

**Gyno-Daktarin® 1200mg vaginal capsule
miconazole nitrate**

**INFORMATION FOR PEOPLE USING GYNO-DAKTARIN® 1200MG
VAGINAL CAPSULE**

Before you start to use your medicine, read this leaflet carefully all the way through as it contains important information. It does not contain the complete information about this medicine. If there is anything that you do not understand or if you need further information or advice, ask your pharmacist or doctor who will have more details.

This leaflet applies only to Gyno-Daktarin vaginal capsule. **Please do not throw it away as you may need to refer to it again.**

WHAT IS YOUR MEDICINE?

The name of your medicine is Gyno-Daktarin 1200mg vaginal capsule and its active ingredient is miconazole nitrate. The Gyno-Daktarin vaginal capsule contains 1200 mg miconazole nitrate.

• **Other ingredients**

Gyno-Daktarin vaginal capsule also contains liquid paraffin, white petrolatum, lecithin, gelatin, glycerol, titanium dioxide (E171), sodium ethyl parahydroxybenzoate (E215)*, sodium propyl parahydroxybenzoate (E217) and medium chain triglycerides.

*This may cause allergic reactions (possibly delayed)

• **What should your medicine look like?**

Gyno-Daktarin vaginal capsule is a white, egg-shaped, soft gelatin vaginal capsule and is supplied in a pack containing one capsule.

• **What type of medicine is Gyno-Daktarin vaginal capsule?**

Gyno-Daktarin vaginal capsule is one of a group of medicines called "antifungals" which are used to treat infections caused by fungi including yeasts, and some bacteria.

- **Market Authorisation holder:** Janssen-Cilag Ltd, 50-100 Holmers Farm Way, High Wycombe, Bucks, HP12 4EG, UK

- **Manufacturers:** Gyno-Daktarin 1200 mg vaginal capsules are manufactured by Janssen-Cilag S.A., Val-de-Reuil, France or McGregor Cory Ltd, Middleton Road, Banbury, Oxon OX16 4RS, UK

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WHAT IS YOUR MEDICINE USED FOR?

Gyno-Daktarin vaginal capsule is used to treat fungal infections of the vagina. Signs of these infections include: itching, redness and whitish discharge. Gyno-Daktarin vaginal capsule works by destroying the fungus that causes the infection and some of the bacteria, which may also be present.

REMEMBER - THIS MEDICINE HAS BEEN PRESCRIBED FOR YOU ONLY. NEVER GIVE IT TO ANYONE ELSE. IT MAY HARM THEM EVEN IF THEIR SYMPTOMS ARE THE SAME AS YOURS.

WHEN NOT TO USE YOUR MEDICINE

Do not use Gyno-Daktarin vaginal capsule if:

- You have ever experienced an allergic reaction (hypersensitivity) to Gyno-Daktarin vaginal capsule in the past.
- You know you are allergic to miconazole or any of the other ingredients contained in Gyno-Daktarin vaginal capsule.

An allergic reaction may be recognised as a rash or itching at the site of infection which gets worse after using Gyno-Daktarin vaginal capsule.

Inform your doctor before using the medicine if any of the above applies to you. Your doctor will then decide whether Gyno-Daktarin vaginal capsule is suitable for you.

SPECIAL PRECAUTIONS

Make sure that you **do not infect others**: do not allow others to use your flannel or towel. If you have a sexual partner they may have to be treated so that you do not become infected again. If in doubt, ask your doctor.

- **Pregnancy and breast feeding**

If you are pregnant, think you might be pregnant or are planning to become pregnant, you should talk to your doctor who will decide if you can use Gyno-Daktarin vaginal capsule. If you are breast feeding, ask your doctor for advice.

- **Rubber Birth Control devices**

Avoid contact between rubber (latex) birth control devices like a condom or a diaphragm (a rubber cap inserted into the vagina) and Gyno-Daktarin vaginal capsule. This product could damage the rubber (latex), so that pregnancy or sexually transmitted diseases might not be prevented. An alternative form of contraception should be used.

- **Other medicines**

Make sure your doctor knows about any other medicines you are taking.

If you are taking certain medicines that are used to slow down blood clotting, your doctor may wish to check they are working correctly.

The effects and side effects of some medications, when taken with Gyno-Daktarin vaginal capsules, can be increased, These include

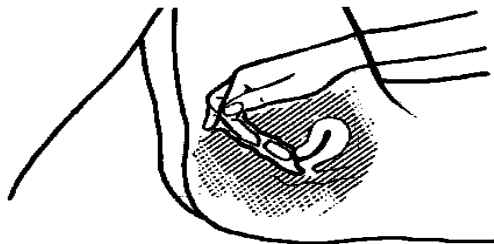
- oral hypoglycaemics (used to treat diabetes)
- phenytoin (used to treat some forms of epilepsy)
- some lipid lowering medicines (used to reduce cholesterol levels) and
- certain types of calcium channel blockers(used to treat high blood pressure)

Ask a doctor or pharmacist before use if you are taking other medicines.

HOW TO USE YOUR MEDICINE NOT FOR USE BY CHILDREN

Follow these instructions carefully: A complete course of treatment consists of one soft vaginal capsule.

1. Gyno-Daktarin vaginal capsule should be used before going to bed at night.
2. Always wash your hands with soap and warm water before inserting the vaginal capsule.
3. Remove Gyno-Daktarin vaginal capsule from its blister pack by pushing it through the foil.
4. Holding the soft vaginal capsule between thumb and index finger, lie on your back, bring your knees up and open your legs. In this position, gently insert the capsule as high into the vagina as possible with your index finger.



5. After inserting the vaginal capsule, wash your hands and rinse and dry thoroughly.
6. Once in the vagina, Gyno-Daktarin vaginal capsule will melt which can lead to "leakage". Gyno-Daktarin vaginal capsule does not stain your skin or your clothes, however, the use of light external sanitary protection is recommended and using at night as suggested.

IF YOU SWALLOW SOME OF YOUR MEDICINE

In the unlikely event of anyone accidentally swallowing Gyno-Daktarin vaginal capsule, contact your doctor or nearest hospital casualty department immediately.

IF YOU THINK YOUR MEDICINE MAKES YOU FEEL ILL

Local irritation may occur. This normally goes away on its own but if it continues, tell your doctor.

Itching and redness following application may indicate an allergy to the medicine (see 'WHEN NOT TO USE YOUR MEDICINE'). In this case, consult your doctor or pharmacist.

More severe allergic reactions have been reported, including rash, shortness of breath or wheezing and feeling faint. If this occurs, stop using Gyno-Daktarin and contact your doctor immediately.

The following side effects have also been reported but it is not known how often they may occur:

- Headache
- Abdominal pain
- Urinary tract infections or pain passing urine
- Period-like cramps
- Vaginal bleeding
- Redness or swelling of the face
- Feeling sick

If your medicine affects you in any other way, you should tell your doctor or pharmacist.

HOW TO STORE YOUR MEDICINE

As with all medicines, Gyno-Daktarin vaginal capsule should be kept out of the reach and sight of children. Do not store above 25°C. Do not use after the expiry date printed on the carton or capsule packaging.

FURTHER INFORMATION

- Vaginal thrush, an extremely common problem affecting women of all ages and which has nothing to do with poor personal hygiene, is often due to a microscopic fungal organism called *Candida albicans*. This is present in everybody, and is normally held in check by the body's natural defences.

However, in certain circumstances *Candida* infections can flourish due to:

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

- Wash gently morning and evening with warm water and dry thoroughly.
- Vaginal infection or reinfection may be prevented by carefully wiping backwards (away from the vagina) after visiting the toilet.
- Avoid all medicated and perfumed bath additives, soaps, etc.
- Avoid wearing tight clothing.

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

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