NEW ZEALAND CONSUMER MEDICINE INFORMATION

FLUCAZOLE®
Fluconazole capsules 150 mg

What is in this leaflet

This leaflet answers some common questions about Flucazole. It does not contain all the information available on this medicine. It does not take the place of talking to your pharmacist or doctor.

All medicines have risks and benefits. Your pharmacist or doctor has weighed the risks of you taking Flucazole against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your pharmacist or doctor.

Keep this leaflet with the medicine. You may want to read it again.

What Flucazole is used for and how it works

Your Flucazole capsule contains fluconazole. It belongs to a group of medicines known as antifungals.

Fluconazole is used to treat vaginal thrush infections. It works by preventing the growth of fungal and yeast organisms.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

Fluconazole is available over the counter at a pharmacy or with a doctor’s prescription.

Before you take Flucazole

When you must not take it

Do not take Flucazole if you have an allergy to the following:

- any medicine containing fluconazole
- medicines related to fluconazole such as miconazole, ketoconazole, itraconazole, clotrimazole or voriconazole
- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take this medicine if you are taking any of the following medicines:

- cisapride (used to treat stomach problems)
- astemizole (an antihistamine used to treat allergies)
- erythromycin (an antibiotic used in the treatment of infections)
- pimozide (an antipsychotic medicine)
- quinidine (a medicine used to treat an irregular heartbeat).

Do not give Flucazole to a child under the age of 18 years unless prescribed by a doctor. Safety and effectiveness in children younger than 18 years have not been established.

Do not take Flucazole if you are pregnant. It may affect your developing baby if you take it during pregnancy.

Do not breast-feed if you are taking this medicine. The active ingredient in Flucazole passes into breast milk and there is a possibility that your baby may be affected.

Tell to your pharmacist or doctor if you are not sure whether you should take this medicine.

Before you take it

Tell your pharmacist or doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your pharmacist or doctor if you have any other health problems, including:

- any liver problems
- any heart problems
- any kidney problems.

If you have not told your pharmacist or doctor about any of the above, tell them before you take Flucazole.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop. Some medicines and Flucazole may interfere with each other. These include:

- cisapride (used to treat stomach problems)
- pimozide (an antipsychotic medicine)
- some medicines used to treat allergies such as terfenadine or astemizole
- some medicines for diabetes such as chlorpropamide, glipizide, tolbutamide, glibenclamide, gliclazide, pioglitazone or rosiglitazone
- some antibiotic, antiviral and antifungal medicines such as...
rifampicin, rifabutin, zidovudine,
saquinavir, voriconazole,
amphotericin B and
erthyromycin
• some medicines used in
problems with the immune
system, such as cyclosporin,
tacrolimus or sirolimus
• warfarin (used to stop blood
clots)
• some medicines used to treat
epilepsy such as phenytoin or
carbamazepine
• theophylline (used to treat
asthma)
• some benzodiazepines such as
midazolam or triazolam
• hydrochlorothiazide (used for
treating fluid problems)
• alfentanil (used in anaesthesia)
• amitriptyline and nortriptyline
(used in the treatment of
depression)
• some medicines used to treat
high blood pressure and angina
such as nifedipine, isradipine,
losartan, verapamil, amldipine
and felodipine
• amiodarone (used to treat
irregular heart beats)
• celecoxib (used in the treatment
of arthritic conditions)
• cyclophosphamide (used in the
treatment of some cancers)
• fentanyl (an analgesic used in
the treatment of severe chronic
pain)
• halofantrine (used to treat
malaria)
• some medicines used to treat
high cholesterol such as
atorvastatin, simvastatin and
fluvastatin
• methadone (used in the
treatment of dependence on
opioid drugs)
• NSAIDs (non-steroidal anti-
inflammatory drugs) such as
naproxen, lornoxicam,
meloxicam and diclofenac
• prednisone (used as an anti-
inflammatory and also in some
immune system disorders)
• tofacitib (used in the treatment
of rheumatoid arthritis)
• vinca alkaloids, such as
vincristine and vinblastine (used
in the treatment of cancers)
• Vitamin A and its derivatives.

These medicines may be affected
by Flucazole or may affect how well
it works. You may need different
amounts of your medicines, or you
may need to take different
medicines.

Your pharmacist or doctor has more
information on medicines to be
careful with or avoid while taking
Flucazole.

How to take Flucazole

Directions for use
Take ONE capsule as a single
dose.
Swallow whole with a glass of
water.

Your Flucazole capsule can be
taken any time of the day.

It does not matter if you take this
medicine before or after food.

Follow all directions given to you by
your pharmacist or doctor and read
the instructions on the carton.

Your Flucazole capsule is a single
dose treatment for vaginal thrush
infections which you take by mouth.

While you are taking Flucazole

Things you must do
Tell your pharmacist or doctor if the
symptoms of your infection do not
improve within a few days, or if they
become worse.

If you are a woman of child-bearing
age, you should avoid becoming
pregnant while taking Flucazole.

Tell your doctor immediately if you
become pregnant in the same
month as taking Flucazole.

If you are about to be started on any
new medicine, remind your
pharmacist or doctor that you have
recently taken Flucazole.

Tell all doctors, dentists and
pharmacists who treat you that you
have recently taken Flucazole.

Things you must not do
Do not give Flucazole to anyone
else, even if they have the same
condition as you.

Do not use Flucazole to treat any
other medical complaints.

Things to be careful of
This medicine is not expected to
affect your ability to drive a car or
operate machinery.

Side effects

Tell your pharmacist or doctor as
soon as possible if you do not feel
well while you are taking Flucazole.

All medicines can have some
unwanted effects. Sometimes they
are serious, most of the time they
are not. You may need medical
treatment if you get some of the
side effects.

Tell your pharmacist or doctor if
you notice any of the following
and they worry you:
• nausea or feeling sick
• headache
• stomach pain, indigestion,
diarrhoea.

These are the more common side
effects of Flucazole. They are
usually mild and short-lived.

Tell your doctor immediately if
you notice any of the following:
• swelling of the face, lips or
tongue which may cause
difficulty in swallowing or
breathing
• asthma, wheezing, shortness of
breath
• sudden or severe itching, skin
rash, hives
• fainting, seizures or fits
• flaking of the skin
• yellowing of the skin or eyes,
also called jaundice
• bleeding or bruising more easily
than normal, reddish or purplish
blotches under the skin
• signs of frequent or worrying
infections such as fever, severe
chills, sore throat or mouth
ulcers
• fast or irregular heart beat.
These side effects are usually rare but can be serious and need urgent medical attention.

The list of side effects mentioned above is not complete. If you should suffer from any of these side effects or any other undesired effect please tell your pharmacist or doctor.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

In case of overdose

Immediately contact your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to the Emergency department at your nearest hospital, if you think that you may have taken too much, or if anyone else has taken Flucazole by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the pack of Flucazole with you if you can.

Keep telephone numbers for these places handy.

Storage conditions

Do not take this medicine after the expiry date shown on the pack or if the packaging shows signs of tampering.

Keep your Flucazole capsule in the blister pack until it is time to take it.

Store your Flucazole capsule below 25°C. Keep out of reach of children. Avoid exposure to heat and moisture.

Do not store Flucazole, or any other medicine, in the bathroom or near a sink.

Disposal

If you do not take your Flucazole capsule or it has passed the expiry date, ask your pharmacist what to do with it.

List of ingredients

Flucazole comes in a pack containing one capsule.

Each capsule contains 150mg of the active ingredient fluconazole.

The capsule also contains lactose, maize starch, sodium lauryl sulphate, colloidal hydrated silica, magnesium stearate, gelatin, titanium dioxide (E171) and Tekprint Ink SW-9008 and SW-9009.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11-183,
Ellerslie,
Auckland.
Freephone: 0800 168 169

Date of Information

6 April 2018 (Based on data sheet dated 6 April 2018)