#### ITRACONAZOLE 100 mg CAPSULES (Itraconazole)

#### Package leaflet: Information for the use

Read all of this leaflet carefully before you start taking 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, pharmacist or nurse.
- 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 of the side effects, talk to your doctor, pharmacist or nurse. This
- includes any possible side effects not listed in this leaflet. See section 4. What is in this leaflet
- 1. What Itraconazole Capsules are and what they are used for
- 2. What you need to know before you take
- **Itraconazole Capsules**
- 3. How to take Itraconazole Capsules
- 4. Possible side effects
- 5. How to store Itraconazole Capsules 6. Contents of the pack and other
- information

What Itraconazole Capsules are and what they are used for

Itraconazole Capsules belong to a group of medicines called antimycotics for systemic use, also known as "antifungals", which are used to treat infections caused by fungi including yeasts.

- Itraconazole Capsules are used to treat fungal infections of the:
- vagina
- skin
- Iungs
- mouth nails

internal organs.

#### What you need to know before 2 you take Itraconazole Capsules

### DO NOT take Itraconazole if you are:

- allergic to itraconazole or any of the other ingredients of this medicine (listed
- in section 6) taking any hay fever antihistamine products containing terfenadine,
- astemizole or mizolastine taking certain medicines used to treat
- angina (chest pain) and high blood
- pressure, such as bepridil and nisoldipine taking cisapride (a drug used for certain
- - digestive problems) taking midazolam (by mouth) or
  - triazolam, medicines taken for anxiety or
  - to help you to sleep (tranquillisers) taking certain cholesterol lowering drugs,
  - for example, atorvastatin, lovastatin or simvastatin
  - taking pimozide or sertindole (drugs for
  - certain conditions affecting thoughts, feelings and/or behaviour)
  - taking levacetylmethadol, which is used for the treatment of opioid-dependency
  - taking ergot alkaloids (drugs used to treat migraine headaches) such as
  - dihydroergotamine and ergotamine taking ergot alkaloids (drugs used after
  - giving birth) such as ergotamine (ergonovine) and methylergometrine (methylergonovine)
  - taking certain medicines used to treat

- ergot alkaloids (drugs used to treat migraine headaches) such as dihydroergotamine and ergotamine ergot alkaloids (drugs used after giving birth) such as ergotamine (ergonovine) and methylergometrine (methylergonovine)
- eletriptan, which is used to treat migraine headaches
- certain medicines used to treat irregular heart beat rhythms, such as quinidine and dofetilide.
- Return to your doctor as soon as possible if you are taking any of these medicines to discuss vour treatment.

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#### Some medicines may significantly decrease how well itraconazole works:

- · medicines used for the treatment of epilepsy (for example carbamazepine, phenytoin and phenobarbital) medicines for the treatment of tuberculosis (for example rifampicin, rifabutin and isoniazid).
- Tell your doctor if you are taking any of these medicines in order that adequate measures can be taken.

Combination with some other medicines may require either an adjustment to your dose of Itraconazole Capsules, or to the dose of the other drugs. Examples are:

- certain antibiotics such as clarithromycin, erythromycin and rifabutin certain drugs that act on the heart and blood vessels (digoxin, disopyramide and some calcium channel blockers such as dihydropyridines, verapamil and
- cilostazol) drugs that avoid blood coagulation, such as warfarin
- methylprednisolone, budesonide, fluticasone and dexamethasone, which are oral or intravenous use drugs used to treat inflammatory processes, asthma and allergies
- cyclosporin, tacrolimus and rapamycin (also named sirolimus), that are usually given after an organ transplant • certain antiviral protease inhibitors, such
- as ritonavir, indinavir and saquinavir · certain medicines used to treat cancer e.g. busulphan, docetaxel and
- trimetrexate and vinca alkaloids certain medicines used for the treatment of anxiety or to help you sleep (tranquilisers), such as buspirone, alprazolam and brotizolam
- fentanyl, a strong medicine for pain • atorvastatin, a drug used to lower
- cholesterol halofantrine, a drug used to treat malaria
- repaglinide, a drug used to treat diabetes
- ebastine, a medicine for allergy · reboxetine, a medicine used to treat
- depression
- the tranquilliser midazolam when given intravenously
- a painkiller known as alfentanil.
- There must be sufficient gastric acidity to assure itraconazole absorption by the body. Therefore:
- any medicines that neutralise gastric acidity (antacids) should not be taken within two hours before or after taking
- Itraconazole Capsules • if you take medicines that stop the production of gastric acid, you should take Itraconazole Capsules with a cola
- beverage. Inform your doctor before taking

The recommended dose is: constipation The recommended dose depends on the type and area of infections and is described • decreased sense of taste (dysgeusia) in the table below: TYPE OF CAPSULES DURATION INFECTION PER DAY 2 capsules 1 dav Vaginal nfectior twice daily (thrush) (2 capsules in the morning and 2 in the evening) 2 capsules Pityriasis 7 days versicolor once daily 7 days Skin 2 capsules once daily infection of 15 days the groin 1 capsule once daily Skin 2 capsules 7 days infection of once daily or 15 days the arms or and legs 1 capsule once daily Athletes foot 1 capsule 30 days once daily 30 days Skin infection 1 capsule of the hand once daily 1 capsule Infections of 15 days once daily the mouth Infections o 2 capsules 3 months the nails once daily 200 mg Internal Longer infections once or periods twice daily depending on response Your doctor may sometimes prescribe Itraconazole Capsules at different dosages or for different lengths of time than those

shown above. It is important that you carry on taking your medicine for as long as your doctor has told you to. This will help to prevent your

infection returning. DO NOT stop your treatment just because you feel better. Talk to your doctor if this applies to you.

In skin infections, the lesions will disappear a few weeks after finishing the treatment. This is characteristic of the spots produced by the fungus. Although itraconazole kills the fungus, the lesion does not disappear until new skin has grown. Similarly, lesions on the nails will disappear 6 to 9 months after finishing your treatment. Therefore, do not worry if you don't notice an improvement during the treatment. Always follow your doctor's advice.

#### If you take more ltraconazole than you should

If you (or someone else) swallow a lot of the capsules all together or if you think a child has swallowed any of the capsules, contact your nearest hospital casualty department or your doctor immediately. Please take this leaflet, any remaining capsules and the container with you to the hospital or doctor so that they know which capsules were consumed.

#### If you forget to take Itraconazole

DO NOT take a double dose to make up for a forgotten capsule. Take the next dose as

- indigestion (dyspepsia) • bloating (flatulence). • an elevated level of the pigment bilirubin in the blood, shown by blood test (hyperbilirubinaemia) changes in the liver function (shown by blood tests) unusual hair loss or thinning (alopecia) itching (pruritus) • irregular periods (menstrual irregularity) • water retention (oedema). Rare (may affect up to 1 in 1,000 people): reduction in the number of white blood cells (leucopenia) usually shown by blood tests reductions of sensation to pain or touch (hypoaesthesia) problems with sight (visual disturbance) ringing in the ears (tinnitus) inflammation of the pancreas which causes severe pain in the abdomen and back (pancreatitis) increases in liver function tests usually shown by blood tests (hepatic enzyme increased) increase in frequency of urination (pollakiuria) fever (pyrexia). Very rare (may affect up to 1 in 10,000 people): Iow blood levels of potassium (hypokalaemia) • fatal acute hepatic failure inflammation of the liver (hepatitis) serious hepatotoxicity serious allergic reaction which causes swelling of the face or throat (angioedema). Not known: (frequency cannot be estimated from the available data): abnormally low number of white blood cells (neutropenia) usually shown by blood test reduction in blood platelets, which increases risk of bleeding or bruising (thrombocytopenia) usually diagnosed by blood test
  - anaphylactic reaction • serious allergic reaction which causes difficulty in breathing or dizziness (anaphylactoid reaction)
  - serious allergic reaction which causes swelling of the face or throat
  - (angioneurotic oedema)
  - itchy rash, joint pain, fever and enlarged lymph nodes (serum sickness)
  - high levels of triglycerides in the blood (hypertriglyceridemia) shown by blood
  - tests • problems with sight including blurred
  - vision and double vision
  - hearing loss (may be permanent) leukocytoclastic vasculitis
  - · sensitivity of the skin to light
  - (photosensitivity)
  - muscle pain (myalgia)
  - joint pain (arthralgia) unexpected passing of urine or need to
  - urinate (pass urine) more often (urinary incontinence)
  - difficulty in getting or keeping an erection (erectile dysfunction).

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

# Reporting of side effects

If you get any side effects, talk to your

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- irregular heart beat rhythms, e.g.
- quinidine and dofetilide
- taking eletriptan, which is a drug used to
- treat migraine headaches.

#### Warnings and precautions Talk to your doctor or pharmacist or nurse before taking Itraconazole. If you have:

a liver problem, as it may be necessary to adjust your dose of Itraconazole. If your doctor decides to prescribe Itraconazole Capsules, you should be

- given instructions about potential symptoms that can appear (also read Section 4, Possible side effects). See your doctor if any of the following symptoms appear during your course of treatment with Itraconazole capsules: lack of appetite, feeling sick, vomiting, fatigue, abdominal pain, pale stools or very dark
- urine. If you have to take ltraconazole Capsules continuously for more than one month, your doctor may ask you for regular blood analysis.
- heart problems. If your doctor decides to prescribe Itraconazole Capsules, you should be given instructions about
- potential symptoms that can appear (also read Section 4, Possible side effects). Inform your doctor immediately if you have wheezing, unexpected weight gain, swelling of the legs or abdomen, unusual fatigue or early insomnia (when you can't fall asleep until very late).
- Acquired Immunodeficiency Syndrome (AIDS) or any condition in which your immune system is not working as well as it should be
- decreased gastric acidity
- a kidney problem, as it may be necessary to adjust your dose of Itraconazole
- suffered an allergic reaction in the past to any other antifungal agent.

You should also tell your doctor immediately, if during treatment with Itraconazole capsules, you experience tingling, numbness or weakness in feet or hands.

#### Other medicines and Itraconazole

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

- any hay fever antihistamine products containing terfenadine, astemizole or mizolastine
- certain medicines for angina or high blood pressure such as bepridil or nisoldipine
- cisapride (a drug used for certain digestive problems)
- midazolam (by mouth) or triazolam, which are medicines taken for anxiety or
- to help you to sleep (tranquillisers)
- certain cholesterol lowering drugs, for example, atorvastatin, lovastatin or simvastatin
- pimozide and sertindole (drugs for certain conditions affecting thoughts,
- feelings and/or behaviour)
- levacetylmethadol, which is used for the treatment of opioid-dependency

Itraconazole Capsules if any of the above applies to you. Your doctor will then decide whether Itraconazole Capsules are suitable for you. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

- Itraconazole with food, drink and alcohol • Always take Itraconazole immediately
- after a meal as this helps the body absorb the medicine If you are also taking medicines that stop the production of gastric acid, you should
- take Itraconazole Capsules with a cola beverage DO NOT take alcohol.

## Pregnancy, breast-feeding and fertility

#### Pregnancy

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 of child bearing age and could become pregnant, adequate contraceptive precautions should be taken to ensure that you do not become pregnant while you are taking your medicine
- After you stop taking your medicine itraconazole remains in the body for some time, therefore you should continue to use adequate contraceptive precautions until you have had your next menstrual period.

#### **Breast-feeding**

If you are breast-feeding ask your doctor before taking Itraconazole Capsules, as small amounts of the medicine could be present in your milk.

## **Driving and using machines**

 Taking Itraconazole Capsules is not expected to affect your ability to drive or use machines.

#### Itraconazole contains sucrose

Patients who are intolerant to sucrose should note that Itraconazole contain a small amount of sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

#### How to take Itraconazole 3 Capsules

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

Itraconazole Capsules should be swallowed with a glass of water (unless you have decreased gastric acid in which case you should swallow with a cola beverage) immediately after a meal



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

#### Stop taking Itraconazole capsules and contact your doctor immediately or go to the casualty department at your nearest hospital if you have:

- sudden signs of allergic reaction such as severe irritation of your skin, swelling of the lips, tongue, face or neck leading to severe difficulty in breathing; skin rash or hives (also known as nettle rash or urticaria). These may be signs of a severe allergic reaction.
- severe skin disorders with peeling and/or rashes with small pustules (with a fever) or blistering of the skin, mouth, eyes and genitals, with fever, chills, aching muscles and generally feeling unwell. These could be signs of a serious allergy called "exfoliative dermatitis".
- severe blistering rash in which layers of the skin may peel off to leave large areas of raw exposed skin over the body. You may feel generally unwell, have a fever, chills or aching muscles. This could be an illness called "Toxic Epidermal Necrolysis".
- blistering or peeling of the skin around the lips, eyes, skin rash, blistering affecting the skin, mouth, eyes, genitals or anus, flu-like symptoms of fever. This could be an illness called "Stevens-Johnson syndrome".
- skin rash or skin lesions with a pink/red ring and a pale centre which may be itchy, scaly, or filled with fluid. The rash may appear especially on the palms or soles or your feet. These could be signs of a serious allergy to the medicine called 'erythema multiforme'.
- lack of appetite, feeling sick (nausea), being sick (vomiting), tiredness, stomach pain (abdominal pain), muscle weakness, yellowing of the skin or whites of your eyes (jaundice), very dark urine, pale stools and hair loss have occurred. These may be signs that the medicine is affecting your liver.
- · a disorder of the nerves which can cause a tingling sensation, numbress or weakness in the limbs (peripheral neuropathy)
- shortness of breath, unexpected weight gain, swelling of the legs or abdomen, unusual tiredness (fatigue) or begin to wake up short of breath at night. These may be signs of heart failure reactions. Shortness of breath can also be a sign of fluid on the lungs (pulmonary oedema).

#### Tell your doctor or pharmacist if you notice any of the following side effects:

Uncommon (may affect up to 1 in 100 people):

- hypersensitivity
- headache
- dizziness
- tingling/ numbress (paraesthesia)
- diarrhoea

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 at: www.mhra.gov.uk/yellowcard By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Itraconazole Capsules

#### Keep this medicine out of the sight and reach of children.

Do not store above 25° C. Store in the original package in order to protect from light.

Do not use this medicine after the expiry date which is stated on the outer packaging. The expiry date refers to the last day of that month.

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 to protect the environment.

Contents of the pack and other 6 information

#### What Itraconazole Capsules contain:

 The active substance is itraconazole. Each capsule contains 100 mg itraconazole. • The other ingredients are sugar spheres (maize starch and sucrose 224.31 mg per capsule), poloxamer 188 and poloxamer 68, hypromellose. The capsule shells consist of indigo carmine (E132), quinoline yellow (E104), titanium dioxide (E171), purified water and gelatin.

#### What Itraconazole Capsules look like and contents of the pack:

Itraconazole 100 mg Capsules are hard gelatin capsules (size 0) with a green opague cap and body containing yellowish-beige spherical microgranules. Itraconazole 100 mg Capsules are available in pack sizes of 4, 6, 8, 14, 15, 16, 28, 30, 32, 60, 84 and 90, and hospital packs of 50 (50x1).

Not all pack sizes may be marketed.

#### Marketing Authorisation Holder and Manufacturer

#### Marketing authorisation holder

TEVA UK Limited, Eastbourne, BN22 9AG

## Manufacturer

Laboratorios Liconsa, S.A., Avda. Miralcampo, No 7, Polígono Industrial Miralcampo 19200 Azuqueca de Henares (Guadalajara), Spain.

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