

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.

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 + 10mg/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 or pharmacist. 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 after 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 or pharmacist.
- 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 or pharmacist. 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. Cortimyk is used to treat athlete's foot with severe itching.

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

#### **2. What you need to know before you use Cortimyk**

**Do not use Cortimyk:**

- if you are allergic to miconazole nitrate, 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 or pharmacist before using Cortimyk.**

- Avoid contact with eyes.
- If any signs occur on irritation or hypersensitivity, discontinue the treatment.
- Normal hygiene is important to prevent infections or relapse of infection.

### **Children**

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

[Be careful when small children are treated on larger areas since there is a risk of significant absorption.]

### **Other medicines and Cortimyk**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. Treatment with warfarin (e.g. Waran), taken oral, may be affected by Cortimyk. If you are treated with anticoagulant medicines, your doctor therefore might want to follow the effect of this treatment.

### **Pregnancy and breast-feeding**

No adverse fetal effects have been demonstrated. However, you should consult your doctor or pharmacist before using Cortimyk during pregnancy.

Hydrocortisone passes into breast milk but is unlikely to affect breast-fed babies. However, you should consult your doctor or pharmacist before using Cortimyk during breastfeeding.

### **Cortimyk contains benzoic acid and butylhydroxyanisole**

Cortimyk contains benzoic acid which can be a-mildly irritant to the skin, eyes and mucous membranes. Cortimyk contains butylhydroxyanisole which may cause local skin reactions (e.g. contact dermatitis) or irritation of eyes and mucous membranes.

## **3. How to use Cortimyk**

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

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

**Athlete's foot:** Wash and dry the feet carefully before applying the cream. Treat every morning and evening. Apply a thin layer of the cream on and 1-2 cm outside the infected area. Rub the cream into the skin with your finger until it has fully penetrated. When the itching, irritation and redness has disappeared, the treatment shall continue at least one week weeks to prevent relapse.

Do not treat for more than 4 weeks without your doctor's prescription. If the symptoms not have improved after 1 week, contact your doctor for advice.

[For itching fungal skin infections, the cream shall be applied thinly on the infected skin area according to your doctor's prescription.]

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

**If you use more Cortimyk than you should**

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. Overdose is not expected since the cream only shall be used on the skin.

**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.

Uncommon (may affect up to 1 in 100 people): Skin irritation.

Rare (may affect up to 1 in 1,000 people): contact allergy. If you get such allergic reaction, discontinue the treatment and contact your doctor.

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 **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 macrogolglycerides, 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**

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**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 9 March 2017**