



HAB PHARMACEUTICALS & RESEARCH LTD.
10, Pharmacy, Selaqui, Dehradun, Uttarakhand - 248011

PRODUCT NAME	SIGNATURE MYSTATIN VAGINAL CREAM
GENERIC NAME	Nystatin Cream USP 100,000 IU/5 gm

1.3 Product Information

1.3.1 Summary of Product Characteristic (SmPC)

1. Name of the medicinal product

SIGNATURE MYSTATIN VAGINAL CREAM

(Nystatin Cream USP 100,000 IU/5 gm)

2. Qualitative and Quantitative Composition

2.1 Label Claim

Composition :-

Nystatin USP.....100,000 IU/5 gm

Cream base.....q.s.

Preservatives:-

Methyl Paraben..... 0.1 % w/w

Propyl Paraben 0.05

2.2 Quantitative Composition

Sr. No.	Ingredient Description	Label Claim	Spec.	Function	Quantity/ Tablet (in Kg)
ACTIVE INGREDIENT					
1	Nystatin	100000 IU/5 g	USP	Active	0.490
EXCIPIENTS					
1	Methyl Hydroxy Benzoate	--	BP	Preservative	0.100
2	Propyl Hydroxy Benzoate	--	BP	Preservative	0.050
3	Cetomacrogol -1000	--	BP	Solubilizer & Emulsifier	3.000
4	Cetostearyl Alcohol	--	BP	Emulsifier	9.000
5	Hard Paraffin	--	BP	Antioxidant	2.000
6	Light Liquid Paraffin	--	BP	Moisture retention	5.000
7	Propylene Glycol	--	BP	Humectant	5.000
8	Sodium EDTA	--	BP	Chelating Agent	0.100
9	Polysorbate-80	--	BP	Surfactant, Emulsifier & Solubilizer	0.300
10	Sodium Dihydrogen Phosphate	--	BP	Buffering Agents	0.030
11	Purified Water	--	BP	Solvent	74.966

Batch Size: 100 Kg

3. Pharmaceutical Form



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PRODUCT NAME	SIGNATURE MYSTATIN VAGINAL CREAM
GENERIC NAME	Nystatin Cream USP 100,000 IU/5 gm

A pale yellow colour cream filled in aluminium tube.

4.1 Pharmacodynamic Properties

Nystatin is an antibiotic with antifungal activity against a wide variety of yeasts and yeast-like fungi. The antifungal activity of Nystatin is at least in part dependent on its binding to a sterol moiety, primarily ergosterol, present in the membrane of sensitive fungi, which results in an increase in the permeability of the membrane and leakage of intra-cellular components.

Nystatin exhibits no appreciable activity against bacteria.

4.2 Indications

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

4.3 Contraindications

Nystatin cream is contraindicated in patients with a history of hypersensitivity to any of its components.

4.4 Side Effects

Nystatin is virtually non-toxic and non-sensitizing and is well tolerated by all age groups including debilitated infants, even on prolonged administration. Large oral doses have occasionally produced diarrhoea and gastrointestinal disturbance.

Local irritation and sensitization (including rash, dermatitis, pruritis and burning) have been reported. The frequency of adverse events reported in patients using Nystatin cream is less than 0.1%.

4.5 Special Warnings and Precautions for Use

Nystatin topical preparations should not be used for the treatment of systemic or ophthalmic infections.

If local sensitisation develops, treatment should be discontinued.

Nystatin topical preparations should be prescribed for a pregnant woman only if the potential benefit to the mother outweighs the potential risk to the fetus. It is not known whether Nystatin is excreted in human milk.

Caution should be exercised when Nystatin is prescribed for a nursing woman.

4.6 Interactions with other Medicines

No information provided

4.7 Fertility, Pregnancy and Lactation

Pregnancy

It is not known whether this cream can cause fetal harm when used by a pregnant woman or can affect reproductive capacity. Nystatin cream should be prescribed for a pregnant woman only if the potential benefit to the mother outweighs the potential risk to the fetus.

Nursing Mothers

It is not known whether Nystatin is excreted in human milk. Caution should be exercised when Nystatin is prescribed for a nursing woman.

4.8 Effects on the ability to drive and use Machines



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No Relevant

4.9 Dosage and Administration

Adults and Pediatric Patients (Neonates and Older)

Apply liberally to affected areas twice daily or as indicated until healing is complete.

4.10 Overdose

No Information Provided

4.11 Storage

Store in a cool, dark and dry place.

Keep out of the reach and sight of children,

4.13 Pharmaceutical Particulars:

List of Excipients:

Methyl Hydroxy Benzoate, Propyl Hydroxy Benzoate, Cetomacrogol-1000, Cetostearyl Alcohol, Hard Paraffin, Light Liquid Paraffin, Propylene Glycol, Sodium Edetate, Polysorbate-80, Sodium Dihydrogen Phosphate, Purified Water.

4.14 Incompatibilities

Not Applicable

4.15 Shelf life

30 Months

4.16 Special precautions for disposal and other handling

4.17 Nature and contents of container

Manufactured By:

Hab Pharmaceuticals & Research Ltd.,
10, Pharmacy, Selaqui,
Dehradun, Uttarakhand - 248011,
India

Marketing authorization holder

Hab Pharmaceuticals & Research Ltd.,
10, Pharmacy, Selaqui,
Dehradun, Uttarakhand - 248011
India

Patient Information Leaflet
SIGNATURE MYSTATIN VAGINAL CREAM
(Nystatin USP 100,000 IU per 5 gm)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have questions about the medicine, ask your health care provider.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness seem to be the same as yours.
- If you get any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet.

What is in this leaflet-

1. What SIGNATURE MYSTATIN VAGINAL CREAM and what it is used for
2. What you need to know before you take SIGNATURE MYSTATIN VAGINAL CREAM.
3. How to take SIGNATURE MYSTATIN VAGINAL CREAM.
4. Possible side effects
5. How to store SIGNATURE MYSTATIN VAGINAL CREAM.
6. Contents of the pack and other information.

WHAT SIGNATURE MYSTATIN VAGINAL CREAM IS AND WHAT IT IS USED FOR

SIGNATURE MYSTATIN VAGINAL CREAM is a light yellow cream for application to the skin. It is used to treat skin infections caused by either fungi and/or bacteria, such as ringworm, athlete's foot and infected nappy rash

WHAT YOU NEED TO KNOW BEFORE YOU TAKE SIGNATURE MYSTATIN VAGINAL CREAM

Do not use SIGNATURE MYSTATIN VAGINAL CREAM

- If you are allergic to nystatin, chlorhexidine hydrochloride or any of the other ingredients of this medicine
Warnings and precautions
Talk to your doctor or pharmacist before using SIGNATURE MYSTATIN VAGINAL CREAM. SIGNATURE MYSTATIN VAGINAL CREAM may in rare cases cause severe allergic reactions, leading to a drop in blood pressure and even to unconsciousness. Early symptoms of a severe allergic reaction may be skin rash or asthma. If you notice these symptoms, stop using SIGNATURE MYSTATIN VAGINAL CREAM and contact your doctor as soon as possible
Take special care with SIGNATURE MYSTATIN VAGINAL CREAM
- SIGNATURE MYSTATIN VAGINAL CREAM is for external use only and should not be used near your eyes, mouth or be swallowed.
- If swallowed accidentally, seek medical advice immediately.
- If SIGNATURE MYSTATIN VAGINAL CREAM gets in your eyes accidentally, you should rinse your eyes immediately and contact your doctor.
- If you are unsure about anything, please ask your doctor or pharmacist

Other medicines and SIGNATURE MYSTATIN VAGINAL CREAM

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy, breast-feeding and fertility

Pregnancy

Do not use SIGNATURE MYSTATIN VAGINAL CREAM if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine

HOW TO USE SIGNATURE MYSTATIN VAGINAL CREAM

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. For application to the skin only. Apply the cream to the infected area two or three times daily. The cream should be applied for one week after your infection has healed. If the infected area has not improved within seven days of starting treatment, consult your doctor. If the condition does not improve within 14 days of starting treatment, or if a new infection appears, you should stop using SIGNATURE MYSTATIN VAGINAL CREAM and consult your doctor. An alternative treatment may be needed

IF YOU FORGET TO USE MYSTATIN VAGINAL CREAM

Apply the cream as soon as you remember and then continue the rest of your treatment as usual. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you experience any of the following reactions stop using SIGNATURE MYSTATIN VAGINAL CREAM and get immediate medical help

Swelling of the face, lips, tongue or throat; a red itchy skin rash; wheezing or difficulty breathing; feeling faint and dizzy; a strange metallic taste in the mouth; collapse. You may be having an allergic reaction

If you develop a rash or your skin becomes itchy, red, dry or inflamed where you have used this medicine, stop using it and talk to your doctor or pharmacist

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

HOW TO STORE SIGNATURE MYSTATIN VAGINAL CREAM

Store in cool, dry and dark place. Keep this medicine out of the sight and reach of children.

CONTENTS OF THE PACK AND OTHER INFORMATION

What SIGNATURE MYSTATIN VAGINAL CREAM contains

The active ingredients are: Nystatin USP 100,000 IU per 5 gm

Pack of 10X50