.

Treatment should be continued until healing is complete.

SIDE EFFECTS

Less frequent: Local irritation, sensitisation, rash, dermatitis, pruritis, postular eruptions, Stevens-Johnson syndrome and burning.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Treatment

Treatment of overdosage should be symptomatic and supportive.

IDENTIFICATION:

A smooth yellow unctuous mass.

PRESENTATION

15 g is packed in an aluminium, collapsible tube sealed with a white self piercing high density polyethylene cap, and placed in a unit cardboard carton together with a leaflet.

STORAGE INSTRUCTIONS

Store at or below 25 ºC.

Protect from light.

Keep the container tightly closed.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

L/20.1.6/394

NAME AND BUSINESS ADDRESS OF THE HOLDER OF

THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

DATE AND PUBLICATION OF THE PROFESSIONAL INFORMATION

Date on registration certificate:

17 October 1983

Date of most recently revised approved professional information:

18 June 2020

Die Afrikaanse Professionele Inligting is op versoek beskikbaar. Mediese Blitslyn: 0800 118

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