PACKAGE LEAFLET: INFORMATION FOR THE USER

Gyno-Daktarin® 20 mg/g vaginal cream

Miconazole nitrate

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

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.
In this leaflet it is called Gyno-Daktarin cream.
Gyno-Daktarin cream contains a medicine called miconazole nitrate. This belongs to a group of medicines called 'antifungals'.
Gyno-Daktarin cream is used for infections of the vagina and the skin around the vagina. Signs of these infections include itching, redness and white discharge. The infections, such as thrush (*Candida*), are caused by fungi and yeasts.
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 or any of the other ingredients of this medicine (listed in section 6)

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 rubber 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, as their effects and side effects may be increased
- A medicine for some forms of epilepsy, called phenytoin, as its effects and side effects may be increased

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 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) which is mildly irritant to the skin, eyes, mouth and nostrils
- Butylated hydroxyanisole (E320) which may cause local skin reactions (such as contact dermatitis), or irritation to the eyes, mouth and nostrils.

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 or 14 days:

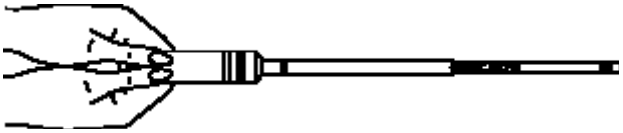
- **7 day course** - insert two applicators full of cream into the vagina at bedtime each day for 7 days
- **14 day course** - insert one applicator full of cream into the vagina at bedtime each day for 14 days

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

Inserting the cream with an applicator

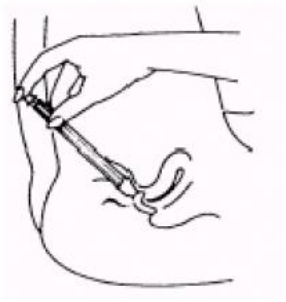
- Remove the cap from the tube. Use the top of the cap to pierce the metal seal on the cap
- Screw the yellow end of the applicator with the green band onto the tube.

- Squeeze the tube so that the applicator barrel pushes the plunger to the stop mark (figure 1)



1

- 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)



2

- 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

Very common (affects more than 1 in 10 people)

- Headache
- Local irritation (around or inside the vagina), itching or burning sensation of the vagina or treated area. This is much milder than an allergic reaction. Tell your doctor or pharmacist if these feelings continue
- Discomfort or pain in and around the vagina

Common (affects fewer than 1 in 10 people)

- Painful periods
- Pain in the abdomen (stomach)
- Feeling sick (nausea)

Uncommon (affects fewer than 1 in 100 people)

- Urinary tract infections or pain when passing urine
- Discharge or bleeding from the vagina
- Redness of the face
- Skin rash or hives (also known as nettle rash or urticaria)

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. 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 carton and tube, after 'EXP'. 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 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. The used applicators can be put in the bin with your household rubbish.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Gyno-Daktarin cream contains

The active substance is miconazole nitrate. Each gram of cream contains 20mg miconazole nitrate (2% w/w).

The other ingredients are tefose, labrafil, mineral oil, benzoic acid (E210), butylatedhydroxyanisole (E320) and purified water.

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

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

Product procured from within the EU and repackaged and distributed by the parallel product authorisation holder:

PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath.

Gyno-Daktarin is a registered trademark of JANSSEN PHARMACEUTICA N.V.

MANUFACTURER

FAMAR ABE 49th Kml – Avlonas, Greece.

Parallel Product Authorisation Number: PPA 465/291/1

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For information in large print, type, CD or Braille phone 1800 709 122