1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS:

S2

PROPRIETARY NAME AND DOSAGE FORM

NYSTACID ORAL SUSPENSION

COMPOSITION

Each 1 ml of NYSTACID ORAL SUSPENSION contains 100 000 units nystatin.

Excipients

Disodium edetate, ethanol, flavour cherry, flavour peppermint, glycerol, methyl hydroxybenzoate, polysorbate, propyl hydroxybenzoate, purified water, sodium saccharin, sorbitol solution 70%, sucrose refined white H1

Preservatives:

Methyl hydroxybenzoate 0,1 % *m/v*

Propyl hydroxybenzoate 0,02 % *m/v*

Contains sugar: Sucrose 500 mg; sorbitol solution 70% 1,042 mg

Contains sweetener: Sodium saccharin 2,5 mg

CATEGORY AND CLASS

A 20.1.7 Antifungal antibiotic

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Nystatin is a fungistatic and fungicidal antibiotic. It is effective against several fungi and yeasts, especially the *Candida* genus.

INDICATIONS

The prevention and treatment of *candida* infections of the oral cavity.

CONTRAINDICATIONS

Hypersensitivity to NYSTACID ORAL SUSPENSION.

WARNINGS AND SPECIAL PRECAUTIONS

Not known.

Excipients

NYSTACID ORAL SUSPENSION contains sucrose which may have an effect on the glycaemic control of patients with diabetes mellitus.

Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take NYSTACID ORAL SUSPENSION.

Patients with the rare hereditary condition of sorbitol intolerance should not take NYSTACID ORAL SUSPENSION.

INTERACTIONS

Not known.

HUMAN REPRODUCTION

Not known.

DOSAGE AND DIRECTIONS FOR USE

Shake the bottle before use.

Adults and children: The usual dose is 1 ml to 2 ml (100 000 to 200 000 units) four times daily, held in the mouth for a time before swallowing. This dose may be increased to 4 ml to 6 ml (400 000 to 600 000 units) four times daily for severe infections.

Infants: The usual dose is 1 ml to 2 ml (100 000 to 200 000 units) four times daily, dropped in the mouth. For prophylaxis in the new-born, the suggested dosage regimen is 1 ml (100 000 units) once daily.

SIDE EFFECTS

NYSTACID ORAL SUSPENSION may cause nausea, vomiting and diarrhoea after oral administration.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Symptoms

Nausea, vomiting and diarrhoea.

Treatment

Treatment is supportive and symptomatic.

IDENTIFICATION

A yellow suspension with a pleasant cherry-mint odour.

PRESENTATION

20 ml is packed in an amber glass bottle sealed with a white polypropylene screw cap with an expanded polyethylene liner, together with a black polypropylene screw cap with rubber teat and glass pipette in a clear bag, packed into a pre-printed cardboard carton together with a leaflet.

STORAGE INSTRUCTIONS:

Store at or below 25 °C in airtight containers.

Protect from light.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

R/20.1.7/316

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

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

Date of registration: 25 July 1988

Date of the most recent amendment to the professional information as approved by the Authority: 25 July 1988

Botswana: BOT0701062 S2

Namibia: NS1 90/20.1.7/001087

ZA_NYSTSUS_8807_03