Also, upon completing your course of Itraconazole Oral Solution, do not take any of the medicines listed above for 2 weeks.

Tell your doctor if you have:

• problems appear during your course of treatment:

Stop taking Itraconazole Oral Solution and see your doctor immediately if you:

Tell your doctor if you are using the following medicines as they:

Itraconazole is one of a group of medicines called “antifungals”. These medicines are used to treat and stop you from getting fungal infections. Itraconazole is one of a group of medicines called “antifungals”. These medicines are used to treat and stop you from getting fungal infections caused by fungi including:

Tell your doctor if you are using any of the following medicines as they:

To treat yeast infections of the mouth, throat or food pipe (pharyngitis) if you have a poor immune system

To stop you from getting fungal infections you have blood cancer or have had a bone marrow transplant and have had a transplant of blood stem cells

Do not take Itraconazole Oral Solution with food or drink as it

Always take it one hour before any food or drink as this helps

There are some medicines that you should not take whilst taking Itraconazole Oral Solution. These are shown in the heading “Do not take Itraconazole Oral Solution if:

Take special care with the following medicines:

• have a very serious fungal infection (see under ‘Take special

• have a history of severe heart failure, unless you have

• are pregnant or breast-feeding

• are allergic to it (e.g. you have had a reaction to it)

• are under 18 years of age

• have a very low white blood cell count

• have lupus erythematosus

• are using any of the following medicines:

• have kidney or liver problems

• have a history of gout

• are taking any of the following medicines:

• are taking any of the following medicines as they

• have had an organ transplant

• have a history of severe drug reactions

• have a history of irritable bowel syndrome

• have recently taken any of the following medicines:

• have a very low blood sodium level

• are taking any of the following medicines as they

• are taking any of the following medicines as they contain important information for you.

• are allergic to it (e.g. you have had a reaction to it)

• are allergic to it (e.g. you have had a reaction to it)

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

Please tell your doctor or pharmacist if you are taking or have

Itraconazole Oral Solution is a white to off-white, opaque, round, film-coated tablet of 50mg or 100mg.

The medicine contains:

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These medicines are used to treat and stop you from getting fungal infections caused by fungi including:

Tell your doctor if you have any of the following symptoms:

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The medicine contains:

• if you have any side effects, talk to your doctor or pharmacist.

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DRIVING AND USING MACHINES
Itraconazole can sometimes cause dizziness, blurred/double vision or fainting. Do not drive or use machines if you have these symptoms.

Itraconazole Oral Solution contains sorbitol (E422)
This medicine contains 12 mg/5 ml sorbitol in each 20 ml dose which is equivalent to 0.15 g/ml.

If you are pregnant or breast-feeding, do not take this medicine unless recommended by your doctor. You may carry out extra checks while you are taking this medicine.

Itraconazole Oral Solution contains propylene glycol (E1522)
This medicine contains 27 mg/5 ml propylene glycol in each 20 ml dose which is equivalent to 0.35 g/ml.

Itraconazole Oral Solution contains glycine (E880)
This medicine contains 1 mmol sodium (23 mg) per 20 ml that is to say essentially sodium-free.

3. HOW TO TAKE ITRACONAZOLE ORAL SOLUTION
Always take Itraconazole Oral Solution exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

3.1. Administration
• Always take the solution one hour before any food or drink as this helps the body absorb the medicine.
• A graduated measuring cup is provided. Ensure you fill the cup to the correct mark.
• You should swallow the oral solution around in your mouth for approximately 20 seconds before swallowing it.
• Do not rinse your mouth after swallowing the oral solution.

3.2. Treatment of yeast infections of the mouth, throat or food pipe (oesophagus)
The usual dose is 20 mg per day for one week. This may be taken either all at once or in two divided doses during the day. If after one week of using the oral solution, your infection has not cleared, your doctor may decide to continue your treatment for more weeks.

3.3. Treatment of yeast infections of the mouth, throat or food pipe (oesophagus), which have already been treated with another antifungal but still have not cleared
The usual oral dose is 20 mg twice daily for 2 weeks. If the infection has not cleared, the treatment may be continued for an additional two weeks. The higher dose of 400 mg (5 ml) daily should be used for more than 14 days if there are signs of improvement during this time.

Prevention of fungal infections
The dose is calculated according to your body weight (5 mg per kg) given in two divided doses. Your doctor will tell you exactly how much you should take.

Use in children and the elderly
Itraconazole Oral Solution is not normally given to children or the elderly. Your doctor may prescribe it in special cases.

If you take Itraconazole Oral Solution more than you should contact your doctor or local hospital without delay

4. POSSIBLE SIDE EFFECTS
Use all medicines, Itraconazole Oral Solution can cause side effect after taking the medicine. Some of these effects are not serious and do not everybody gets them.

4.1. Serious side effects
Stop taking Itraconazole Oral Solution and contact your doctor immediately if you have:
• any sudden weakness, difficulty in breathing, swelling of the face, neck, arms, hands, legs, feet, tongue or lips (an allergy, especially affecting the whole body). These may be symptoms of a severe hypersensitivity or allergic reaction.
• severe lack of appetite, feeling or being sick, unusual tiredness, difficulty swallowing, repeat pyrexia, especially after a single dose of itraconazole.
• increased heart rate, any sudden wheeziness, difficulty in breathing, swelling of the face, mouth or tongue, facial swelling, chest pain.
• increase in blood urea level, increase in blood creatine phosphokinase levels
• loss of control of urination or increased need to urinate (passing urine) without any other reason.
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• bruising or infections
• new onset of tiredness or unusual tiredness
• feeling sick (nausea), being sick (vomiting), muscle cramps or irregular heart beat (possible symptoms of low blood levels of magnesium), unusual fatigue, unusual tiredness, difficulty speaking, low blood levels of potassium, constipation
• incontinence of the faeces, feeling of pain in the lower abdomen (stomach) pain, unusually dark urine, or pale stools.
• fever, chills, sore throat, tiredness and generally feeling unwell. These may be symptoms of severe liver problems
• unusual tiredness or unusual weight gain, swelling of the legs, unusual fatigue
• increase in blood pressure, unusual tiredness
• difficulty breathing, unusual tiredness, prompts of liver damage (jaundice), fever, chills, sore throat, tiredness and generally feeling unwell.

4.2. Uncommon side effects (may affect up to 1 in 100 people are)
• certain blood disorders which may increase the risk of bleeding, bruising or infections
• muscle cramps or irregular heart beat (possible symptom of low blood levels of potassium)
• constipation
• shivering
• general swelling
• hives
• increased feeling or sensitivity, especially in the skin
• unusual tiredness (abnormal menstrual bleeding or cycle)
• muscle pain, painful joints

The following side effects have been reported in patients taking Itraconazole Oral Solution and have not been known frequency:
• increased in blood pressure
• increase in blood urea level
• red rash
• rash
• flushing
• tremors
• increased heart rate
• red blood pressure
• dry mouth
• difficulty speaking
• increased heart rate
• diarroea
• nausea
• vomiting
• weight gain
• unusual tiredness
• abnormal liver function tests

Report of side effects of medicines can help to protect the environment.

5. MORE INFORMATION ABOUT TAKING AND STOPPING MEDICATIONS
Keep out of the sight and reach of children. Do not store above 25°C.

6. WHAT ITRACONAZOLE ORAL SOLUTION CONTAINS
What Itraconazole Oral Solution looks like and contents of the pack
In a clear yellow solution, available in bottles containing 150 ml together with a graduated measuring cup, in a cardboard carton.

7. MORE INFORMATION ON TAKING MEDICATIONS
How do I take the medicine?

Itraconazole Oral Solution contains:
• Itraconazole 250 mg/5 ml
• The other ingredients are hydroxypropyl-β-cyclodextrin, sorbitol (E422), propylene glycol (E1520), sodium saccharin (saccharin dihydrate, hydrochloride, hydroxyethyl cellulose, saccharin sodium, sodium hydroxide, propylene glycol and saccharin.

Other side effects
Tell your doctor if any of the following symptoms get worse or you feel any symptoms of hearing loss, ringing in your ears.

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