PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

ASPEN FLUCONAZOLE 50 mg

ASPEN FLUCONAZOLE 100 mg

ASPEN FLUCONAZOLE 150 mg

ASPEN FLUCONAZOLE 200 mg

Capsule

Read all of this leaflet carefully before you start taking ASPEN FLUCONAZOLE

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

WHAT ASPEN FLUCONAZOLE CONTAINS

The active substance is fluconazole

Each ASPEN FLUCONAZOLE 50 mg capsule contains 50 mg of fluconazole.

Each ASPEN FLUCONAZOLE 100 mg capsule contains 100 mg of fluconazole.

Each ASPEN FLUCONAZOLE 150 mg capsule contains 150 mg of fluconazole.

Each ASPEN FLUCONAZOLE 200 mg capsule contains 200 mg of fluconazole.

The other ingredients are:

ASPEN FLUCONAZOLE 50 mg contains colloidal silicon dioxide, FD&C Red 3 (C.I. 45430), gelatin, lactose monohydrate, magnesium stearate, Patent Blue V (C.I. 42051), pregelatinised starch, sodium lauryl sulphate, titanium dioxide (C.I. 77891).

Contains sugar: Lactose monohydrate 57,40 mg

ASPEN FLUCONAZOLE 100 mg and ASPEN FLUCONAZOLE 200 mg contain colloidal silicon dioxide, gelatin, lactose monohydrate, magnesium stearate, Patent Blue V (C.I. 42051), pregelatinised starch, sodium lauryl sulphate, titanium dioxide (C.I. 77891).

Contains sugar:

ASPEN FLUCONAZOLE 100 mg: Lactose monohydrate 114,80 mg

ASPEN FLUCONAZOLE 200 mg: Lactose monohydrate 229,60 mg

ASPEN FLUCONAZOLE 150 mg contains colloidal silicon dioxide, gelatin, lactose monohydrate, magnesium stearate, pregelatinised starch, sodium lauryl sulphate, titanium dioxide (C.I. 77891).

Contains sugar: Lactose monohydrate 172,20 mg

WHAT ASPEN FLUCONAZOLE IS USED FOR

ASPEN FLUCONAZOLE is used to treat fungal infections of the skin, hair, groin (jock itch), fingernails and toenails. It is also used to treat vaginal yeast infections caused by the species *Candida*.

BEFORE YOU TAKE ASPEN FLUCONAZOLE

It is important that the following information is read and understood. If you have any concerns or questions, ask your doctor, pharmacist or healthcare provider.

Do not take ASPEN FLUCONAZOLE

- If you are hypersensitive (allergic) to fluconazole or any of the other ingredients of ASPEN FLUCONAZOLE. If you have any allergies to food, preservatives or dyes, tell your doctor or pharmacist or healthcare provider.
- If you are pregnant or breastfeeding. ASPEN FLUCONAZOLE has not been tested in pregnant women and therefore should not be taken during pregnancy. If you do become pregnant while using this medication, contact your doctor. ASPEN FLUCONAZOLE passes into breast milk, and therefore if you wish to use this medication while you are breastfeeding, you should discuss it with your doctor first.
- If you are taking astemizole, terfenadine or cisapride.

Take special care with ASPEN FLUCONAZOLE

- If you have any kidney or liver problems, or alcohol abuse problems, make sure you tell your doctor. These conditions would affect the amount of ASPEN FLUCONAZOLE in your blood and therefore may increase your chances of side effects, or the medication might not have the proper effect. Tell the doctor if you suffer from achlorhydria (absence of stomach acid), or hypochlorhydria (decreased amount of stomach acid). These two conditions would decrease the amount of medicine in your blood.
- If ASPEN FLUCONAZOLE is given to children, as ASPEN FLUCONAZOLE has not been tested in children.
- If you are over the age of 60 as ASPEN FLUCONAZOLE has not been tested in the elderly. It is therefore unknown what effect age has in the way ASPEN FLUCONAZOLE is

broken down in the body. Should you develop any side effects when using this medication, or if you have any other illnesses, discuss it with your doctor, pharmacist or healthcare professional.

Taking ASPEN FLUCONAZOLE with food and drink

Do not drink any alcoholic beverages while you are on ASPEN FLUCONAZOLE, as it might cause liver problems.

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

Pregnancy and breastfeeding

You should not take ASPEN FLUCONAZOLE if you are pregnant or breastfeeding your baby (see Do not take ASPEN FLUCONAZOLE).

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 taking ASPEN FLUCONAZOLE.

Driving and using machinery

Since adverse reactions such as dizziness has been reported in patients receiving ASPEN FLUCONAZOLE, you should not drive, use machinery or perform any tasks that require concentration, until you are certain that ASPEN FLUCONAZOLE does not adversely affect your ability to do so (see POSSIBLE SIDE EFFECTS).

Important information about some of the ingredients in ASPEN FLUCONAZOLE

ASPEN FLUCONAZOLE contains lactose which may have an effect on your blood sugar if you have diabetes mellitus.

If you have the rare hereditary conditions of lactose or galactose intolerance you should not take ASPEN FLUCONAZOLE.

Taking other medicines with ASPEN FLUCONAZOLE

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 and rifabutin
- Ciclosporin
- Warfarin
- Antidiabetic agents
- Terfenadine
- Cisapride
- Astemizole
- Theophylline
- Oral contraceptives

HOW TO TAKE ASPEN FLUCONAZOLE

Always take ASPEN FLUCONAZOLE exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Do not share medicines prescribed for you with any other person.

The usual dose of ASPEN FLUCONAZOLE is:

Adults:

- Tinea cruris (ringworm of the groin; jock itch), Tinea corporis (ringworm of the body), Tinea pedis (ringworm of the foot; athletes foot) - 150 mg (one capsule) orally once weekly for 2 to 4 weeks. Duration of treatment may be longer depending on the severity and type of infection.
- Onchomycosis (fungal infection of the fingernail and toenail) - 150 mg (one capsule) once weekly until regrowth of new nail. Longer treatment for up to 6 months may be required for toenail infections, depending on the severity of the infection.
- Vaginal infections - 150 mg (one capsule) orally as a single dose.

Children:

- ASPEN FLUCONAZOLE has not been tested in children and therefore not recommended (see Do not take ASPEN FLUCONAZOLE).

For vaginal infections, symptom relief begins within 24 hours after taking the capsule.

Your doctor will tell you how long your treatment with ASPEN FLUCONAZOLE will last. Do not stop treatment early because different fungal infections takes different times to improve.

It is important that you take the medicine for the full time of treatment, for the medicine to be effective, even if your symptoms clear up or you begin to feel better.

The doctor may prescribe different doses for different patients. If your dose is different from that stated above, do not change it. Follow your doctor's instructions or the label instructions on the medicine. Your dose may be different if you are suffering from other illnesses as well.

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

If you take more ASPEN FLUCONAZOLE than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take a dose of ASPEN FLUCONAZOLE

Take your missed dose as soon as you remember, if within a few hours after missing a dose. Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE EFFECTS

ASPEN FLUCONAZOLE can have side effects.

Not all side effects reported for ASPEN FLUCONAZOLE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ASPEN FLUCONAZOLE, please consult your healthcare provider for advice.

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

- Headache
- Diarrhoea
- Nausea
- Abdominal pain

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

- Skin eruptions or allergies such as hives

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

STORING AND DISPOSING OF ASPEN FLUCONAZOLE

Store at or below 25 °C away from heat and direct light.

Keep in the original packaging until required for use.

Do not store in the bathroom, near the kitchen sink, or in other damp places, where heat and moisture may cause the medicine to break down.

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

ASPEN FLUCONAZOLE 50 mg:

14 capsules are packed in transparent polyvinyl chloride/polyvinylidene chloride or opaque polyvinyl chloride/ACLAR blister strips sealed with an aluminium foil backing. The blister strips are packed into a pre-printed unit cardboard carton together with a leaflet.

60 capsules are packed in a white cylindrical polypropylene securitainer sealed with a white cylindrical low-density polyethylene tamper evident Snap-On cap together with a white low-density polyethylene filler and a leaflet.

ASPEN FLUCONAZOLE 100 mg:

10 capsules are packed in colourless polyvinyl chloride/polyvinylidene chloride or transparent to opaque colourless polyvinyl chloride/ACLAR blister strips sealed with an aluminium foil backing. The blister strips are packed into a pre-printed unit cardboard carton together with a leaflet.

60 capsules are packed in a white cylindrical polypropylene container sealed with a white

cylindrical low-density polyethylene tamper evident Snap-On cap together with a white low-density polyethylene filler and a leaflet.

ASPEN FLUCONAZOLE 150 mg:

1 or 4 capsules are packed in transparent polyvinyl chloride/polyvinylidene chloride or opaque polyvinyl chloride/ACLAR blister strips sealed with an aluminium foil backing. The blister strips are packed into a pre-printed unit cardboard carton together with a leaflet.

60 capsules are packed in a white cylindrical polypropylene container sealed with a white cylindrical low-density polyethylene tamper evident Snap-On cap together with a white low-density polyethylene filler and a leaflet.

ASPEN FLUCONAZOLE 200 mg:

28 capsules are packed in transparent polyvinyl chloride/polyvinylidene chloride or opaque polyvinyl chloride/ACLAR blister strips sealed using an aluminium foil backing. The blister strips are packed into a pre-printed unit cardboard carton together with a leaflet.

60 capsules are packed in a white cylindrical polypropylene securitainer sealed with a white cylindrical low-density polyethylene tamper evident Snap-On cap together with a white low-density polyethylene filler and a leaflet.

Not all packs and pack sizes are necessarily marketed.

IDENTIFICATION OF ASPEN FLUCONAZOLE

ASPEN FLUCONAZOLE 50 mg:

A No. 4 capsule with a white opaque body and a dark blue cap containing a white to off-white powder.

ASPEN FLUCONAZOLE 100 mg:

A No. 2 capsule with a white opaque body and light blue cap containing a white to off-white powder.

ASPEN FLUCONAZOLE 150 mg:

A No. 1 capsule with a white opaque body and a white opaque cap containing a white to off-white powder.

ASPEN FLUCONAZOLE 200 mg:

A No. 0 capsule with a white opaque body and a blue cap containing a white to off-white powder.

REGISTRATION NUMBERS

ASPEN FLUCONAZOLE 50 mg: 37/20.2.2/0369

ASPEN FLUCONAZOLE 100 mg: 37/20.2.2/0370

ASPEN FLUCONAZOLE 150 mg: 37/20.2.2/0371

ASPEN FLUCONAZOLE 200 mg: 37/20.2.2/0372

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

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912 (South Africa)

Tel: +27 11 239 6200 (Other)

DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

Date of registration: 28 May 2004

Date of the most recently revised patient information leaflet as approved by the Authority:

28 May 2004

Botswana:	S2
ASPEN FLUCONAZOLE 50 mg:	BOT0801272
ASPEN FLUCONAZOLE 150 mg:	BOT0801274
ASPEN FLUCONAZOLE 200 mg:	BOT0801273

Namibia:	NS2
ASPEN FLUCONAZOLE 50 mg:	10/20.2.2/0523
ASPEN FLUCONAZOLE 150 mg:	10/20.2.2/0524
ASPEN FLUCONAZOLE 200 mg:	10/20.2.2/0525

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