KENSTATIN **NYSTATIN ORAL SUSPENSION USP 100000 IU/ML**		
MODULE I :	**ADMINISTRATIVE PARTICULARS OF THE PRODUCT**	
Document	**1.3**	**Product Information**

1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

1. Name of the medicinal product

1.1 (Invented) Name of the medicinal product
KENSTATIN (**NYSTATIN ORAL SUSPENSION USP 100,000 IU/ML**)

1.2 Strength
Each ml of reconstituted Suspension contains:
Nystatin USP 100000 IU
Excipients Q.S.

1.3 Pharmaceutical Form
Oral Suspension

2. Qualitative and Quantitative Formula

Batch Size: 1000 Lit.

Sr. No.	Name of Raw Material	Specification	Qty./ ml (mg)	Qty./ Bottle (mg)	Qty./ Batch (Kg)	Function
1.	Nystatin	USP	20.00	600.00	20.00	Antifungal
2.	Sorbitol 70% solution	BP	300.00	9000.00	300.00	Sweetner
3.	Sodium Methyl Paraben	BP	2.00	60.00	2.00	Preservative
4.	Sodium Propyl Paraben	BP	1.00	30.00	1.00	Preservative
5.	Sodium Benzoate	BP	1.00	30.00	1.00	Preservative
6.	Sodium Saccharine	BP	0.75	22.50	0.75	Sweetner
7.	Xanthan Gum	BP	2.00	60.00	2.00	Suspending agent
8.	Glycerin	BP	40.00	1200.00	40.00	Sweetner
9.	Colloidal Anhydrous Silica	BP	5.40	162.00	5.40	Glidant
10.	Bronopol	BP	0.25	7.50	0.25	Preservative
11.	Flavour Mix Fruit	IHS	2.50	75.00	2.50	Flavouring agent
12.	Flavour Peppermint	IHS	2.50	75.00	2.50	Flavouring agent
13.	Purified Water	BP	Q.S. to 1 ml	Q.S. to 30 ml	Q.S. to 1000 Lit.	Solvent

3. Pharmaceutical form
A Clear coloured flavoured Suspension.

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4. Clinical particulars

4.1 Therapeutic Indication:

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 of administration:

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 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.

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 for use:

Nystatin Oral Suspension contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption 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 Fertility, 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 gastrointestinal 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 use machines:
Not relevant.

4.8 Undesirable effects:
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.

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 Pharmacodynamic Properties:
Pharmacotherapeutic group: 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 A_1.
Nystatin is active against a wide range of yeasts and yeast-like fungi, including Candida albicans.

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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. Pharmaceutical particulars
6.1 List of Excipients:
Sorbitol 70% Solution BP
Sodium Methyl Paraben BP
Sodium Propyl Paraben BP
Sodium Benzoate BP
Sodium Saccharine BP
Xanthan Gum BP
Glycerin BP
Colloidal Anhydrous Silica BP
Bronopol BP
Flavour Mix Fruit
Flavour Peppermint
Purified Water BP

6.2 Incompatibilities:
None known

6.3 Shelf life:
24 Months

6.4 Special precautions for storage:
Store below 30°C. Keep medicines out of the reach of children.

6.5 Nature and contents of container:
Primary Packaging: 30 ml Amber Pet Bottle.
Secondary Packaging: Such 1 Bottle is packed in printed carton along with printed insert.

6.6 Special precautions for disposal:
No special requirements.

7. REGISTRANT
SANGHARSH LIFECARE PVT. LTD.
A-502/503, Solitair Corporate Park, Near
Divya Bhaskar House, S.G. Highway,
Makarba, Ahmedabad-380051, Gujarat, India.

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8. DATE OF REVISION OF THE TEXT

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9. NAME AND ADDRESS OF MANUFACTURER

BRUSSELS LABORATORIES PVT. LTD.

33, Changodar Industrial Estate,
Sarkhej-Bavla Highway, Changodar-382210,
Dist.: Ahmedabad, Gujarat (India).