

Adiclair®

Suspension · 100,000 I.U. / ml

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 Adiclair® 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.
- 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.

In this leaflet

1. What Adiclair® is and what it is used for
2. Before you take Adiclair®
3. How to take Adiclair®
4. Possible side effects
5. How to store Adiclair®
6. Further information

1. What Adiclair® is and what it is used for

1.1 Adiclair® is an antifungal polyene antibiotic.

1.2 Adiclair® is used for topical treatment of nystatin-sensitive fungal infections in the cavity of mouth and throat, oesophagus and gastrointestinal tract (candida infection).

2. Before you take Adiclair®

2.1 Do not take Adiclair®

If you are hypersensitive (allergic) to the active substance nystatin, methyl-4-hydroxybenzoate, propyl-4-hydroxybenzoate and/or one of the excipients of Adiclair®.

2.2 Take special care with Adiclair®

Children:

Because of the high osmolality of nystatin, the use in heavily underweight premature infants is not recommended.

2.3 Taking other medicines

There are no interactions with other medicines known.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

2.4 Pregnancy and breast-feeding

Nystatin, the active substance of Adiclair®, is hardly resorbed after administration of therapeutic oral doses, from intact skin or mucous membranes. Nystatin does not pass the placental barrier and it is not expected to transfer into the breast milk.

Adiclair® can be used during pregnancy and lactation.

2.5 Driving and using machines

No special precautions are necessary.

2.6 Important information about some of the ingredients of Adiclair®

This medicinal product contains sucrose (saccharose). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

1 ml Adiclair® contains 0.566 g sucrose (sugar) corresponding to approx. 0.047 bread units (BU). If you are on a diabetes diet, you should consider this.

Adiclair® may be harmful to your teeth (caries).

3. How to take Adiclair®

Always take Adiclair® exactly as described in this patient information leaflet. You should check with your doctor or pharmacist if you are not sure.

3.1 Dosage

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

Infants:

If mouth, throat and oesophagus are infected (e.g. oral thrush) 3–6 times daily 0.5–1 ml suspension (50,000–100,000 I.U. Nystatin) should be instilled into the mouth.

If the gastrointestinal tract is infected, 3–6 times daily 1–2 ml suspension (100,000–200,000 I.U. Nystatin) should be instilled into the mouth.

Children and adults:

If mouth, throat and oesophagus are infected (e.g. oral thrush) 3–6 times daily 1 ml suspension (100,000 I.U. Nystatin) should be instilled into the mouth.

3.2 Method of administration

Before use, you should shake the suspension vigorously.

Package with pipette: Suspension is to be drawn up to the desired mark (0.5 or 1 ml).

Package with pump: 1 actuation corresponds to 0.5 ml, 2 actuations correspond to 1 ml).

The suspension should be kept in the mouth as long as possible before swallowing.

When treating the oesophagus, the suspension should ideally be swallowed while laying.

The suspension should be taken after the meals.



3.3 Duration of treatment

In the treatment of yeast mycoses, all sources of infection have to be eliminated in order to prevent a relapse.

In order to achieve an enduring success of the therapy, Adiclair® should be taken regularly at least for 2 weeks.

In cases of persistent disease, an extension of therapy duration is possible.

Please consult your doctor or pharmacist whenever you get the impression of the effect of Adiclair® being too strong or too weak.

3.4 If you take more Adiclair® than you should

If you notice side effects, stop taking Adiclair® and ask your doctor or pharmacist.

3.5 If you forgot taking Adiclair®

Don't use the double dosage, but continue the treatment as prescribed by your doctor or 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® 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

The nystatin contained in Adiclair® is generally well tolerated in oral use.

In rare cases, hypersensitive reactions of skin and mucous membranes were observed.

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, which may also be delayed in time.

4.2 Countermeasures for side effects

If side effects occur, please stop taking Adiclair® and tell your doctor or pharmacist.

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.

4.3 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®

Keep out of the reach and sight of children.

Do not use Adiclair® after the expiry date which is stated on the outer package and on the container.

Do not store above 30 °C!

Store bottle in the folding carton!

Instructions on the storage after the first opening of preparation

The shelf life after first opening is 6 months.

6. Further Information

6.1 What Adiclair® contains

The active substance is:

1 ml suspension contains 100,000 I.U. nystatin

The other ingredients are:

Methyl-4-hydroxybenzoate, propyl-4-hydroxybenzoate, glycerol, sucrose, colloidal silica, raspberry flavour, purified water.

For diabetics, the intake per ml suspension is calculated with less than 0.05 bread units (BU).

6.2 What Adiclair® looks like and contents of the pack

Appearance

Yellow, homogeneous suspension

Packs

Adiclair® is available in the following packs:

24 ml suspension (pipette)

48 ml suspension (pump)

6.3 Marketing authorisation holder and manufacturer

Ardeypharm GmbH, Loerfeldstraße 20, 58313 Herdecke, Germany

This leaflet was last approved in July 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.