

The PL includes alternative texts for different legal status in different countries as follows:

- [Boxed texts] are only applicable for OTC versions.
- [Grey-shaded texts in brackets] are only applicable for prescription versions.
- To be completed nationally depending on legal status.

For OTC use in Sweden, please refer to the approved Swedish package leaflet published on MPA's web site.

Package leaflet: Information for the user

Cortimyk 20 mg/g + 10 mg/g cream

miconazole nitrate and hydrocortisone

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse within 7 days.

[Read all of this leaflet carefully before you start using this medicine because it contains important information for you.]

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.]

What is in this leaflet

1. What Cortimyk is and what it is used for
2. What you need to know before you use Cortimyk
3. How to use Cortimyk
4. Possible side effects
5. How to store Cortimyk
6. Contents of the pack and other information

1. What Cortimyk is and what it is used for

Cortimyk contains the active substances miconazole nitrate and hydrocortisone. Miconazole nitrate is an antifungal substance and hydrocortisone is a mild acting corticosteroid with antipruritic and anti-inflammatory effect.

Adults and children over 10 years:

Cortimyk is used to treat athlete's foot with severe itching.

[Cortimyk can also be used for treatment of other fungal skin infections.]

If you have previously been treated by a doctor for inflamed fungal infections with uncomfortable and severe itching located in skin folds such as under the arms, the hollow of the knee, under the breasts, in the groin

and in skin folds on the abdomen and if you experience the same symptoms again, you may use Cortimyk cream.

[Cortimyk is primarily used for initial treatment. Long-term treatment with Cortimyk should be avoided, since the cream contains cortisone. Therefore, when the itching and inflammation (irritation) have disappeared, your doctor may prescribe continued treatment with another cream containing only the fungicidal agent (miconazole), with no cortisone instead.]

2. What you need to know before you use Cortimyk

Do not use Cortimyk:

- if you are allergic to miconazole nitrate, other similar antifungal medicines, hydrocortisone or any of the other ingredients of this medicine (listed in section 6).
- if your skin is infected by virus (herpes or chicken pox) or some bacteria (tubercular skin disease).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Cortimyk.

- Be careful when you apply Cortimyk. Avoid contact with eyes. Wash your hands after every treatment [unless the treatment is intended for your hands].
- [Long-term treatment (over 4-6 weeks) with Cortimyk should be avoided, since the cream contains cortisone.]
- Since Cortimyk can damage certain synthetic materials, it is recommended that you wear cotton underwear if it will come in contact with the treated area.
- Avoid contact with latex products (e.g. latex diaphragms, latex condoms), as the ingredients in Cortimyk can damage latex products.
- Contact your doctor if you experience blurred vision or other visual disturbances.
- Do not apply Cortimyk to your scalp, face or behind your ears. Your doctor needs to examine you to ensure that you get the correct treatment for fungal infections in these areas.
- Long-term treatment with corticosteroids can cause thinning of the skin. This should especially be considered in elderly as thinning of the skin occurs naturally with age. Cortimyk should therefore only be used for short periods of time and according to the recommended dosing.

If you are taking oral anticoagulant agents such as warfarin, stop using Cortimyk immediately and seek advice from your doctor or pharmacist if you experience unexpected bleeding or bruising, nosebleeds, coughing up blood, blood in the urine, black tarry stools or coffee ground vomit during treatment with Cortimyk. Close monitoring of International Normalized Ratio (INR) levels are required under the supervision of a healthcare professional during treatment with Cortimyk.

Children

Do not use Cortimyk for children below 10 years without a doctor's prescription.

[Be careful when you treat large body areas on small children or when applying under occlusive dressings (including diapers) on small children. There is a risk of a significant degree of absorption of the medicinal product (see also "Cortimyk contains benzoic acid and butylhydroxyanisole"). Avoid treating the face.]

Other medicines and Cortimyk

Talk to your doctor, pharmacist or dentist if you are taking, have recently taken or might take any other medicines

- Oral anticoagulant agents (drugs used to thin the blood), such as warfarin, may be affected by Cortimyk.

The effect and side effects of certain other medicines may be intensified if they are used at the same time as Cortimyik. Examples of such medicines are diabetes medication that is taken orally and phenytoin (to treat epilepsy).

Pregnancy and breast-feeding

Pregnancy

Caution is recommended if used during pregnancy. You should consult your doctor or pharmacist before using Cortimyik during pregnancy. Treatment of large body areas and use under occlusive dressings should be avoided.

Breast-feeding

It is not known whether administration of Cortimyik on the skin can result in hydrocortisone and miconazole passing into breast milk. You should consult your doctor or pharmacist before using Cortimyik during breast-feeding. Application to the breasts should be avoided. Treatment of large areas and use under occlusive dressings should be avoided during this time.

Driving and using machines

No known risks.

Cortimyik contains benzoic acid and butylhydroxyanisole

Cortimyik contains 2 mg/g benzoic acid which may cause local irritation. Benzoic acid may increase the risk of jaundice (yellowish skin and eyes) in newborn babies (up to 4 weeks old). Do not use Cortimyik for children under 10 years without a doctor's prescription.

Cortimyik contains butylhydroxyanisole which may cause local skin reactions (e.g. contact dermatitis) or irritation of eyes and mucous membranes.

3. How to use Cortimyik

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

[Always use this medicine exactly as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.]

Note for athlete's foot:

Wash and dry the feet carefully before using Cortimyik. Use a separate towel for areas with a fungal infection. In this way you will avoid infecting others. Change your socks every day.

For treatment of athlete's foot and for treatment of recurrent inflamed fungal infections in skin folds for adults and children over 10 years:

Apply a thin layer of the cream on the infected area of skin and 1-2 cm outside the infected area twice daily (morning and evening). Rub in until the cream has completely disappeared. Wash your hands after each treatment [unless the treatment is intended for your hands].

[When the itching and inflammation (irritation) have disappeared, your doctor may recommend that you continue the treatment with another cream containing only the fungicidal agent and not cortisone.]

When the skin looks healthy again, the treatment [with Cortimyik or another cream containing only the fungicidal agent] should continue for at least one more week. This prevents relapse. [The total treatment time can vary between 2-6 weeks depending on the severity of the infection and where it is located. Always follow your doctor's advice concerning duration of treatment.]

You should talk to your doctor if your symptoms worsen or do not improve within 7 days. Do not continue the treatment for longer than a period of 4 weeks without a doctor's recommendation. Contact your doctor if the symptoms do not disappear completely or if they reappear after maximum treatment of 4 weeks.

Cortimyk does not discolour clothes or skin and can easily be removed with soap and water.

[Use in children]

Be careful when you treat large body areas on small children or when applying under occlusive dressings (including diapers) on small children. There is a risk of a significant degree of absorption of the medicinal product. Avoid application on the face.]

The elderly

Thinning of the skin occurs naturally in the elderly. Corticosteroids should therefore be used sparingly and for short periods of time.

If you use more Cortimyk than you should

- your skin may become irritated. These problems usually disappear when the treatment is discontinued.
- your whole body may be affected since cortisone enters the bloodstream.

Contact your doctor, hospital or poison information centre if you have used too much medicine or if a child by accident has taken the medicine.

If you forget to use Cortimyk

Apply a thin layer next morning or evening.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Cortimyk and contact your doctor immediately if you develop any of the following symptoms (angioedema or anaphylactic reaction) which have been reported (occurring in an unknown number of users):

- swelling of the face, tongue or throat
- difficulties with swallowing or breathing
- hives
- sudden skin rash
- dizziness or feeling faint

Other side effects that may occur:

Uncommon (may occur in up to 1 in 100 users): Skin irritation, burning sensation of the skin, hives, itching, irritability.

Have been reported (occurring in an unknown number of users): Hypersensitivity. Local reactions such as rash, contact eczema, reddening of the skin, inflammation of the skin, loss of pigment in the skin. Blurred vision.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V*](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cortimyk

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

Do not store above 25°C

Do not use this medicine after the expiry date which is stated on the carton and tube after <[To be completed nationally]>.

The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to do with medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Cortimyk contains

- The active substances are miconazole nitrate and hydrocortisone. 1 gram of cream contains 20 mg miconazole nitrate and 10 mg hydrocortisone.
- The other ingredients are pegoxol 7 stearate, oleoyl macroglycerides, light liquid paraffin, anhydrous disodium edetate, benzoic acid, butylhydroxyanisole, water, sodium hydroxide and hydrochloric acid for pH adjustment.

What Cortimyk looks like and contents of the pack

White cream

Pack sizes:

Tube with 20 g

[Tube with 2×20 g and 50 g]

Marketing Authorisation Holder

<To be completed nationally>

Manufacturer

Farmaclair

440 avenue du Général de Gaulle

14200 Hérouville St Clair

France

This medicinal product is authorised in the Member States of the EEA under the following names:

Sweden: Cortimyk

Norway: Cortimyk

This leaflet was last revised in 2025-09-15