

PATIENT INFORMATION LEAFLET
ZUCAN 2 mg/ml

SCHEDULING STATUS:

Ⓢ4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

ZUCAN 2 mg/ml (Solution for infusion)

Please read this leaflet carefully before taking ZUCAN solution for infusion.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- ZUCAN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT ZUCAN CONTAINS:

Active ingredient:

Fluconazole (each ml of solution for infusion contains 2 mg fluconazole)

Inactive ingredients:

Sodium chloride, water for injection.

2. WHAT ZUCAN IS USED FOR:

ZUCAN infusion is used for treating and preventing fungal infections.

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ZUCAN belongs to a group of antifungal medicines called imidazole's and is used for the treatment of the various types of fungal infections. The medicine works by stopping the growth of the fungus.

3. BEFORE YOU ARE ADMINISTERED ZUCAN:

You should not be administered ZUCAN:

- If you are allergic (hypersensitive) to fluconazole or to other similar medicines such as ketoconazole and itraconazole or to any of the other ingredients of **ZUCAN** infusion.
- If you are taking other medicines known to affect your heart and be metabolised in the same way as **ZUCAN**, such as cisapride, pimozone and quinidine.
- If you have kidney disease and require more than one dose of **ZUCAN**.
- If you are taking a medicine called astemizole. Concurrent use may cause heart abnormalities.
- If you are pregnant or breastfeeding your baby.

Take special care with ZUCAN:

If any of the below apply to you talk to your doctor or nurse:

- You have currently, or have previously had, problems with your liver.
- You have AIDS or have an infection that affects your whole body.
- You have heart disease.
- You receive warfarin or any other medicine which reduces blood coagulation.
- You have kidney disease.
- You have severe skin reactions.

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Pregnancy and breastfeeding:

- Before starting treatment, you must inform your doctor if you are pregnant or intend to become pregnant. **ZUCAN** is contra-indicated in pregnancy. Women of child-bearing potential should use reliable contraception during long-term treatment with **ZUCAN** infusion.
- Fluconazole enters breast milk, so women are advised not to breastfeed their babies while they are taking **ZUCAN**.

Driving and using machines:

- Dizziness or loss of balance can occur in people receiving **ZUCAN** so care should be taken when driving or operating machinery.

Important information about some of the ingredients of ZUCAN:

ZUCAN is formulated in sodium chloride i.e. it contains sodium ions.

Using other medicines with ZUCAN:

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription or traditional medicines. The use of these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare profession for advice.

If **ZUCAN** infusion and certain other medication are taken at the same time, the effect of treatment may be affected. This applies to the following:

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- disopyramide, dofetilide and quinidine – used to restore the natural rhythm of the heart
- amitriptyline, nortriptyline and reboxetine – used to treat depression
- bosentan and carbamazepine – use to treat epilepsy
- astemizole, mizolastine – used to treat allergic reactions
- halofantrine – used to treat malaria
- dihydroergotamine, ergometrine, ergotamine, methylergometrine and eletriptan – used to treat migraines
- rifabutin – used to treat certain bacterial infections (mycobacterial infections)
- busulfan, docetaxel, trimetrexate and the vinca alkaloids – used to treat abnormal growth of tissue e.g. tumor
- pimozide and sertindole – used to treat mental disorders
- buspirone – used to treat anxiety
- alprazolam, brotizolam, diazepam, midazolam and triazolam – used to treat sleeplessness and anxiety
- bepridil, verapamil, felodipine, nifedipine and nisoldipine – used to treat various conditions including high blood pressure, migraines, alter heart rate, reduce chest pain and Raynaud's disease
- budesonide, dexamethasone, fluticasone and methylprednisolone – used to relieve inflammation
- warfarin – used to stop blood from clotting
- cisapride – used to assist digestion
- indinavir, ritonavir and saquinavir – used in the treatments of AIDS

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- ciclosporin, sirolimus and tacrolimus – used to reduce the body’s ability to fight infection or foreign matter
- alfenatil, fentanyl and levacetyl-methadol – used to reduce pain
- nateglinide and repaglinide – used in the treatment of diabetes
- sildenafil, vardenafil and cilosatazol – used to treat erectile dysfunction
- atorvastatin, lovastatin, and simvastatin – used to lower cholesterol
- conivaptan and tolvaptan - used to help control body water balance by reducing urination
- hydrochlorothiazide - used to treat water retention
- oral contraceptives – used to prevent pregnancy
- rifampicin – used to treat tuberculosis
- phenytoin – used in the treatment of seizures
- sulfonylurea hypoglycaemics – used in the treatment of diabetes
- celecoxib, parecoxib – used to treat pain and fever
- nevirapine and zidovudine - used in the treatment of HIV and AIDS
- losartan – used to treat high blood pressure

4. HOW TO RECEIVE ZUCAN:

ZUCAN will be administered to you by an injection. Your doctor will decide on the suitable dose and duration of the treatment based on the type and severity of the infection that you have.

Treatment will normally continue until the infection is gone.

If you receive more ZUCAN than you should:

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Since your healthcare professional will administer **ZUCAN**, he/she will control the dosage. However, in the event of overdosage, your doctor will manage the overdosage.

If you are worried you have been given too much or have any questions about the dose, talk to your doctor or nurse.

5. POSSIBLE SIDE EFFECTS:

ZUCAN may have side effects.

Not all side effects reported for **ZUCAN** are included in this leaflet.

Should your general health worsen while receiving this medicine, please consult your doctor, pharmacist other healthcare professional for advice.

If any of the following happens, stop taking ZUCAN and tell your doctor immediately:

Less frequent: Serious allergic reaction, yellowing of the skin, rash, Stevens-Johnson Syndrome, Lyell's Syndrome, swelling of the hands; feet; ankles; face; lips; mouth or throat which may cause difficulty in swallowing or breathing

These are very serious side effects. If you have them, you may have had a serious allergic reaction to **ZUCAN**. You may need urgent medical attention.

Tell your doctor immediately if you notice any of the following:

Frequent: Liver damage, irritation and pain at the site of the injection

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Less frequent: shaking which may occur with fever, abnormal amount of uncontrolled muscular action, abnormal vision, liver failure, inflammation of the liver, liver failure/damage, prolonged QT intervals, torsades de pointes.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent: Headache, nausea, vomiting, abdominal pain, diarrhoea, flatulence, rash, a sensation of tingling (pins and needles)

Less frequent: Low white blood cell count, decrease in platelet count in the blood, flushing, low potassium concentrations in the blood, increased levels of cholesterol, increased concentration of lipids in the blood, dizziness, light-headedness, seizures, sleeplessness, nervousness, tiredness, distorted sense of taste, trouble digesting food, thirst, baldness, dry skin, abnormal odour, stiffness, thick whitish/yellowish vaginal discharge, increased frequency and volume of urination, female sexual dysfunction, intermenstrual bleeding, abnormally heavy or prolonged bleeding during menstrual period, feeling of discomfort or uneasiness, very low blood sugar levels

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORAGE AND DISPOSAL OF ZUCAN:

Do not use after the expiry date stated on the aluminium pouch. The expiry date refers to the last day of the month.

Store at or below 25 °C.

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Do not freeze.

Keep the bag in the aluminium pouch in order to protect from light

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN