

Gyno-Daktarin® 20 mg/g vaginal cream

Miconazole nitrate

Gyno-Daktarin is a registered trademark

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.

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1 What Gyno-Daktarin cream is and what it is used for

The name of your medicine is Gyno-Daktarin 20 mg/g vaginal cream. It is called Gyno-Daktarin cream in this leaflet.

Gyno-Daktarin cream is for use in adults.

Gyno-Daktarin cream contains a medicine called miconazole nitrate. This belongs to a group of medicines called 'antifungals'.

It is used for infections of the vagina and the skin around the vagina. Signs of these infections include itching, redness and white discharge.

Gyno-Daktarin cream works by destroying the fungus that causes the infection and some of the bacteria which may also be present.

Your sexual partner may also need to be treated. Ask your doctor for advice.

About vaginal thrush

Vaginal thrush is a very common problem affecting women of all ages. It has nothing to do with poor hygiene. It is often caused by a fungus (*Candida albicans*) that is present in everybody. The fungus is normally kept in check by the body's defences.

Sometimes the fungus can become a problem due to:

- Recent use of antibiotics
- Pregnancy
- Use of oral contraceptives
- Wearing tight clothing
- Over use of hot baths and bath additives

You can prevent infections coming back by:

- Washing the infected area in the morning and evening with plain, warm water. It is important that you dry thoroughly
- Wiping backwards (away from the vagina) after visiting the toilet
- Not using medicated and perfumed bath additives
- Not wearing tight clothing

2 What you need to know before you use Gyno-Daktarin cream

Do not use Gyno-Daktarin cream:

- If you are allergic to miconazole nitrate, any of the other ingredients of this medicine (listed in section 6) or to other similar antifungal medicines

Do not use this medicine if this applies to you. If you are not sure, talk to your doctor or pharmacist before using Gyno-Daktarin cream.

Warnings and Precautions

Talk to your doctor or pharmacist before using Gyno-Daktarin cream:

- If you are using a 'barrier' method of contraception. This includes condoms or diaphragms. This is because Gyno-Daktarin cream can damage the latex and stop them working properly. Talk to your doctor about using another type of contraception while you are using this medicine
- Do not allow other people to use your flannel or towel. This will stop them from getting your infection.

Children and adolescents

Gyno-Daktarin cream is not recommended for use in children or adolescents under the age of 18.

Other medicines and Gyno-Daktarin cream

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription or herbal medicines.

In particular, tell your doctor if you are taking:

- Medicines to thin the blood (anticoagulants) such as warfarin. Your doctor will need to check that the anticoagulant is working properly
- Medicines for diabetes, taken by mouth
- Medicines that act on the heart and blood vessels called 'calcium channel blockers' such as dihydropyridines and verapamil
- Medicine for epilepsy called phenytoin
- Medicines to lower cholesterol called lovastatin or simvastatin

Tell your doctor before taking, or if you are already taking any of the above. They may need to alter your treatment.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

You may still be able to use Gyno-Daktarin cream if your doctor thinks you need to.

Gyno-Daktarin cream contains Benzoic Acid (E210) and Butylated hydroxyanisole (E320)

- This medicine contains 2 mg Benzoic acid per gram of cream, which is equivalent to
 - 30 mg Benzoic acid in a 15 g tube of cream
 - 80 mg Benzoic acid in a 40 g tube of cream
 - 156 mg Benzoic acid in a 78 g tube of cream
- Benzoic acid may cause local irritation.
- Butylated hydroxyanisole (E320). This can cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

3 How to use Gyno-Daktarin cream

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

Using the cream

- Each tube of Gyno-Daktarin cream is sealed. You will need to use the cap to pierce the seal
- Do not swallow the cream

For infections of the vagina

Your doctor may suggest treatment over 7 days:

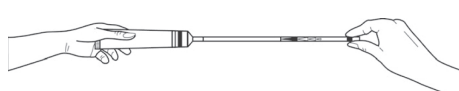
- Insert the cream into the vagina once daily before bedtime for 7 days

Your doctor will tell you how much cream to use and for how long you should use it.

Filling the applicator with cream

- Remove the cap from the tube. Use the top of the cap to pierce the metal seal on the cap
- Screw the yellow end of the applicator with the **green band** onto the tube
- Squeeze the tube while at the same time gently and slowly pulling the inner white plunger of the applicator until it reaches the stop mark (figure 1)

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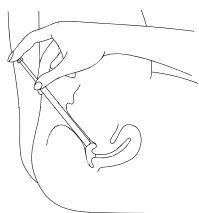


3 How to use Gyno-Daktarin cream (continued)

Inserting the cream into your vagina

- Unscrew the filled applicator and replace the cap on the tube
- Lie down with your knees bent and spread apart. Insert the yellow end of the applicator with the green band well into your vagina
- Push the plunger firmly but gently. Empty the cream into your vagina by pushing the plunger as far as it will go (figure 2)

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- Remove the applicator and put it in the bin with your household rubbish
- Always wash your hands with soap and water after using the cream
- The cream does not stain your skin or clothes but you may want to use a sanitary towel

For infections outside the vagina

- Apply the cream to the affected area twice each day
- Lightly cover the skin around your vagina with a thin, even layer of cream
- Always wash your hands with soap and water after using the cream

Your doctor will tell you how often and for how long to use the cream.

When to stop using Gyno-Daktarin cream

Keep using the cream until the course is finished, even during your period. Do this, even if the redness, itching and discharge go away before the end of the course.

If you swallow Gyno-Daktarin cream

If a large amount of cream is eaten or swallowed talk to a doctor or go to the nearest hospital casualty department straight away.

If you forget to use Gyno-Daktarin cream

- Don't worry, apply the next dose of cream as usual and keep using the cream as your doctor has told you
- Do not use a double dose of cream to make up for a missed dose

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4 Possible side effects

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

Stop using Gyno-Daktarin cream and tell your doctor straight away if you notice the following. You may need medical treatment.

- Severe irritation or reddening of the skin, swelling of the face, lips, tongue or throat, light headedness, wheezing or difficulty breathing or other signs of allergy during the first few days of treatment. This only happens in a small number of people

Other side effects:

- Local irritation (around or inside the vagina), itching or burning sensation of the treated area. This is much milder than an allergic reaction. Tell your doctor or pharmacist if these feelings continue
- Skin rash or hives (also known as nettle rash or urticaria)

- Stomach pain
- Low stomach pains (pelvic cramps)
- Headache
- Infection of urine or pain in passing urine
- Vaginal bleeding
- Feeling sick (nausea)
- Redness of the face

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Gyno-Daktarin cream

Keep this medicine out of the sight and reach of children. Do not store above 25°C.

Do not use Gyno-Daktarin cream:

- After the expiry date which is stated on the packaging. The expiry date refers to the last day of that month
- If the tube seal is missing or broken
- If the cream is not white in colour

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

6 Contents of the pack and other information

What Gyno-Daktarin cream contains

The active substance is miconazole nitrate. Gyno-Daktarin cream contains 2% miconazole nitrate.

The other ingredients are purified water, PEG-6, PEG-32, glycol stearate, oleoyl macroglycerides, liquid paraffin, benzoic acid (E210) and butylated hydroxyanisole (E320).

What Gyno-Daktarin cream looks like and contents of the pack

Gyno-Daktarin cream comes in an aluminium tube containing 15 g, 40 g or 78 g of white cream with disposable applicators.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Janssen-Cilag Ltd., 50-100 Holmers Farm Way, High Wycombe, Bucks, HP12 4EG, UK

Manufacturer:

Janssen Pharmaceutica NV, Turnhoutseweg 30, B-2340 Beerse, Belgium

OR

McGregor Cory Ltd, Exel, Middleton Close, Banbury, Oxfordshire OX16 4RS, UK

For information in large print, tape, CD or Braille, telephone 0800 7318450.

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