2D_UN VARNISHED AREA
65 x 36 MM

KRISHAT®

Nystatin

Oral Suspension BP 100,000 IU/1ml

Strawberry Flavoured

NAFDAC Reg. No.: B4-6328

30 ml + Dropper

KRISHATPHARMA

Composition:
Each ml contains:
Nystatin BP ..... 100,000 IU
In a flavoured syrup base ..... q.s.

Direction for Use:
The drops should be held in the mouth and swirled around before swallowing. Continue treatment for 48 hours after symptom have subsided.

Dosage: Refer Insert.

Storage:
Do not store above 30°C. Protect from light. Avoid Freezing. The shelf life after opening the bottle when kept under the conditions of temperature listed above (below 30°C) is 14 days.
Keep the medicine out of reach of children.

SHAKE WELL BEFORE USE.

For treatment of oral candidal infections only.

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KRISHAT®

Nystatin

Oral Suspension BP 100,000 IU/1ml

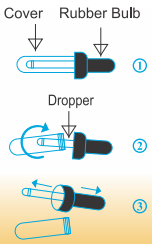
Strawberry Flavoured

NAFDAC Reg. No.: B4-6328

30 ml + Dropper

KRISHATPHARMA

Direction for Using Dropper: Unscrew the cover on the dropper by rotating it. Pull out the rubber bulb and Dropper, now use the dropper. After every use, wash the dropper and screw back the cover.



Manufactured for:
KRISHAT PHARMA IND LTD
Km 15,Lagos Ibadan/Expressway, Opp Oriental Foods, Ibadan, Oyo State, Nigeria.
www.krishatpharma.com

Manufactured by:
S Kant
HEALTHCARE
1802-1805, G.I.D.C., Phase-III, Vapi - 396 195, Gujarat. India.
M. L. No.: G-986

65 mm

36 mm

KRISHAT®

Nystatin Oral Suspension BP 100,000 IU/1ml

Strawberry Flavoured

COMPOSITION:
Each ml contains:
Nystatin BP ..... 100,000 IU
In a Flavoured syrup base ..... q.s.

List of Excipients:
Sucrose (Sugar Pharma Grade) BP, Methyl Hydroxybenzoate BP, Propyl Hydroxybenzoate BP, Sorbitol (Non-Crystallising) 70% BP, Microcrystalline Cellulose BP, Glycerol BP, Carmellose Sodium (Sodium CMC) HVP BP, Polysorbate 80 BP, Saccharin Sodium BP, Flavour Strawberry Supreme I H S, Sodium Benzoate BP, Bronopol BP, Sodium Metabisulphite BP, Disodium Hydrogen Phosphate (Dihydrate) BP, Sodium Citrate Anhydrous BP, Hydrochloric Acid 36% BP, Sodium hydroxide BP, Purified Water BP

VISUAL DESCRIPTION:
Yellow coloured homogenous suspension with strawberry odour.

PHARMACEUTICAL FORM
Liquid-Oral suspension

DESCRIPTION:
Nystatin is a polyene antifungal drug to which many moulds and yeasts are sensitive, including Candida spp. Nystatin has some toxicity associated with it when given intravenously, but it is not absorbed across intact skin or mucous membranes. It is considered as relatively safe drug for treating oral or gastrointestinal fungal infections.

INDICATIONS:
Nystatin Oral Suspension is indicated for the treatment of cutaneous or mucocutaneous mycotic infections caused by Candida species

DIRECTION FOR USE:
The drops should be held in the mouth and swirled around before swallowing. Continue treatment for 48 hours after symptom have subsided.

DOSAGE:
Oral Candidiasis
Infants (1 month to 2 years)
1ml should be dropped into the mouth four times a day.
Children (≥ 2 years) and adults
For the treatment of denture sores, and oral infections in children (≥ 2 years) and adults caused by *candidas albicans*. 1ml of the suspension should be dropped into the mouth four times daily; it should be kept in contact with the affected areas as long as possible.
Intestinal candidiasis
Infants (1 month to 2 years)
1ml should be dropped into the mouth four times a day.
Adults
For the treatment of intestinal candidosis 5ml of the suspension should be dropped into the mouth four times daily.
Paediatric population (≥ 2 years)
1ml should be dropped into the mouth four times a day.
For prophylaxis a total daily dosage of 1 million units has been found to suppress the overgrowth of candidas albicans in patients receiving broad-spectrum antibiotic therapy.
For prophylaxis in the newborn the suggested dose is 1ml once daily.
The longer the suspension is kept in contact with the affected area in the mouth before swallowing, the greater will be its effect.
Administration should be continued for 48 hours after clinical cure to prevent relapse.
Older people
No specific dosage recommendations or precautions.
If signs and symptoms worsen or persist (beyond 14 days of treatment), the patient should be reevaluated, and alternate therapy considered.
OR
As directed by physician.

CONTRAINDICATIONS:
Severe dermatological events have been reported in amongst others Stevens-Johnson syndrome (SJS) acute generalised exanthematous pustulosis (AGEP) If this happens, stop the treatment.

INTERACTIONS:
During treatment you should avoid concomitant use with the following medicines: - Medicines interacting with the functioning of the bowels
- Medicines preventing contact with gastric mucosa

WARNING & PRECAUTIONS:
General
This medication is not to be used for the treatment of systemic mycoses. Discontinue treatment if sensitization or irritation is reported during use.
Carcinogenesis, Mutagenesis, Impairment Of Fertility
No long-term animal studies have been performed to evaluate carcinogenic potential. There also have been no studies to determine mutagenicity or whether this medication affects fertility in males or females.

Pregnancy: Teratogenic Effects Category C.
Animal reproduction studies have not been conducted with Nystatin oral suspension. It is also not known whether Nystatin oral suspension can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Nystatin oral suspension should be given to a pregnant woman only if clearly needed.

Nursing Mothers
It is not known whether Nystatin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Nystatin is administered to a nursing woman.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES
None known

SIDE-EFFECTS:
Nystatin is well tolerated even with prolonged therapy. Oral irritation and sensitization have been reported.
Gastrointestinal: Diarrhoea (including one case of bloody diarrhoea), nausea, vomiting, gastrointestinal upset/ disturbances.
Dermatologic: Rash, including urticaria has been reported rarely. Stevens-Johnson syndrome has been reported very rarely.
Other: Tachycardia, bronchospasm, facial swelling, and non-specific myalgia have also been rarely reported.

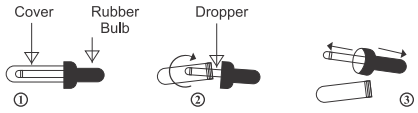
OVERDOSE:
Oral doses of nystatin in excess of 5 million units daily have caused nausea and gastrointestinal upset.
Treatment is supportive and symptomatic.

PHARMACOLOGY
PHARMACODYNAMIC PROPERTIES:
Nystatin is an antifungal antibiotic, active against yeasts and yeast like fungi, including Candida albicans. The antifungal activity is probably due to the binding of sterols in the cell membrane of the fungus with a resultant change in membrane permeability allowing leakage of intracellular components.

PHARMACOKINETICS :
Nystatin is poorly absorbed from the gastrointestinal tract after oral administration.
It is not absorbed through the skin or mucous membrane when applied topically.

STORAGE CONDITIONS:
Do not store above 30°C. Protect from light. Avoid Freezing.
The shelf life after opening the bottle when kept under the conditions of temperature listed above (below 30°C) is 14 days.

Direction for Using Dropper:
Unscrew the cover on the dropper by rotating it. Pull out the rubber bulb and Dropper, now use the dropper. After every use, wash the dropper and screw back the cover.



SHAKE WELL BEFORE USE.

Keep the medicine out of reach of children.

For treatment of oral candida infections only.

PRESENTATION:
30/60ml bottle with polystyrene dropper having graduation at 0.25 ml, 0.5 ml and 1.00 ml.

Date of Review: 05-01-2022

Manufactured for:
KRISHAT PHARMA IND LTD
Km 15,Lagos Ibadan/Expressway,
Opp Oriental Foods, Ibadan,
Oyo State, Nigeria.
www.krishatpharma.com
NAFDAC Reg. No.: B4-6328

Manufactured by:
S Kant HEALTHCARE Ltd.
1802-1805, G.I.D.C., Phase-III, Vapi - 396 195, Gujarat. India.
M. L. No.: G-986

XXXX

220 mm

135 mm

National Agency for Food & Drug Administration & Control (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) TEMPLATE

1. NAME OF THE MEDICINALPRODUCT

Nystatin Oral Suspension BP 100,000 IU / 1 mL

2. QUALITATIVE AND QUANTITATIVECOMPOSITION

Each ml contains 100,000 I.U. nystatin.

Excipient(s) with known effect:

Also contains 600.0mg sucrose; 0.3 mmol (1.3mg) sodium; 0.20mg propyl p-hydroxybenzoate; 1.8mg methyl p-hydroxybenzoate and 0.280mg sodium metabisulphite.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral Suspension.

4. CLINICAL PARTICULARS

4.1 Therapeuticindications

Indications

The prevention and treatment of candidal infections of the oral cavity, oesophagus and intestinal tract.

The suspension also provides effective prophylaxis against oral candidosis in those born of mothers with vaginal candidosis.

4.2 Posology and method ofadministration

Posology

Oral Candidiasis

Infants (1 month to 2 years)

1ml should be dropped into the mouth four times a day.

Children (≥ 2 years) and adults

For the treatment of denture sores, and oral infections in children (≥ 2 years) and adults caused by *candidasalbicans*. 1ml of the suspension should be dropped into the mouth four times daily; it should be kept in contact with the affected areas as long as possible.

Intestinal candidiasis

Infants (1 month to 2 years)

1ml should be dropped into the mouth four times a day.

Adults

For the treatment of intestinal candidosis 5ml of the suspension should be dropped into the mouth four times daily.

Paediatric population(≥ 2 years)

1ml should be dropped into the mouth four times a day.

For prophylaxis a total daily dosage of 1 million units has been found to suppress the overgrowth of candidasalbicans in patients receiving broad-spectrum antibiotic therapy.

For prophylaxis in the newborn the suggested dose is 1ml once daily.

The longer the suspension is kept in contact with the affected area in the mouth before swallowing, the greater will be its effect.

Administration should be continued for 48 hours after clinical cure to prevent relapse.

Older people

No specific dosage recommendations or precautions.

If signs and symptoms worsen or persist (beyond 14 days of treatment), the patient should be reevaluated, and alternate therapy considered.

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions foruse

Nystatin Oral Suspension BP contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactosemalabsorption or sucrase-isomaltase insufficiency should not take this medicine. This should also be taken into account in patients with diabetes mellitus.

Nystatin Oral Suspension contains 0.3 mmol (or 1.3 mg) sodium per 1 ml dose. To be taken into consideration by patients on a controlled sodium diet.

Nystatin Oral Suspension contains sodium metabisulphite (E223) which may rarely cause severe hypersensitivity reactions and bronchospasm.

Nystatin Oral Suspension contains propyl p-hydroxybenzoate and methyl p-hydroxybenzoate which may cause allergic reactions (possibly delayed).

Nystatin oral preparations should not be used for treatment of systemic mycoses.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Pregnancy and Lactation

Pregnancy

Animal reproductive studies have not been conducted with Nystatin.

It is not known whether Nystatin can cause foetal harm when administered to a pregnant woman or can affect reproductive capacity; however absorption of nystatin from the gastro-intestinal tract is negligible. Nystatin should be prescribed during pregnancy only if the potential benefits to be derived outweigh the possible risks involved.

Breastfeeding

It is not known whether Nystatin is excreted in human milk. Although gastrointestinal absorption is insignificant, caution should be exercised when Nystatin is prescribed for a breast-feeding woman

4.7 Effects on ability to drive and usemachines

Not reported.

4.8 Undesirableeffects

Nystatin is generally well tolerated by all age groups, even during prolonged use. If irritation or sensitisation develops, treatment should be discontinued. Nausea has been reported occasionally during therapy.

Large oral doses of Nystatin have occasionally produced diarrhoea, gastrointestinal distress,nausea and vomiting. Rash, including urticaria has been reported rarely. Steven-Johnson Syndrome has been reported very rarely. Hypersensitivity and angioedema, including facial oedema have been reported.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

4.9 Overdose

Since the absorption of nystatin from the gastro-intestinal tract is negligible, overdosage or accidental ingestion causes no systemic toxicity. Oral doses of nystatin in excess of 5 million units daily have caused nausea and gastrointestinal upset.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeuticgroup: Antifungals for topical use, ATC code: D01AA01

Nystatin is a mixture of antifungal polyenes produced by the growth of certain strains of Streptomyces noursei, or by any other means. It consists largely of Nystatin A1.

Nystatin is active against a wide range of yeasts and yeast-like fungi, including Candida albicans.

5.2 Pharmacokinetic properties

Nystatin is a tetraene macrolide. There is no data available on the pharmacokinetics as it is not absorbed from the gastro-intestinal tract, skin or vagina and most of the use is topical. Microbial growth-inhibiting concentrations have been shown to be in the range 3-6mg/l.

5.3 Preclinical safety data

No long-term animal studies have been performed to evaluate the carcinogenic potential of nystatin. No studies have been performed to determine the mutagenicity of nystatin or its effect on male or female fertility.

6. PHARMACEUTICALPARTICULARS

6.1 List ofexcipients

Sucrose, Methyl Hydroxy Benzoate, Propyl Hydroxy Benzoate, Sorbitol 70% (Non-crystallizing), Microcrystalline Cellulose, Glycerol, Carmellose Sodium [Sodium Carboxy methyl Cellulose] (HVP grade),Polysorbate 80, Saccharin Sodium, Strawberry Liquid Flavor, Sodium Hydroxide, Sodium Benzoate, Bronopol, Sodium Metabisulfite, Disodium phosphate (dihydrate), Sodium citrate anhydrous, Hydrochloric Acid (36 %), Purified Water.

6.2 Incompatibilities

Not Applicable

6.3 Shelflife

36months.

6.4 Special precautions forstorage

Do not store above 30°C. Protect from light. Avoid Freezing.

Keep the medicine out of reach of children.

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

30 ml amber colour glass bottle with silver roll on pilfer proof cap along with 1 dropper and leaflet.

6.6 Special precautions for disposal <and otherhandling>

Shake well before use.

Any unused product or waste material should be disposed of in accordance with local requirements.

7. APPLICANT/MANUFACTURER

M/s KRISHAT PHARMA INDUSTRIES LIMITED

9 KILOMETER, OLD LAGOS ROAD,

PODO, IBADAN,

NIGERIA.

Manufactured by:

SKant

HEALTHCARE Ltd.

1802-1805, G.I.D.C.,Phase III,

Vapi - 396 195. Gujarat, INDIA.