



6. Further Information

6.1 What Adiclair® contains

The active substance is:

1 film-coated tablet contains:
500,000 I.U. nystatin

The other ingredients are:

Lactose monohydrate, stearic acid (Ph. Eur.), magnesium stearate, povidone K 25, talcum, propylene glycole, poly(-carbocymethyl)starch, sodium salt, hypromellose, titanium dioxide, cellulose powder, colloidal silica, iron(III)-hydroxide-oxide x H₂O.

For diabetics, the use of 1 film-coated tablet Adiclair® is calculated as 0.05 bread units.

6.2 What Adiclair® looks like and contents of the pack

Appearance

Light beige, smooth, round film-coated tablets

Packs

Adiclair® is available in the following packs:

- 20 film-coated tablets
- 50 film-coated tablets
- 100 film-coated tablets

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.

Package leaflet: Information for the user

Adiclair®

Film-coated tablets · 500,000 I.U.

For use in adults, adolescents and children

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 talk to your doctor or pharmacist.

In this leaflet

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3. How to take Adiclair®
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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 verified, nystatin-sensitive, intestinal infections with yeast, particularly after or during a therapy with cytostatics, corticosteroids or antibiotics.
- for elimination or diminution of the gastrointestinal yeast reservoir as adjuvant in a local therapy of established oral or vaginal infections with yeast.

2. Before you take Adiclair®

2.1 Do not take Adiclair®

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

2.2 Take special care with Adiclair®

Children:

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

2.3 Taking other medicines

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

There are no interactions with other medicines known.



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 lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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:

For the treatment of yeast-mycoses, please take 2 film-coated tablets (1,000,000 I.U. nystatin) 3 times daily. If necessary, the daily dosage can be increased to up to 12 film-coated tablets.

During a therapy with medicines stimulating the growth of yeast, please take 1 film-coated tablet (500,000 I.U. nystatin) 3 times daily.

For diminution or elimination of the appearance of yeast in the gastrointestinal tract as adjuvant in a local therapy of established oral or vaginal infections with yeast 1–2 film-coated tablets (500,000 – 1,000,000 I.U. nystatin) have to be taken 3 times daily.

3.2 Method of administration

For oral use.

The film-coated tablets should be taken after the meals with a sufficient amount of liquid (e.g. 1 glass of water).

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 treatment success you should take Adiclair® regularly for at least for 2 weeks.

For the diminution of elimination of the appearance of yeast in the gastrointestinal tract in established yeast infections of the mucous membranes (oral or vaginal candidiasis) 1–2 film-coated tablets of Adiclair® should be taken 3 times daily. The treatment should be continued until there is no risk of disease anymore.

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 adverse effects, please discontinue taking Adiclair® and ask your doctor or pharmacist. If you have further questions regarding the use of the medicine, please 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.

Taking daily dosages which are too high can uncommonly favour the occurrence of temporary gastrointestinal disturbances in sensitive patients.

In individual cases, allergic reactions of the skin and the mucous membranes have been observed.

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

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.

Keep blister in the folding carton!

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

Do not store above 30 °C!