PACKAGE LEAFLET: Information for the patient

PRONYSTIN

Film-coated tablets – 500 000 UI

(Nystatin)

Read all of this leaflet carefully because it contains important information for you.

To be sure of the success of the therapy, the film-coated tablets Pronystin should always be used according the prescription.

- Keep this leaflet. You may need to read it again.
- Ask your doctor or pharmacist if you need more information or advice.
- You must talk to a doctor if you feel worse or if you do not feel better after 7 days.
- If you have any side effects, or if you notice side effects not listed in this leaflet, talk to your doctor or pharmacist.

In this leaflet:

1. WHAT PRONYSTIN IS AND WHAT IT IS USED FOR?

Pronystin film – coated tablets contain as active substance nystatin which is used to treat fungal infections (antifungal).

They are indicated for topical intestinal treatment of proven yeast infections of the gastrointestinal tract sensitive to nystatin, particularly as a result of therapy with antibiotics, cytostatics or corticosteroids.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PRONYSTIN?

Do not take Pronystin:

- if you are hypersensitive (allergic) to nystatin, to a related drug (amphotericin B, natamycin), to the colouring agents Ponceau 4R (E 124) and Sunset Yellow FCF (E 110) or to any of the other excipients of Pronystin film – coated tablets;
- to treat systemic fungal infections (affecting the internal organs).

Take special care with Pronystin

Children

Due to high osmolarity of nystatin, it should not be used in preterm infants or in those extremely underweight.

Taking Pronystin with other medicines

Tell your doctor or pharmacist if you are taking / using or have recently taken / used other medicines, including medicines obtained without a prescription.

Pregnancy / Lactation

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 using this medicine.

Nystatin, the active substance of Pronystin, in therapeutic doses taken orally, is not absorbed by the intact skin or mucous membranes.

Nystatin does not cross the placenta and it is not expected to be excreted in the human milk.

The film-coated tablets Pronystin can be used during pregnancy and lactation.

Driving and using machines

There are no experiences regarding the effects of this medicine on the ability to drive or use machines.

Important informations for some of the excipients of Pronystin

This medicine contains lactose. If you know that you suffer from any intolerance to some sugars, take the film-coated tablets Pronystin only after first talking to your doctor.

The film-coating of Nystatin tablets contains AZO colouring agents, as Ponceau 4R (E 124) and Sunset Yellow FCF (E 110) which may cause allergic reactions.

Pronystin film-coated tablets contain less than 1 mmol sodium (23 mg) per each tablet, that is to say essentially sodium-free.

3. HOW TO TAKE PRONYSTIN?

Always take the film-coated tablets Pronystin as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

For the treatment of fungal infections in the gastrointestinal tract - particularly during treatment with drugs that promote yeast growth in this tract (e.g., broad-spectrum antibiotics, corticosteroids, cytostatics) take 1 film-coated tablet 3 times daily.

If necessary, the dosage of Pronystin can be increased.

Method of administration

Take the film-coated tablets Pronystin after food, whole, with some liquid.

Duration of administration

The duration of treatment is 2 weeks, or as long as the treatment with drugs that promote yeast growth continues.

Talk to your doctor or pharmacist if you have the impression that the effect of the film-coated tablets Pronystin is too strong or too weak.

If you take more Pronystin than you should

Too limited information is available regarding the overdose following oral use of nystatin.

As the absorption of nystatin by the gastrointestinal tract after oral administration is negligible even in high doses, undesirable effects in the organism are not expected in case of an overdose.

In case of an overdose, the usual precautions to eliminate a medicinal product from the gastrointestinal tract, should be taken.

If you forget to take Pronystin

Do not take a double dose if you forget to take the previous dose. Continue treatment according the prescription.

If you stop the treatment with Pronystin

You may put at risk the success of the treatment. Talk to your doctor or pharmacist before you stop treatment with Pronystin.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, the film-coated tablets Pronystin can cause side effects, although not everybody gets them.

For the evaluation of side effects, the following frequency indicators are used:

Very common	more than 1 in 10 patients
Common	1 to 10 patients among 100
Uncommon	1 to 10 patients among 1,000
Rare	1 to 10 patients among 10,000
Very rare	less than 1 in 10,000 patients
Unknown	Cannot be evaluated.

Possible side effects:

Nystatin, the active substance of Pronystin is in general well – tolerated.

Often gastrointestinal disturbances, nausea, vomiting and diarrhoea may occur.

Uncommon side effects are: skin rash, including urticaria.

Rarely, Stevens-Johnson's syndrome (fever and painful blisters on the skin or mucosa) may be noticed.

Unknown: skin reactions with acute pustules often associated with fever and changes in blood count (acute generalized exanthematous pustulosis (AGEP)).

Azo colouring agents, Ponceau 4R (E 124) and Sunset Yellow FCF (E 110) may cause allergic reactions.

Special notes:

In case of a hypersensitivity reaction, the medicine should be interrupted, and your doctor will advise you for the right treatment.

Talk to your doctor or pharmacist if you have any of the side effects, or if you notice side effects not listed in this leaflet.

5. HOW TO STORE PRONYSTIN?

Keep this medicine out of the sight and reach of children!

Do not use this medicine after the expiry date which is stated on the blister and carton.

Do not store above 25ºC.

6. FURTHER INFORMATION

What Pronystin film-coated tablets contain:

The **active substance** is Nystatin.

1 film-coated tablet contains 500 000 UI. nystatin.

The **excipients** are:

tablet core: cellactose, croscarmellose sodium, povidone, colloidal anhydrous silica, magnesium stearate;

film-coating: Opadry II pink (polyvinyl alcohol, titanium dioxide, macrogol, talc, Ponceau 4R (E 124), Sunset yellow FCF (E 110)).

Contents of the pack

Box with 20 film-coated tablets

Box with 30 film-coated tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

This leaflet was last revised in October 2023.