

Adiclair[®] Cream

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 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.

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

1.1 Mode of action

Nystatin contained in Adiclair[®] is specifically effective against infections with *Candida albicans* and other fungi. Thereby, Nystatin binds to the cell membranes, inhibits the growth and destroys the fungal cells.

1.2 Adiclair[®] is used

to treat Nystatin-sensitive fungal infections of the skin

2. Before you take Adiclair[®]

2.1 Do not take Adiclair[®]

If you are hypersensitive (allergic) to the active substance nystatin, methyl-4-hydroxybenzoate (paraben) 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 and premature infants is not recommended.

2.3 Other medicines and Adiclair[®]

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.

Advice:

Due to paraffin as an excipient of the medicinal product, Adiclair[®] applied in the vaginal or anal area may decrease the tensile properties of latex condoms and therefore weaken its effectiveness.

2.4 Pregnancy and breast-feeding

A therapeutic dose of Nystatin, the active substance of Adiclair[®] is hardly resorbed after oral intake, from intact skin or from 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[®]:

Methyl-4-hydroxybenzoate (paraben) may cause allergic reactions (possibly delayed). Cetyl alcohol may cause local skin reactions (contact dermatitis). Propylene glycole may cause skin irritation.

3. How to take Adiclair[®]

Always take Adiclair[®] 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: Apply the cream to the infected area two or three times daily – in severe cases also more frequently.

3.2 Method of administration

For application to the skin only. Adiclair® has to be applied thinly on the skin and rub in gently.

3.3 Duration of treatment

To prevent a relapse, in the treatment of candida yeast infections on the skin or mucous membranes sources of infection must be eliminated completely. Continue treatment for 8 – 10 days after all symptoms subside in order to ensure therapeutic success. Please consult your doctor or pharmacist whenever you get the impression that the effect of Adiclair® is too strong or too weak.

3.4 If you take more Adiclair® than you should

If, by mistake on odd occasion, you apply more Adiclair® than you should, this will have no negative impacts. In this case continue the use as prescribed by your doctor or described in this package leaflet.

3.5 If you forgot using Adiclair®

Don't use the double dosage, but continue the application 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

Nystatin as contained in Adiclair® is generally well tolerated on external use.

Nystatin as contained in Adiclair® cream is usually well tolerated on external application. Rare cases of hypersensitive reactions may occur.

Methyl 4-hydroxybenzoate (parabene) may cause cause hypersensitive reactions, which may also be delayed in time.

If you notice side effects, stop use of 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.

4.2 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®

Keep out of the reach and sight of children.

Do not use Adiclair 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: 6 month

6. Further information

6.1 What Adiclair® contains

The active ingredient is: Nystatin

1 g cream contains: 100,000 I.U. Nystatin. Other excipients: methyl 4-hydroxybenzoate (Ph. Eur.) (parabene) as preservative, macrogol stearate 2000, macrogol stearate 5000, cetyl alcohol (Ph. Eur.), sorbitan sesquileate, glycerol monostearate, viscous paraffin, propylene glycol, purified water.

6.2 What Adiclair® looks like and contents of the pack

Appearance: smooth, pale yellow cream.

Packs:

Pack with 20 g cream

Pack with 50 g cream

6.3 Marketing Authorisation Holder and Manufacturer

Ardeypharm GmbH, Loerfeldstr. 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.