

Adclair[®] Nystatin Mundgel

100,000 I.U. / g

For use in adults, children and infants

Active substance: Nystatin



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

This medicinal product is available without prescription. However, you still need to take Adclair[®] Nystatin Mundgel carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 28 days.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Adclair[®] Nystatin Mundgel is and what it is used for

- 1.1 Adclair[®] Nystatin Mundgel is an antimycotic drug specifically directed against yeast.
- 1.2 Adclair[®] is used to treat Nystatin-sensitive yeast infections in the oral cavity (oral thrush)

2. Before you take Adclair[®] Nystatin Mundgel

2.1 Do not take Adclair[®] Nystatin Mundgel

– if you are hypersensitive (allergic) to the active substance nystatin, methyl-4-hydroxybenzoate, propyl-4-hydroxybenzoate and/or one of the excipients of Adclair[®] Nystatin Mundgel.

In the case of hypersensitivity to nystatin or one of the other excipients (e.g. burning, itching) discontinue using this product.

Experiences in patients treated with chemotherapy are not available.

2.2 Take special care with Adclair[®] Nystatin Mundgel

There is no need for special measures of precautions.

Children:

Because of the high osmolality of nystatin (2282 mOsm/L), the use in heavily underweight and premature infants is not recommended.

2.3 Other medicines and Adclair[®] Nystatin Mundgel

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines, including medicines obtained without a prescription. There are no interactions with other medicines known.

2.4 Pregnancy and breast-feeding

Due to its molecular size, Nystatin is not absorbed after oral administration in normal doses, does not pass the placental barrier and it is not expected to transfer into the breast milk.

2.5 Driving and using machines

No special precautions are necessary.

2.6 Important information about some of the ingredients of Adclair[®] Nystatin Mundgel

This product contains sucrose.

If you know you have an intolerance to some sugars, contact your doctor before taking Adclair[®] Nystatin Mundgel. Adclair[®] Nystatin Mundgel can be harmful to the teeth (caries).

3. How to take Adclair[®] Nystatin Mundgel

Always take Adclair[®] Nystatin Mundgel exactly as it is described in this leaflet or your doctor has told you. Check with your doctor or pharmacist if you are not sure.

3.1 Dosage

Unless otherwise prescribed by the doctor, the recommended dose is:

Take Adclair[®] Nystatin Mundgel 3 – 6- times daily - in severe cases every 2 hours in each case 1 g (1 measuring spoon).

3.2 Method of administration

After oral intake, Adclair[®] Nystatin Mundgel has to be kept a few minutes in the mouth before swallowing.

For the treatment of yeast infection in the oral cavity additional administration of Adclair[®] Nystatin Mundgel by a cotton bud on infected areas has approved its worth. Due to its adhesion properties mouth gel is suitable for treatment in the oral cavity.

In infants, the application of ½ – 1 measuring spoon (½ – 1 g of mouth gel) into the oral cavity after meal has been experienced as useful. Thus efficacy of nystatin in the oral cavity can be optimized. Also in infants a longer retention time of mouth gel in the oral cavity is desirable.

3.3 Duration of treatment

Normally within a few days of treatment a distinctively improvement of symptoms occur. Treatment should be continued for additional 2 days after all symptoms subside. Duration of treatment should not exceed 28 days.

Please consult your doctor or pharmacist whenever you get the impression of the effect of Adclair[®] Nystatin Mundgel being too strong or too weak.

3.4 If you apply more Adclair[®] Nystatin Mundgel than you should

Even if you apply more Adclair[®] Nystatin Mundgel than you should, no negative impacts are to be expected. In the case of nausea, vomiting and diarrhea discontinue Adclair[®] Nystatin Mundgel and contact your doctor or pharmacist.

3.5 If you forgot using Adiclair® Nystatin Mundgel

If you apply to less or forget to apply Adiclair® Nystatin Mundgel continue the application as described in this package leaflet.

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

4. Possible side effects

Like all medicines, Adiclair® Nystatin Mundgel can cause side effects, although not everybody gets them. For the assessment of side effects, the following data on frequency are used as a basis:

Very common:	More than 1 of 10 patients treated
Common:	Less than 1 of 10, but more than 1 of 100 patients treated
Uncommon:	Less than 1 of 100, but more than 1 of 1,000 patients treated
Rare:	Less than 1 of 1,000, but more than 1 of 10,000 patients treated
Very rare:	Less than 1 of 10,000 patients treated, or unknown

4.1 Possible side effects

Due to its molecular size nystatin applied to the oral cavity in normal doses is not absorbed and systemic adverse effects are not to be expected.

In the case of using extreme high dosages uncommon appearance of nausea and in more rare cases vomiting and diarrhea can arise. In this case stop taking the drug.

In rare cases at local application of nystatin allergic reactions can occur, characterized by itching, erythema, papules, vesicles not only restricted to the area of application but spread beyond.

Rarely, a Stevens-Johnson-Syndrome (fever and painful lesions of skin and mucosal membranes) was observed.

Methyl-4-hydroxybenzoate and propyl-4-hydroxybenzoate may cause hypersensitive reactions, that may also be delayed in time.

If side effects occur the application should be stopped or more specifically canceled in case of hypersensitive reactions and a doctor should be asked.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

4.2 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 Bundesinstitut für Arzneimittel und Medizinprodukte, Abt. Pharmakovigilanz, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, Website: www.bfarm.de. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Adiclair® Nystatin Mundgel

Keep out of the reach and sight of children.

Do not use Adiclair® Nystatin Mundgel after the expiry date which is stated on the tube and on the outer carton.

Storage conditions:

Do not store above 25 °C !

Instructions on the storage after the first opening of preparation: Usability of the tube after first opening: 28 days

6. Further information

6.1 What Adiclair® Nystatin Mundgel contains

The active ingredient is:

1 g mouth gel contains: 100,000 I.U. Nystatin. Other excipients: methyl 4-hydroxybenzoate (Ph. Eur.), propyl 4-hydroxybenzoate (Ph. Eur.) glycerol, sucrose hyetelose, raspberry flavouring , purified water.

6.2 What Adiclair® Nystatin Mundgel looks like and contents of the pack

Appearance:

Yellow homogenous gel.

Packs:

Pack with 25 g mouth gel

Pack with 50 g mouth gel

Marketing Authorisation Holder and Manufacturer

Pharma-Zentrale GmbH · Loerfeldstraße 20 · 58313 Herdecke Germany

Pharmaceutical entrepreneur

Ardeypharm GmbH, Loerfeldstr. 20, 58313 Herdecke, Germany

This leaflet was last approved in February 2015.

Dear Patient!

It is possible that the leaflet in your medicine pack may differ from this version.

This leaflet is an internal, unofficial translation of the German package leaflet and may not apply to other countries.