PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

ASPEN FLUCONAZOLE IV

Infusion

Read all of this leaflet carefully before you are given ASPEN FLUCONAZOLE IV.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine 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.

WHAT ASPEN FLUCONAZOLE IV CONTAINS

Each 1 ml infusion of ASPEN FLUCONAZOLE IV contains 2 mg of fluconazole.

The other ingredients are sodium chloride and water for injection.

Sugar free

WHAT ASPEN FLUCONAZOLE IV IS USED FOR

- Infection of brain membranes and maintenance treatment to prevent relapse in patients with AIDS.

- Yeast infections in body and mouth/throat.
- Prevention of fungal infections in patients who are at risk of such infections as a result of chemotherapy and radiotherapy.

BEFORE RECEIVING ASPEN FLUCONAZOLE IV

You should not be given ASPEN FLUCONAZOLE IV if you are:

- Allergic to the medicine or related compounds.
- Breastfeeding.
- Pregnant.
- Using astemizole, cisapride or terfenadine; ASPEN FLUCONAZOLE IV should be avoided because of the risk of irregular heart beat.

Take special care with ASPEN FLUCONAZOLE IV

If you have any kidney, liver problems or alcohol abuse problems, make sure you tell your doctor. These conditions could affect the amount of ASPEN FLUCONAZOLE IV in your blood and therefore may increase your chances of side effects.

Receiving ASPEN FLUCONAZOLE IV with food

ASPEN FLUCONAZOLE IV may be taken with food or on an empty stomach.

Pregnancy and breastfeeding

Always tell your healthcare provider if you are taking any other medicine. If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before being given ASPEN FLUCONAZOLE IV.

This medicine should not be given during pregnancy. If you do become pregnant whilst being given this medication, contact your doctor. ASPEN FLUCONAZOLE IV passes into

breast milk, and therefore if this medication is to be given to you whilst you are breastfeeding, you should discuss it with your doctor first.

Driving and using machinery

ASPEN FLUCONAZOLE IV is not likely to affect your ability to drive or operate machines.

Using other medicines with ASPEN FLUCONAZOLE IV

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

- Rifampicin
- Hydrochlorothiazide
- Phenytoin, zidovudine, rifabutin, cyclosporin, warfarin and nortriptyline
- Theophylline
- Midazolam
- Cisapride
- Tacrolimus
- Terfenadine
- Effectiveness of oral contraceptives may be reduced

HOW TO RECEIVE ASPEN FLUCONAZOLE IV

ASPEN FLUCONAZOLE IV is an infusion. You will not be expected to give yourself ASPEN FLUCONAZOLE IV. It will be given to you by a person who is qualified to do so.

Recommended dosage of ASPEN FLUCONAZOLE IV:

Recommended dosage in adults

Infection of brain membranes (cryptococcal meningitis): the dose is 400 mg on the first day followed by 200 mg once daily. The dose may be increased to 400 mg depending on the patient's response. Treatment for cryptococcal meningitis is 6 to 8 weeks.

Prevention of relapse of cryptococcal disease in patients with AIDS: after the patient received a full course of the first treatment, 100 mg to 200 mg daily.

Systemic candidiasis (yeast infection): the dose is 400 mg on the first day followed by 200 mg daily. Dose, based on clinical response, may be increased to 400 mg daily.

Oropharyngeal (mouth and throat) candidiasis: usual dose is 50 mg to 100 mg once daily for 7 to 14 days, and if necessary, longer in patients with a poor immune system.

Prevention of relapse of oropharyngeal candidiasis in patients with AIDS: after the patient received a full course of first treatment, 150 mg once weekly.

Oesophageal candidiasis: recommended dose is 200 mg on the first day followed by 100 mg to 200 mg once daily. The dose may be increased to 400 mg/day depending on the patient's response. Patients should be treated for at least 3 weeks and for at least 2 weeks after symptoms have disappeared.

Prevention of candidiasis: 50 mg to 400 mg once daily, depending on the patients risk for developing fungal infection.

Recommended dosage in elderly

The dosage is the same as for adults, but the possibility of decreased liver and kidney function should be considered, in which case the dosage must be adjusted.

Recommended dosage in children

Cryptococcal infection and systemic candidiasis: the dose is 6 mg/kg/day to 12 mg/kg/day, depending on severity of disease.

Oropharyngeal candidiasis: usual dose is 6 mg/kg on the first day, followed by 3 mg/kg once daily. Treatment is given for at least 2 weeks to prevent relapse.

Oesophageal candidiasis: usual dose is 6 mg/kg on the first day, followed by 3 mg/kg once daily. Doses up to 12 mg/kg/day may be used depending on the patient's response. Patients should be treated for a minimum of 3 weeks and for at least 2 weeks after symptoms have disappeared.

Prevention of fungal infections in patients with a poor immune system, at risk as a result of too few white blood cells, following chemotherapy or radiotherapy: 3 mg/kg/day to 12 mg/kg/day, depending on how serious and for how long the patient has had too few white blood cells.

For children with decreased kidney function the daily dose should be reduced in accordance with the adult dose, depending on the degree of kidney damage.

Children 4 weeks of age and younger

ASPEN FLUCONAZOLE IV is excreted slowly by neonates.

1 to 2 weeks of age: same mg/kg dosing as in older children, but given every 72 hours.

3 to 4 weeks of age: same mg/kg dosing, but given every 48 hours.

If you have the impression that the effect of ASPEN FLUCONAZOLE IV is too strong or too weak, talk to your doctor or pharmacist.

ASPEN FLUCONAZOLE IV is for single use only. Discard any unused portion. The diluted solution is stable for 24 hours and should be stored between 18 °C and 24 °C.

If you receive more ASPEN FLUCONAZOLE IV than you should

You may experience unpleasant side effects.

Since a healthcare provider will administer this medicine, he/she will control the dosage. However, in the event of overdosage, your doctor will manage the overdosage.

If you missed a dose of ASPEN FLUCONAZOLE IV

Since a healthcare provider will administer this medicine, he/she will control the dosage. However, in the event of a missed dose, your doctor will manage the missed dose.

Effects when treatment with ASPEN FLUCONAZOLE IV is stopped

Your treatment with ASPEN FLUCONAZOLE IV will not be stopped unless instructed by your doctor.

POSSIBLE SIDE EFFECTS

ASPEN FLUCONAZOLE IV can have side effects.

NOTE: Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while receiving this medicine, please consult your healthcare provider for advice.

These are the most common and usually mild to moderate in nature:

- headache
- watery stools
- feeling sick
- stomach pain

This is usually a rare side effect and if it does develop check with your doctor immediately:

- skin reactions or allergies such as hives

STORING AND DISPOSING OF ASPEN FLUCONAZOLE IV

Store at or below 25 °C. Do not freeze.

Keep in original packaging until required for use.

Any unused portion of the solution must be discarded. The diluted solution is stable for 24 hours and should be stored between 18 °C and 24 °C.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF ASPEN FLUCONAZOLE IV

50 ml, 100 ml or 200 ml are packed in a transparent, colourless type I glass vial sealed with a grey, type I bromobutyl rubber stopper and a natural aluminium and polypropylene flip-off

cap. The vial is labelled with a self-adhesive label and placed into a cardboard unit carton together with a leaflet.

200 ml are packed in a transparent polyvinyl chloride plastic bag with a connecting tube sealed with a bisfenol A polycarbonate plastic stopper and a twist-off closure. The bag is packed in an outer metallic overwrap.

Not all packs and pack sizes are necessarily marketed.

IDENTIFICATION OF ASPEN FLUCONAZOLE IV

Transparent colourless solution free from visible particles.

REGISTRATION NUMBER

A39/20.2.2/0572

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

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