

**PACKAGE LEAFLET: INFORMATION FOR THE USER****Blicanz™ Thrush Relief 150 mg Capsule  
Fluconazole**

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to doctor if you do not feel better or if you feel worse after seven days.

**What is in this leaflet:**

1. What Blicanz™ is and what it is used for
2. What you need to know before you take Blicanz™
3. How to take Blicanz™
4. Possible side effects
5. How to store Blicanz™
6. Contents of the pack and other information.

The name of your medicine is Blicanz™ Thrush Relief 150 mg Capsule, and is referred as 'Blicanz™' throughout the leaflet.

**1. What Blicanz™ is and what it is used for**

Blicanz™ is a full course of treatment for thrush.

**Only use this product if you have been previously diagnosed by your doctor as having thrush.**

The active substance in Blicanz™ is fluconazole.

Fluconazole belongs to a group of medicines called azoles and is an antifungal agent which fights the cause of infections such as thrush.

**2. What you need to know before you take Blicanz™**

**Do not take Blicanz™ if you:**

- Are allergic to fluconazole, to other medicines you have taken to treat fungal infections or to any of the other ingredients of this medicine (listed in section 6). The symptoms may include

itching, reddening of the skin or difficulty in breathing;

- Are taking astemizole, terfenadine (antihistamine medicines for allergies);
- Are taking cisapride (used for stomach upsets);
- Are taking pimozide (used for treating mental illness);
- Are taking quinidine (used for treating heart arrhythmia);
- Are taking erythromycin (an antibiotic for treating infections);
- Are taking ergot derivatives (ergotamine used for migraine);

Do not use this medicine if you are suffering from *Tinea Capitis* (fungal infection of the scalp)

**Warnings and Precautions**

**Talk to your doctor or pharmacist or nurse before taking Blicanz™ if:**

- You are aged under 16 or over 60 years;
- You have had thrush more than twice in the last six months;
- You have had any disease or illness affecting the liver or kidneys, or have had any unexplained jaundice;
- You have heart diseases, including heart rhythm problems, or low levels of potassium, magnesium or calcium in your blood;
- You suffer from any other chronic diseases or illness;
- You or your partner have been exposed to a sexually transmitted disease;
- You are unsure whether you have thrush or this is the first time you have had these symptoms.
- if the fungal infection does not improve, as alternative antifungal therapy may be needed.
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking this medicine.

Serious skin reactions including drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with fluconazole treatment.

Stop taking this medicine and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

**Men:**

Do not use Blicanz™ without talking to your doctor first if:

- Your sexual partner does not have thrush;
- You have pain or difficulty on passing urine;
- You have an abnormal discharge from your penis;
- You have sores, ulcers or blisters on your penis;
- Your penis has started to smell.

**Women**

If you have any of the following symptoms do not use Blicanz™ and see your doctor as soon as possible:

- Irregular vaginal bleeding;
- Abnormal vaginal bleeding or a blood-stained discharge;
- Ulcers, blisters or sores of the vagina or vulva;
- Lower abdominal pain;
- Pain or difficulty in passing urine;
- A foul smelling discharge from the vagina.

This is because Blicanz™ may not be the right treatment for you.

**Other medicines and Blicanz™**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor, immediately if you are taking terfenadine, astemizole (an antihistamine for treating allergies), cisapride (used for stomach upsets), pimozide (used for treating mental illness), quinidine (used for treating heart arrhythmia) or erythromycin (an antibiotic for treating infections) as these should not be taken with Blicanz™ (see section 2 "Do not take Blicanz™ if you").

There are some medicines that may interact with Fluconazole.

Make sure your doctor knows if you are taking any of the following medicines as a dose adjustment or monitoring may be required to check that the medicines are still having the desired effect:

- Warfarin (or similar drugs) that thin the blood to prevent blood clots;
- Anti-arrhythmics (to control irregular heart beats);
- Amiodarone (used for rhythm disorders);
- Hydrochlorothiazide, nifedipine, isradipine, amlodipine, felodipine and losartan (for hypertension-high blood pressure);
- Medicines for diabetes such as chlorpropamide, glibenclamide, glipizide or tolbutamide;
- tofacitinib (used for treating rheumatoid arthritis)
- tolvaptan used to treat hyponatremia (low levels of sodium in your blood) or to slow kidney function decline
- ibrutinib (used for treating blood cancer)
- Vitamin A (nutritional supplement);
- Statins (atorvastatin, simvastatin and fluvastatin or similar medicines) used for reducing high cholesterol levels;

- Carbamazepine, phenobarbital or phenytoin (used to control epilepsy);
- Benzodiazepines (midazolam, triazolam or similar medicines) used to help you sleep or for anxiety;
- Ciclosporin, everolimus, sirolimus or tacrolimus (to prevent transplant rejection)
- Medicines for treating infections (antibiotics) such as azithromycin, erythromycin, rifampicin, rifapentine or rifabutin;
- Amphotericin B, voriconazole, ketoconazole (anti-fungal);
- Abrocitinib (used to treat atopic dermatitis, also known as atopic eczema)
- Halofantrine (used for treating malaria);
- Oral contraceptives such as ethinylloestradiol, levonorgestrel, norethindrone;
- Theophylline (used to control asthma);
- Alfentanil, fentanyl or methadone (for treating pain);
- Celecoxib, flurbiprofen, naproxen, ibuprofen, lornoxicam, meloxicam, diclofenac (Non-Steroidal Anti-Inflammatory Drugs (NSAID));
- Amitriptyline, nortriptyline (used as anti-depressant);
- Cyclophosphamide, prednisone or vinca alkaloids (vincristine, vinblastine or similar medicines) used for treating cancer
- Saquinavir or zidovudine also known as AZT (used in HIV infected patients);
- Ivacaftor (alone or combined with other drugs used for treating cystic fibrosis)
- Olaparib (used for treating ovarian cancer)
- Verapamil (used to manage hypertension and angina)
- Lurasidone (used to treat schizophrenia);

**Blicanz™ with food, drink and alcohol**

- You can take your medicine with or without a meal. Blicanz™ should be swallowed whole with a glass of water.
- There is no known interaction with alcohol.

**Pregnancy, breast-feeding and fertility**

- 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 taking this medicine.

If you are planning to become pregnant, it is recommended to wait a week after a single dose of fluconazole before becoming pregnant.

For longer courses of treatment with fluconazole, talk to your doctor on the need for appropriate contraception during treatment which should continue for one week after the last dose.

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You should not take Blicanz™ if you are pregnant, think you may be pregnant, are trying to become pregnant, unless your doctor has told you so. If you become pregnant while taking this medicine or within 1 week of the most recent dose, contact your doctor.

Fluconazole taken during the first or second trimester of pregnancy may increase the risk of miscarriage.

Fluconazole taken during the first trimester may increase the risk of a baby being born with birth defects affecting the heart, bones and/or muscles.

There have been reports of babies born with birth defects affecting the skull, ears, and bones of the thigh and elbow in women treated for three months or more with high doses (400-800 mg daily) of fluconazole for coccidioidomycosis. The link between fluconazole and these cases is not clear.

- You can continue breast-feeding after taking a single dose of 150 mg Fluconazole. You should not breast-feed if you are taking a repeated dose of Fluconazole.

#### Driving and using machines

- Treatment with Fluconazole has occasionally led to dizziness or fits to occur and could affect your ability to drive or use machinery.

#### Blicanz™ contains Lactose, Methyl parahydroxybenzoate (E218) and Propyl parahydroxybenzoate (E216)

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

E216 and E218 in this medicine may cause allergic reactions (possibly delayed).

#### Information on sodium content

- Fluconazole capsules contain less than 1 mmol sodium (23 mg) per capsule, that is to say essentially ‘sodium-free’.

### 3. How to take Blicanz™

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure. The full course of treatment consists of a single Blicanz™ capsule.

The capsule is to treat thrush at the site of infection and should be swallowed whole with a glass of water (with or without food). The symptoms of thrush should disappear within two days of treatment. If no improvement is seen after seven days, you must tell your doctor.

If the infection returns after seven days another capsule may be taken but if you have more than two infections within six months you should see your doctor.

#### If you take more Blicanz™ than you should

If more than one capsule is taken, tell your doctor straight away or contact the Accident and Emergency Department of your nearest hospital.

### 4. Possible side effects

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

A few people develop **allergic reactions** although serious allergic reactions are rare. If you get any of the following symptoms, **tell your doctor immediately**.

- Sudden wheezing, difficulty in swallowing, breathing or tightness in chest;
- Swelling of eyelids, face, lips, throat or tongue;
- Irregular heart beat;
- Itching all over the body, reddening of the skin or itchy red spots;
- Red or purple discoloration of the skin which may be caused by low platelet count (thrombocytopenia), other blood cell changes, lower number of neutrophils (neutropenia) causing frequent infections;
- Skin rash;
- Severe skin reactions such as a rash that causes blistering (this can affect the mouth, eyes and genitals).

Blicanz™ may affect your liver. The signs of liver problems include:

- Tiredness; - Loss of appetite;
- Vomiting; - Dark urine or pale stools;
- Increases in blood tests of liver function;
- Yellowing of your skin or the whites of your eyes (jaundice).

If any of these happen, stop taking Blicanz™ and **tell your doctor immediately**.

The following undesirable effects have been observed and reported during the treatment of fluconazole with the following frequencies.

Stop taking this medicine and seek medical attention immediately if you notice any of the above symptoms:

- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome)

#### Common: may affect up to 1 in 10 people

- Headache; - Abdominal pain;
- Diarrhoea; - Nausea;
- Vomiting. - Rash

#### Uncommon: may affect up to 1 in 100 people

- Insomnia; - Somnolence (feeling sleepy);
- Dizziness; - Seizures (fits);
- Altered sense of taste; - Vertigo (spinning sensation);
- Decreased appetite; - Myalgia (muscle pain);
- Fatigue, malaise; - Feeling of weakness (asthenia);
- Tingling or numbness in the hands or feet (paraesthesia); - Skin rash which is red and itchy (urticaria);
- Itching (pruritis);
- Fever;
- Dyspepsia (stomach discomfort), constipation, wind, dry mouth;
- Increased sweating;
- Reduction in red blood cells which can make the skin pale and cause weakness or breathlessness (anaemia).

#### Rare: may affect up to 1 in 1,000 people

- Lower than normal white blood cells (leukopenia); that help defend against infections and blood cells that help to stop bleeding
- Tremor;
- blood chemistry changes (high blood levels of cholesterol, fats)
- Hair loss (alopecia);
- Low blood potassium.
- shaking
- abnormal electrocardiogram (ECG), change in heart rate or rhythm
- liver failure
- allergic reactions (sometimes severe), including widespread blistering rash and skin peeling, severe skin reactions, swelling of the lips or face

#### Frequency not known, but may occur (cannot be estimated from the available data):

- hypersensitivity reaction with skin rash, fever, swollen glands, increase in a type of white blood cell (eosinophilia) and inflammation of internal organs (liver, lungs, heart, kidneys and large intestine) (Drug Reaction or rash with Eosinophilia and Systemic Symptoms (DRESS))

#### 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 Website: [www.mhra.gov.uk/yellowcard](http://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 Blicanz™

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C. Store in the original package.
- Do not use this medicine after the expiry date (exp.) which is stated on the pack. The expiry date refers to the last day of the month.
- 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 Blicanz™ contains

- The active substance is Fluconazole.
- The other ingredients are: lactose, maize starch, colloidal anhydrous silica, sodium lauryl sulfate, magnesium stearate.
- The capsule shell contains gelatin, titanium dioxide (E171), Patent blue V (E131), methyl-parahydroxy benzoate (E218), propyl-parahydroxy benzoate (E216) and Sodium Lauryl Sulfate.

#### What Blicanz™ looks like and contents of the pack

- Blicanz™ Thrush Relief is white to off white powder filled in Blue/blue coloured hard gelatin capsule of size ‘1’.

#### Marketing Authorisation Holder and Manufacturer

Name and address: Bristol Laboratories Ltd,  
Unit 3, Canalside, Northbridge Road, Berkhamsted, Hertfordshire, HP4 1EG, United Kingdom.  
Telephone: 0044 (0)1442 200922  
Fax: 0044 (0)1442 873717  
Email: [info@bristol-labs.co.uk](mailto:info@bristol-labs.co.uk)

#### Manufacturer

Bristol Laboratories Ltd,  
Unit 5, Traynor Way, Whitehouse Business Park, Peterlee, SR8 2RU, United Kingdom.

#### Blicanz™ Thrush Relief 150 mg Capsule; PL 17907/0055

#### This leaflet was last revised in August 2024

To request a copy of this leaflet in braille, large print or audio format, please contact the marketing authorisation holder at the address (or telephone, fax, email) above.

**PACKAGE LEAFLET: INFORMATION FOR THE USER****FLUCONAZOLE 150 mg CAPSULE**  
(fluconazole)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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 must talk to doctor if you do not feel better or if you feel worse after few days.

**What is in this leaflet:**

1. What Fluconazole Capsule is and what it is used for
2. What you need to know before you take Fluconazole Capsule
3. How to take Fluconazole Capsule
4. Possible side effects
5. How to store Fluconazole Capsule
6. Contents of the pack and other information.

**1. What Fluconazole Capsule is and what it is used for**

The name of your medicine is Fluconazole 150mg Capsule.

Fluconazole Capsule is a full course of treatment for thrush.

Only use this product if you have been previously diagnosed by your doctor as having thrush.

The active substance in Fluconazole Capsule is fluconazole. Fluconazole belongs to a group of medicines called azoles and is an antifungal agent which fights the cause of infections such as thrush.

**2. What you need to know before you take Fluconazole Capsule****Do not take Fluconazole Capsule if you:**

- Are allergic to fluconazole, to other medicines you have taken to treat fungal infections or to any of the other ingredients of Fluconazole Capsule (listed in section 6). The symptoms may include itching, reddening of the skin or difficulty in breathing
- Are taking astemizole, terfenadine (antihistamine medicines for allergies)
- Are taking cisapride (used for stomach upsets)

- Are taking pimozone (used for treating mental illness)
- Are taking quinidine (used for treating heart arrhythmia)
- Are taking erythromycin (an antibiotic for treating infections)
- Are taking ergot derivatives (ergotamine used for migraine)

Do not use this medicine if you are suffering from *Tinea Capitis* (fungal infection of the scalp)

**Warnings and Precautions****Talk to your doctor or pharmacist or nurse before taking Fluconazole Capsule if:**

- You are aged under 16 or over 60 years.
- You have had thrush more than twice in the last six months
- You have had any disease or illness affecting the liver or kidneys, or have had any unexplained jaundice.
- You have heart diseases, including heart rhythm problems, or low levels of potassium, magnesium or calcium in your blood
- You suffer from any other chronic diseases or illness.
- You or your partner have been exposed to a sexually transmitted disease
- You are unsure whether you have thrush or this is the first time you have had these symptoms.
- if the fungal infection does not improve, as alternative antifungal therapy may be needed.
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking this medicine.

Serious skin reactions including drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with fluconazole treatment. Stop taking this medicine and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

**Men:**

Do not use Fluconazole Capsule without talking to your doctor first if:

- Your sexual partner does not have thrush
- You have pain or difficulty on passing urine
- You have an abnormal discharge from your penis
- You have sores, ulcers or blisters on your penis.
- Your penis has started to smell

**Women**

If you have any of the following symptoms do not use Fluconazole Capsule and see your doctor as soon as possible:

- Irregular vaginal bleeding.

- Abnormal vaginal bleeding or a blood-stained discharge.
- Ulcers, blisters or sores of the vagina or vulva.
- Lower abdominal pain.
- Pain or difficulty in passing urine.
- A foul smelling discharge from the vagina.

This is because Fluconazole Capsule may not be the right treatment for you.

**Other medicines and Fluconazole Capsule**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor, immediately if you are taking Terfenadine or Astemizole (an antihistamine for treating allergies) or cisapride (used for stomach upsets) or pimozone (used for treating mental illness) or quinidine (used for treating heart arrhythmia) or erythromycin (an antibiotic for treating infections) as these should not be taken with Fluconazole Capsule (see section-2: "Do not take Fluconazole Capsule if you")

There are some medicines that may interact with Fluconazole.

Make sure your doctor knows if you are taking any of the following medicines as a dose adjustment or monitoring may be required to check that the medicines are still having the desired effect:

- Warfarin (or similar drugs) that thin the blood to prevent blood clots
- Anti-arrhythmics (to control irregular heart beats)
- amiodarone (used for rhythm disorders)
- Hydrochlorothiazide, nifedipine, isradipine, amlodipine, felodipine and losartan (for hypertension-high blood pressure)
- Medicines for diabetes such as chlorpropamide, glibenclamide, glipizide or tolbutamide
- tofacitinib (used for treating rheumatoid arthritis)
- ibrutinib (used for treating blood cancer)
- Vitamin A (nutritional supplement)
- Statins (atorvastatin, simvastatin and fluvastatin or similar medicines) used for reducing high cholesterol levels
- Carbamazepine, Phenobarbital or phenytoin (used to control epilepsy)
- Benzodiazepines (midazolam, triazolam or similar medicines) used to help you sleep or for anxiety
- Ciclosporin, everolimus, sirolimus or tacrolimus (to prevent transplant rejection)
- Medicines for treating infections (antibiotics) such as azithromycin, erythromycin, rifampicin, rifapentine or rifabutin

- Abrocitinib (used to treat atopic dermatitis, also known as atopic eczema)
- Amphotericin B, voriconazole, ketoconazole (anti-fungal)
- Halofantrine (used for treating malaria)
- Oral contraceptives such as ethinylloestradiol, levonorgestrel, norethindrone.
- Theophylline (used to control asthma)
- Alfentanil, fentanyl or methadone (For treating pain)
- Celecoxib, flurbiprofen, naproxen, ibuprofen, lornoxicam, meloxicam, diclofenac (Non-Steroidal Anti-Inflammatory Drugs (NSAID))
- Amitriptyline, nortriptyline (used as anti-depressant)
- Cyclophosphamide, prednisone or vinca alkaloids (vincristine, vinblastine or similar medicines) used for treating cancer
- Saquinavir or zidovudine also known as AZT (used in HIV infected patients)
- Ivacaftor (alone or combined with other drugs used for treating cystic fibrosis)
- Olaparib (used for treating ovarian cancer)
- VErapamil (used to manage hypertension and angina)
- Tolvaptan used to treat hyponatremia (low levels of sodium in your blood) or to slow kidney function decline
- Lurasidone (used to treat schizophrenia):

**Fluconazole Capsule with food, drink and alcohol**

- You can take your medicine with or without a meal. Fluconazole Capsule should be swallowed whole with a glass of water.
- There is no known interaction with alcohol.

**Pregnancy, breast-feeding and fertility**

- 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 taking this medicine.

If you are planning to become pregnant, it is recommended to wait a week after a single dose of fluconazole before becoming pregnant.

For longer courses of treatment with fluconazole, talk to your doctor on the need for appropriate contraception during treatment which should continue for one week after the last dose.

You should not take Fluconazole if you are pregnant, think you may be pregnant, are trying to become pregnant, unless your doctor has told you so. If you become pregnant while taking this medicine or within 1 week of the most recent dose, contact your doctor.

Fluconazole taken during the first or second trimester of pregnancy may increase the risk of miscarriage.

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Fluconazole taken during the first trimester may increase the risk of a baby being born with birth defects affecting the heart, bones and/or muscles.

There have been reports of babies born with birth defects affecting the skull, ears, and bones of the thigh and elbow in women treated for three months or more with high doses (400-800 mg daily) of fluconazole for coccidioidomycosis. The link between fluconazole and these cases is not clear.

- You can continue breast-feeding after taking a single dose of 150 mg Fluconazole. You should not breast-feed if you are taking a repeated dose of Fluconazole.

#### Driving and using machines

- Treatment with Fluconazole has occasionally led to dizziness or fits to occur and could affect your ability to drive or use machinery.

#### Fluconazole Capsule contains Lactose

- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

#### Fluconazole Capsule contains Methyl parahydroxybenzoate (E218) and Propyl parahydroxybenzoate (E216)

- E216 and E218 in this medicine may cause allergic reactions (possibly delayed)

#### Information on sodium content:

- Fluconazole capsules contain less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

### 3. How to take Fluconazole Capsule

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

The full course of treatment consists of a single Fluconazole Capsule. The capsule is to treat thrush at the site of infection and should be swallowed whole with a glass of water (with or without food). The symptoms of thrush should disappear within two days of treatment. If no improvement is seen after seven days, you must tell your doctor. If the infection returns after seven days another capsule may be taken but if you have more than two infections within six months you should see your doctor.

#### If you take more Fluconazole Capsule than you should:

If more than one capsule is taken, tell your doctor straight away or contact the Accident and Emergency Department of your nearest hospital.

### 4. Possible side effects

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

A few people develop **allergic reactions** although serious allergic reactions are rare. If you get any of the following symptoms, **tell your doctor immediately**.

- Sudden wheezing, difficulty in swallowing, breathing or tightness in chest
- Irregular heart beat
- Red or purple discoloration of the skin which may be caused by low platelet count (thrombocytopenia), other blood cell changes, lower number of neutrophils (neutropenia) causing frequent infections.
- Swelling of eyelids, face, lips, throat or tongue
- Itching all over the body, reddening of the skin or itchy red spots
- Skin rash
- Severe skin reactions such as a rash that causes blistering (this can affect the mouth, eyes and genitals).

Fluconazole may affect your liver. The signs of liver problems include:

- Tiredness
- Vomiting
- Increase in blood tests of liver function
- Yellowing of your skin or the whites of your eyes (jaundice)
- Loss of appetite
- Dark urine or pale stools

If any of these happen, stop taking Fluconazole and **tell your doctor immediately**.

Stop taking this medicine and seek medical attention immediately if you notice any of the above symptoms:

- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome)

The following undesirable effects have been observed and reported during the treatment of fluconazole with the following frequencies.

#### Common: may affect up to 1 in 10 people

- Headache
- Diarrhoea
- Vomiting
- Abdominal Pain
- Nausea
- Rash

#### Uncommon: may affect up to 1 in 100 people

- Insomnia
- Dizziness
- Altered sense of taste
- Somnolence (feeling sleepy)
- Seizures (fits);
- Vertigo (spinning sensation);

- Decreased appetite
- Fatigue, malais
- Tingling or numbness in the hands or feet (paraesthesia)
- Itching (pruritis)
- Skin rash which is red and itchy (urticaria)
- Dyspepsia (stomach discomfort), constipation, wind, dry mouth
- Increased sweating
- Reduction in red blood cells which can make the skin pale and cause weakness or breathlessness (anaemia).
- Myalgia (muscle pain)
- Feeling of weakness (asthenia)
- Fever

#### Rare: may affect up to 1 in 1,000 people

- Lower than normal white blood cells (leukopenia) that help defend against infections and blood cells that help to stop bleeding
- Tremor
- blood chemistry changes (high blood levels of cholesterol, fats)
- Hair loss (Alopecia)
- Low blood potassium
- shaking
- abnormal electrocardiogram (ECG), change in heart rate or rhythm
- liver failure
- allergic reactions (sometimes severe), including widespread blistering rash and skin peeling, severe skin reactions, swelling of the lips or face

#### Frequency not known, but may occur (cannot be estimated from the available data):

- hypersensitivity reaction with skin rash, fever, swollen glands, increase in a type of white blood cell (eosinophilia) and inflammation of internal organs (liver, lungs, heart, kidneys and large intestine) (Drug Reaction or rash with Eosinophilia and Systemic Symptoms (DRESS))

#### 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 Website: [www.mhra.gov.uk/yellowcard](http://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 Fluconazole Capsule

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C. Store in the original package

### 6. Contents of the pack and other information

#### What Fluconazole Capsule contains:

- The active substance is Fluconazole
- The other ingredients are: lactose, maize starch, colloidal anhydrous silica, sodium lauryl sulfate, magnesium stearate.
- The capsule shell contains gelatin, titanium dioxide (E171), Patent blue V (E131), methylparahydroxy benzoate (E218), propyl-parahydroxy benzoate (E216) and Sodium Lauryl Sulfate.

#### What Fluconazole Capsule looks like and contents of the pack.

- Fluconazole 150mg Capsule is white to off white powder filled in Blue/blue coloured hard gelatin Capsule of size '1'.

#### Marketing Authorisation Holder and Manufacturer

Name and address: Bristol Laboratories Ltd,  
Unit 3, Canalside, Northbridge Road, Berkhamsted,  
Hertfordshire, HP4 1EG, United Kingdom.

Telephone: 0044 (0)1442 200922  
Fax: 0044 (0)1442 873717  
Email: [info@bristol-labs.co.uk](mailto:info@bristol-labs.co.uk)

#### Manufacturer

Bristol Laboratories Ltd,  
Unit 5, Traynor Way, Whitehouse Business Park,  
Peterlee, SR8 2RU, United Kingdom.

#### Fluconazole 150mg Capsule; PL 17907/0055

#### This leaflet was last revised in August 2024

To request a copy of this leaflet in braille, large print or audio format, please contact the marketing authorisation holder at the address (or telephone, fax, email) above.