

PACKAGE LEAFLET: INFORMATION FOR THE USER

Gyno-Daktarin® 1200 mg vaginal capsule

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.

What is in this leaflet

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1 What Gyno-Daktarin vaginal capsule is and what it is used for

The name of your medicine is Gyno-Daktarin 1200 mg vaginal capsule. It is called 'Gyno-Daktarin vaginal capsule' or just 'capsule' in this leaflet.

Gyno-Daktarin vaginal capsule is for use in adults.

Gyno-Daktarin vaginal capsule is a white to off white, egg-shaped pessary. When inserted into the vagina it releases a medicine called miconazole nitrate. This belongs to a group of medicines called 'antifungals'.

Gyno-Daktarin vaginal capsule is used for infections of the vagina. Signs of these infections include itching, redness and white discharge.

Gyno-Daktarin vaginal capsule 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 after visiting the toilet (away from the vagina)
- Not using medicated and perfumed bath additives
- Not wearing tight clothing

2 What you need to know before you use Gyno-Daktarin vaginal capsule

Do not use Gyno-Daktarin vaginal capsule:

- If you are allergic to miconazole nitrate, other similar antifungal medicines 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 vaginal capsule.

Warnings and Precautions

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

- If you are using a 'barrier' method of contraception. This includes condoms or diaphragms. This is because Gyno-Daktarin vaginal capsule 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 vaginal capsule is not recommended for use in children or adolescents under the age of 18.

Other medicines and Gyno-Daktarin vaginal capsule

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 may want to check that the anticoagulant is working properly
- Medicines taken by mouth to treat diabetes
- A medicine used to treat epilepsy called phenytoin

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 vaginal capsule if your doctor thinks you need to.

Driving and using machines

This medicine is not likely to affect you being able to drive or use any tools or machines.

Gyno-Daktarin vaginal capsule contains

- sodium ethyl parahydroxybenzoate (E215) and sodium propyl parahydroxybenzoate (E217). These may cause an allergic reaction. This reaction may happen some time after you have inserted the capsule

3 How to use Gyno-Daktarin vaginal capsule

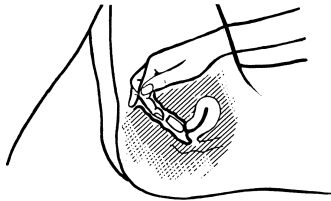
Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Using the capsule

- Do not swallow the capsule
- Use the capsule just before going to bed. This helps it to stay in place
- Only one capsule is used. If your symptoms persist, talk to your doctor or pharmacist

Inserting the capsule

- Wash your hands with soap and warm water before inserting the capsule
- Remove the capsule from the plastic packet by pushing it through the foil
- Lie down with your knees bent and spread apart
- Push the capsule with your forefinger as far as you can into your vagina



- Always wash your hands with soap and warm water after inserting the capsule
- Once in the vagina, the capsule will melt and may leak. It will not stain your skin or clothes but you may want to use a sanitary towel

If you swallow Gyno-Daktarin vaginal capsule

If a capsule is eaten or swallowed talk to a doctor or go to the nearest hospital casualty department straight away.

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.

Tell your doctor straight away if you notice the following. You may need urgent medical treatment.

- A severe allergic reaction. This only happens in a small number of people. An allergic reaction may be recognised as a rash, hives (urticaria), severe irritation, reddening or blistering of your skin, itching, swollen face or lips or throat, or shortness of breath

Tell your doctor, nurse or pharmacist if you notice or suspect any of the following side effects:

Very common side effects (affects more than 1 in 10 patients)

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

Common side effects (affects more than 1 in 100 patients)

- Headache
- Urinary tract infections
- Pain when passing urine
- Painful periods
- Vaginal discharge
- Tummy ache
- Nausea
- Skin rash

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 vaginal capsule

Keep this medicine out of the sight and reach of children. Store in the original package to protect from moisture. Do not store above 30°C.

Do not use Gyno-Daktarin vaginal capsule:

- After the expiry date which is stated on the carton or capsule packaging. The expiry date refers to the last day of that month
- If the plastic packet is broken or missing
- If the capsule is not white to off 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.

6 Contents of the pack and other information

What Gyno-Daktarin vaginal capsule contains

The active substance is miconazole nitrate. Each capsule contains 1200 mg miconazole nitrate.

The other ingredients are liquid paraffin, white petrolatum, lecithin, gelatin, glycerol, titanium dioxide (E171), sodium ethyl parahydroxybenzoate (E215), sodium propyl parahydroxybenzoate (E217) and medium chain triglycerides. (See end of section 2 for more information about some of the other ingredients.)

What Gyno-Daktarin vaginal capsule looks like and contents of the pack

Gyno-Daktarin vaginal capsule comes in a pack containing one capsule. The capsule is egg-shaped and white to off white in colour.

Marketing Authorisation Holder:

JANSSEN-CILAG LTD, 50 – 100 Holmers Farm Way, High Wycombe,
Buckinghamshire HP12 4EG, UK

Manufacturer:

Janssen-Cilag SA, Campus de Maigremont 27100, Val-de-Reuil, France

OR

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

**For information in large print, tape, CD or Braille, telephone
1800 709122.**

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