Nystaland vaginal cream

Nystatin 100.000 IU/g vaginal cream

PROLIFE PHARMA

Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

INDICATIONS

Nystatin is indicated for the treatment of candidiasis in the oral cavity, for the local treatment of monoliasis especially those caused by Candida albicans, including thrush intestinal, anal, vulvovaginal and cutaneous monoliasis and monolial paronychia,

DOSAGE

The usual dosage is 1g (100.000 units) once or twice (100.000 or 200.000 units) daily deposited high in the vagina by means of the applicator. In most cases, 2 weeks of therapy will be sufficient, but more prolonged treatment may be necessary. Administration should generally be continued for at least 48 hours after clinical cure to prevent relapse. It is important that therapy be continued during menstruation

CONTRAINDICATIONS - HYPERSENSITIVITY TO THE DRUG.

Side-effects

Nystatin is relatively nontoxic. A few mild and transient reactions that may occasionally occur after oral administration consist mainly of nausea, vomiting, and diarrhea. The drug is not irritating the skin and mucous membranes, although a few cases of local allergic reactions have been reported. Acquired resistance of Candida albicans to Nystatin does not appear to be a problem, even after prolonged use. Slight irritation of the vulva and surrounding area after vaginal applications is the most common untoward effect.

Precautions

In pregnant women, Nystatin must be administered only in case of real necessity and only under the direct control of physician.

Pregnancy and lactation

The drug should be dispensed to pregnant women only if clearly needed. The use of the vaginal applicator may not be considered desiderable during pregnancy. Appropriate measure should be taken to avoid possible reinfection during sexual intercourse. It is not known whether Nystatin is excreted in human milk. Caution should be exercised when Nystatin is prescribed to a nursing woman.

Overdosage

Oral doses of Nystatin in excess of five millions U. daily have caused nausea and diarrheas. There have been no reports of serious toxic effects or superinfections.

Interactions

With oral treatment, in order to achieve maximum effect from Nystatin, any propulsives or digestives and, generally, any agent capable to isolate the mucous membrane from the activity of the drug, has to be avoided.

Storage

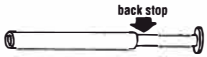
Store at temperature not exceeding 25°C; protect from light.

Packings

Vaginal cream U.S.P: tube of 60 g, 100.000 U./g, with applicator
The applicator consist of a barrel and a removable plunger and it is specifically designed to permit to insert cream deep into the vagina.

How to use the applicator

Remove cap from the tube and use the recessend point on top of the cap to perforate the seal .



Gently screw the threaded end (open end) of the applicator over the tube until it is firmly attached. Pull out the plunger to the back stop.

Hold the tube and applicator horizontally and fill up the applicator (already extended to the back stop) by squeezing the tube.

Remove the applicator from the tube and replace the cap.
In the lying position, insert the filled applicator deep into the vagina and pressing the plunger all the way empty the Nystatin cream into the vagina.

To clean the applicator, separate the plunger from the barrel and wash both sections under a stream of water. Sterilization is not necessary and extremely hot water could damage the plastic applicator.

During pregnancy the applicator should be used on the advice of the physician only. Treatment should be continued for at least two weeks, even if symptoms may disappear in a few days.

KEEP OUT OF THE REACH OF CHILDREN