IRISH MEDICINES BOARD ACT 1995, as amended

Medicinal Products (Control of Placing on the Market) Regulations, 2007, as amended

PA0237/064/001
Case No: 2087402

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Transferred from PA0585/015/001.

Teva UK Limited

Brampton Road, Hampden Park, **Eastbourne**, **East Sussex BN22 9AG**, **United Kingdom**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Fluconazole 2 mg/ml Solution for Infusion

the particulars of which are set out in the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **13/08/2010**.

Signed on behalf of the Irish Medicines Board this

_____

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Fluconazole 2mg/ml Solution for Infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Fluconazole 2mg per ml.
Each 25ml vial contains 50mg fluconazole.
Each 50ml vial contains 100mg fluconazole.
Each 100ml vial contains 200mg fluconazole.

Also contains: sodium 3.8 mmol per 25ml vial, 7.6 mmol per 50 ml vial and 15.2 mmol per 100 ml vial.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for Infusion.

Fluconazole 2mg/ml Solution for Infusion is a clear colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Therapy may be started before the results of the cultures and other laboratory studies are known; however, once results become available, anti-infective therapy should be adjusted accordingly.

Fluconazole is indicated for the treatment of the following conditions:

1. Genital candidiasis. Vaginal candidiasis, acute or recurrent. Candidal balanitis. The treatment of partners who present with symptomatic genital candidiasis should be considered.

2. Mucosal candidiasis. These include oropharyngeal, oesophageal, non-invasive bronchopulmonary infections, candiduria, mucocutaneous and chronic oral atrophic candidiasis (denture sore mouth). Normal hosts and patients with compromised immune function may be treated.

3. Tinea pedis, tinea corporis, tinea cruris, tinea versicolor and dermal *Candida* infections. Fluconazole is not indicated for nail infections.

4. Systemic candidiasis including candidaemia, disseminated candidiasis and other forms of invasive candidal infection. These include infections of the peritoneum, endocardium and pulmonary and urinary tracts. Candidal infections in patients with malignancy, in intensive care units or those receiving cytotoxic or immunosuppressive therapy may be treated.

5. Cryptococcosis, including cryptococcal meningitis and infections of other sites (e.g. pulmonary, cutaneous). Normal hosts, and patients with AIDS, organ transplants or other causes of immunosuppression may be treated. Fluconazole can be used as maintenance therapy to prevent relapse of cryptococcal disease in patients with AIDS.

6. For the prevention of fungal infections in immunocompromised patients considered at risk as a consequence of neutropenia following cytotoxic chemotherapy or radiotherapy, including bone marrow transplant patients.

4.2 Posology and method of administration

Fluconazole may be administered either orally (as capsules or suspension), or by intravenous infusion at a rate of approximately 5-10ml/min, the route being dependent on the clinical state of the patient. On transferring from the intravenous route to the oral route or vice versa, there is no need to change the daily dose.

The daily dose of fluconazole should be based on the nature and severity of the fungal infection. Most cases of vaginal candidiasis respond to single dose therapy. Therapy for those types of infections requiring multiple dose treatment should be continued until clinical parameters or laboratory tests indicate that active fungal infection has subsided. An inadequate period of treatment may lead to the recurrence of active infection. Patients with AIDS and cryptococcal meningitis usually require maintenance therapy to prevent relapse.

Adults

1. Candidal vaginitis or balanitis – 150 mg single oral dose.

2. Mucosal candidiasis – the usual dose is 50 mg once daily for 7 – 14 days. Treatment should not normally exceed 14 days except in severely immunocompromised patients.

Atrophic oral candidiasis associated with dentures – the usual dose is 50 mg once daily for 14 days administered concurrently with local antiseptic measures to the denture.

For other candidal infections of mucosa (except genital candidiasis see above), e.g. oesophagitis, non-invasive bronchopulmonary infections, candiduria, mucocutaneous candidiasis etc., the usual effective dose is 50 mg daily, given for 14 – 30 days.

In unusually difficult cases of mucosal candidal infections the dose may be increased to 100 mg daily.

3. For tinea pedis, corporis, cruris, versicolor and dermal candidal infections the recommended dosage is 50 mg once daily. Duration of treatment is normally 2 to 4 weeks but tinea pedis may require treatment for up to 6 weeks. Duration of treatment should not exceed 6 weeks.

4. For candidaemia, disseminated candidiasis and other invasive candidal infections the usual dose is 400 mg on the first day followed by 200 mg daily. Depending on the clinical response the dose may be increased to 400 mg daily. Duration of treatment is based upon the clinical response.

5a For cryptococcal meningitis and cryptococcal infections at other sites, the usual dose is 400 mg on the first day followed by 200 – 400 mg once daily. Duration of treatment for cryptococcal infections will depend on the clinical and mycological response, but is usually at least 6 – 8 weeks for cryptococcal meningitis.

5b For the prevention of relapse of cryptococcal meningitis in patients with AIDS, after the patient receives a full course of primary therapy, fluconazole may be administered indefinitely at a daily dose of 100 – 200 mg.

6 For the prevention of fungal infections in immunocompromised patients considered at risk as a consequence of neutropenia following cytotoxic chemotherapy or radiotherapy, the dose should be 50 to 400 mg once daily, based on the patient's risk for developing fungal infection. For patients at high risk of systemic infection e.g. patients who are anticipated to have profound or prolonged neutropenia such as during bone marrow transplantation, the recommended dose is 400 mg once daily. Fluconazole administration should start several days before the anticipated onset of neutropenia, and continue for 7 days after the neutrophil count rises above 1000 cells per mm

Children

As with similar infections in adults, the duration of treatment is based on the clinical and mycological response. Fluconazole is administered as a single daily dose each day.

Children over four weeks of age The recommended dose of fluconazole for mucosal candidiasis is 3 mg/kg daily. A loading dose of 6 mg/kg may be used on the first day to achieve steady state levels more rapidly.

For the treatment of systemic candidiasis and cryptococcal infection, the recommended dosage is 6 – 12 mg/kg daily, depending on the severity of the disease.

For the prevention of fungal infections in immunocompromised patients considered at risk as a consequence of neutropenia following cytotoxic chemotherapy or radiotherapy, the dose should be 3 – 12 mg/kg daily, depending on the extent and duration of the induced neutropenia (see adult dosing).

A maximum dosage of 400 mg daily should not be exceeded in children.

Despite extensive data supporting the use of fluconazole in children there are limited data available on the use of fluconazole for genital candidiasis in children below 16 years. Use at present is not recommended unless antifungal treatment is imperative and no suitable alternative agent exists.

Children four weeks of age and younger Neonates excrete fluconazole slowly. In the first two weeks of life the same mg/kg dosing as in older children should be used but administered every 72 hours. During the third and fourth weeks of life the same dose should be given every 48 hours.

A maximum dosage of 12 mg/kg every 72 hours should not be exceeded in children below two weeks of life. For children between 2 – 4 weeks of life 12 mg/kg every 48 hours should not be exceeded.

For children with impaired renal function the daily dose should be reduced in accordance with the guidelines given for adults.

To facilitate accurate measurement of doses less than 10 mg, fluconazole should only be administered to children in hospital using preparations available as oral suspension or intravenous infusion, depending on the clinical condition of the child.

Elderly
The normal dose should be used if there is no evidence of renal impairment. In patients with renal impairment (creatinine clearance less than 50 ml/min) the dosage schedule should be adjusted as described below.

Use in patients with impaired renal function
Fluconazole is excreted predominantly in the urine as unchanged drug. No adjustments in single dose therapy are required. In patients with impaired renal function who will receive multiple doses of fluconazole, the normal recommended dose (according to indication) should be given on day 1, followed by a daily dose based on the following table:

Creatinine clearance (ml/min)	*Percent of recommended dose*
> 50	100 %
≤50 (no dialysis)	50 %
Regular dialysis	100% after each dialysis.

4.3 Contraindications

Fluconazole should not be used in patients with known hypersensitivity to fluconazole or to related azole compounds or to any other ingredient within the formulation *(see section 6.1.)*.

Co-administration with terfenadine or cisapride is contra-indicated in patients receiving fluconazole. *See 'Interactions with other medicinal products and other forms of interaction'*.

4.4 Special warnings and precautions for use

In some patients, especially those with serious underlying diseases such as AIDS and cancer, abnormalities in haematological, hepatic, renal and other biochemical function test results have been observed during treatment with fluconazole but the clinical significance and relationship to treatment is uncertain.

Very rarely, patients who died with severe underlying disease and who had received multiple doses of fluconazole had post-mortem finding which included hepatic necrosis.

These patients were receiving multiple concomitant medications, some known to be potentially hepatotoxic, and/ or had underlying diseases which could have caused the hepatic necrosis.

In cases of hepatotoxicity, no obvious relationship to total daily dose of fluconazole, duration of therapy, sex or age of the patient has been observed; the abnormalities have usually been reversible on discontinuation of fluconazole therapy.

Since a causal relationship with fluconazole cannot be excluded, patients who develop abnormal liver function tests during fluconazole therapy should be monitored for the development of more serious hepatic damage. Fluconazole should be discontinued if clinical signs or symptoms consistent with liver disease develop during treatment with fluconazole.

Patients have occasionally developed exfoliative cutaneous reactions, such as Stevens-Johnson Syndrome and toxic epidermal necrolysis, during treatment with fluconazole. AIDS patients are more prone to the development of more severe cutaneous reactions to many drugs.

If a rash develops in a patient treated for a superficial fungal infection which may be attributed to fluconazole, further therapy with this agent should be discontinued. If patients with invasive/ systemic fungal infections develop rashes, they should be monitored closely and fluconazole discontinued if bullous lesions or erythema multiforme develop.

In rare cases, as with other azoles, anaphylaxis has been reported.

This medicinal product contains 3.8 mmol of sodium per 25 ml vial, 7.6 mmol per 50 ml vial and 15.2 mmol per 100ml vial. This should be taken into consideration by patients on a sodium controlled diet.

4.5 Interaction with other medicinal products and other forms of interaction

The following drug interactions relate to the use of multiple-dose fluconazole, and the relevance to single-dose fluconazole has not yet been established:

Anticoagulants In an interaction study, fluconazole increased the prothrombin time (12%) after warfarin administration in healthy males. In post-marketing experience, as with other azole antifungals, bleeding events (bruising, epistaxis, gastrointestinal bleeding, haematuria and melaena) have been reported in association with increases in prothrombin time in patients receiving fluconazole concurrently with warfarin. Prothrombin time in patients receiving coumarin-type anticoagulants should be carefully monitored.

Benzodiazepines (Short acting) Following oral administration of midazolam, fluconazole resulted in substantial increases in midazolam concentrations and psychomotor effects. This effect on midazolam appears to be more pronounced following oral administration of fluconazole than with fluconazole administered intravenously. If concomitant benzodiazepine therapy is necessary in patients being treated with fluconazole, consideration should be given to decreasing the benzodiazepine dosage and the patients should be appropriately monitored.

Sulphonylureas Fluconazole has been shown to prolong the serum half-life of concomitantly administered oral sulphonylureas (chlorpropamide, glibenclamide, glipizide and tolbutamide) in healthy volunteers. Fluconazole and oral sulphonylureas may be co-administered to diabetic patients, but the possibility of a hypoglycaemic episode should be borne in mind.

Hydrochlorothiazide In a kinetic interaction study, co-administration of multiple-dose hydrochlorothiazide to healthy volunteers receiving fluconazole increased plasma concentrations of fluconazole by 40%. An effect of this magnitude should not necessitate a change in the fluconazole dose regimen in subjects receiving concomitant diuretics, although the prescriber should bear it in mind.

Phenytoin Concomitant administration of fluconazole and phenytoin may increase the levels of phenytoin to a clinically significant degree. If it is necessary to administer both drugs concomitantly, phenytoin levels should be monitored and the phenytoin dose adjusted to maintain therapeutic levels.

Oral contraceptives Two kinetic studies with combined oral contraceptives have been performed using multiple doses of fluconazole. There were no relevant effects on either hormone level in the 50 mg fluconazole study, while at 200 mg daily the AUCs of ethinylestradiol and levonorgestrel were increased 40% and 24% respectively. Thus multiple dose use of fluconazole at these levels is unlikely to have an effect on the efficacy of the combined oral contraceptive.

Rifampicin Concomitant administration of fluconazole and rifampicin resulted in a 25% decrease in the AUC and 20% shorter half-life of fluconazole. In patients receiving concomitant rifampicin, an increase in the fluconazole dose should be considered.

Endogenous steroid Fluconazole 50mg daily does not affect endogenous steroid levels in females: 200 – 400 mg daily has no clinically significant effect on endogenous steroid levels or on ACTH stimulated response in healthy male volunteers.

Ciclosporin A kinetic study in renal transplant patients found fluconazole 200 mg daily to slowly increase ciclosporin concentrations. However, in another multiple dose study with 100 mg daily, fluconazole did not affect ciclosporin levels in patients with bone marrow transplants. Ciclosporin plasma concentration monitoring in patients receiving fluconazole is recommended.

Theophylline In a placebo controlled interaction study, the administration of fluconazole 200 mg for 14 days resulted in an 18 % decrease in the mean plasma clearance of theophylline. Patients who are receiving high doses of theophylline or who are otherwise at increased risk for theophylline toxicity should be observed for signs of theophylline toxicity while receiving fluconazole, and the therapy modified if signs of toxicity develop.

Terfenadine Because of the occurrence of serious dysrhythmias secondary to prolongation of the QTc interval in patients receiving other azole antifungals in conjunction with terfenadine, interaction studies have been performed. One study at a daily dose of 200 mg of fluconazole failed to demonstrate a prolonged QTc interval. Another study at a 400 mg and 800 mg daily dose of fluconazole demonstrated that fluconazole taken in multiple doses of 400 mg per day or greater did significantly increase plasma levels of terfenadine when taken concomitantly.

There have been spontaneously reported cases of palpitations, tachycardia, dizziness, and chest pain in patients taking concomitant fluconazole and terfenadine where the relationship of the reported adverse events to drug therapy or underlying medical conditions was unclear. Because of the potential seriousness of such an interaction, it is recommended that terfenadine should not be taken in combination with fluconazole. *See 'Contraindications'*.

Cisapride There have been reports of cardiac events including torsade de pointes in patients to whom fluconazole and cisapride were co-administered. In most of these cases, the patients appear to have been predisposed to arrhythmias or had serious underlying illnesses, and the relationship of the reported events to a possible fluconazole-cisapride drug interaction is unclear. Because of the potential seriousness of such an interaction, co-administration of cisapride is contra-indicated in patients receiving fluconazole. *(See 'Contraindications'.)*

Zidovudine Two kinetic studies resulted in increased levels of zidovudine most likely caused by the decreased conversion of zidovudine to its major metabolite. One study determined zidovudine levels in AIDS or ARC patients before and following fluconazole 200 mg daily for 15 days. There was a significant increase in zidovudine AUC (20 %). A second randomised, two-period, two-treatment cross-over study examined zidovudine levels in HIV infected patients. On two occasions, 21 days apart, patients received zidovudine 200 mg every eight hours either with or without fluconazole 400 mg daily for seven days. The AUC of zidovudine significantly increased (74 %) during co-administration with fluconazole. Patients receiving this combination should be monitored for the development of zidovudine-related adverse reactions.

Rifabutin There have been reports that an interaction exists when fluconazole is administered with rifabutin, leading to increased serum levels of rifabutin. There have been reports of uveitis in patients to whom fluconazole and rifabutin were co-administered. Patients receiving the two concomitantly should be carefully monitored.

Tacrolimus There have been reports of an interaction when fluconazole is given concomitantly with tacrolimus, leading to increased serum levels of tacrolimus. There have been reports of nephrotoxicity in patients to whom fluconazole and tacrolimus were co-administered. Patients receiving the two concomitantly should be carefully monitored.

The use of fluconazole in patients concurrently taking astemizole, rifabutin, tacrolimus, or other drugs metabolised by the cytochrome P450 system may be associated with elevations in serum levels of these drugs. In the absence of definitive information, caution should be used when co-administering fluconazole. Patients should be carefully monitored.

Interaction studies have shown that when oral fluconazole is co-administered with food, cimetidine, antacids or following total body irradiation for bone marrow transplantation, no clinically significant impairment of fluconazole absorption occurs.

Physicians should be aware that drug-drug interaction studies with other medications have not been conducted, but that such interactions may occur.

4.6 Pregnancy and lactation

Use during pregnancy:
There are no adequate and well controlled studies in pregnant women. There have been reports of multiple congenital abnormalities in infants whose mothers were being treated for 3 or more months with high dose (400 – 800 mg/ day) fluconazole therapy for coccidioidomycosis. The relationship between fluconazole and these events isunclear. Accordingly, fluconazole capsules should not be used in pregnancy or in women of childbearing potential, unless adequate contraception is employed.

Use during lactation:
Fluconazole is found in human breast milk at concentrations similar to plasma, hence its use in nursing mothers is not recommended.

4.7 Effects on ability to drive and use machines

Experience with fluconazole indicates that therapy is unlikely to impair a patient’s ability to drive or use machinery.

4.8 Undesirable effects

Fluconazole is generally well tolerated. The most common side effects observed during clinical trials and associated with fluconazole are:

Nervous System Disorders: Headache.

Skin and Subcutaneous Tissue Disorders: Rash.

Gastrointestinal Disorders: Abdominal pain, diarrhoea, flatulence, nausea.

In some patients, particularly those with serious underlying diseases such as AIDS and cancer, changes in renal and haematological function test results and hepatic abnormalities have been observed during treatment with fluconazole and comparative agents, but the clinical significance and relationship to treatment is uncertain *(see 4.4 Special warnings and special precautions for use).*

Hepatobiliary Disorders: Hepatic toxicity including rare cases of fatalities, elevated alkaline phosphatase, elevated bilirubin, elevated SGOT, elevated SGPT.

In addition, the following undesirable effects have occurred during post- marketing:

Nervous System Disorders: Dizziness, seizures, taste perversion.

Skin and Subcutaneous Tissue Disorders: Alopecia, exfoliative skin disorders including Stevens-Johnson syndrome and toxic epidermal necrolysis.

Gastrointestinal Disorders: Dyspepsia, vomiting.

Blood and Lymphatic Disorders: Leukopenia including neutropenia and agranulocytosis, thrombocytopenia.

Immune System Disorders:Allergic reaction: anaphylaxis (including angio-oedema, face oedema, pruritus), urticaria.

Hepatobiliary Disorders: Hepatic failure, hepatitis, hepatocellular necrosis, jaundice.

Metabolism and Nutrition Disorders: Hypercholesterolaemia, hypertriglyceridaemia, hypokalaemia.

4.9 Overdose

There has been a reported case of overdosage with fluconazole. A 42 year old patient infected with HIV developed hallucinations and exhibited paranoid behaviour after reportedly ingesting 8200 mg of fluconazole, unverified by his physician. The patient was hospitalised and his condition resolved within 48 hours.

In the event of overdosage, supportive measures and symptomatic treatment, with gastric lavage if necessary, may be adequate.

As fluconazole is largely excreted in the urine, forced volume diuresis would probably increase the elimination rate. A three hour haemodialysis session decreases plasma levels by approximately 50 %.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Triazole derivatives, ATC code: J02A C01

Fluconazole, a member of the triazole class of antifungal agents, is a potent and selective inhibitor of fungal enzymes necessary for the synthesis of ergosterol.

Fluconazole shows little pharmacological activity in a wide range of animal studies. Some prolongation of pentobarbital sleeping times in mice (p.o.), increased mean arterial and left ventricular blood pressure and increased heart rate in anaesthetised cats (i.v.) occurred. Inhibition of rat ovarian aromatase was observed at high concentrations.

Fluconazole is highly specific for fungal cytochrome P-450 dependent enzymes. Fluconazole 50mg daily given for up to 28 days has been shown not to affect testosterone plasma concentrations in males or steroid concentrations in females of child-bearing age. Fluconazole 200-400mg daily has no clinically significant effect on endogenous steroid levels or on ACTH stimulated response in healthy male volunteers. Interaction studies with antipyrine indicate that single or multiple doses of fluconazole 50mg do not affect its metabolism.

There have been reports of cases of superinfection with *Candida* species other than *C. albicans*, which are often inherently not susceptible to fluconazole (e.g. *Candida krusei*). Such cases may require alternative antifungal therapy.

5.2 Pharmacokinetic properties

The pharmacokinetic properties of fluconazole are similar following administration by the intravenous or oral route. After oral administration fluconazole is well absorbed and plasma levels (and systemic bioavailability) are over 90% of the levels achieved after intravenous administration. Oral administration is not affected by concomitant food intake. Peak plasma concentrations in the fasting state occur between 0.5 – 1.5 hours post-dose with a plasma elimination half-life of approximately 30 hours. Plasma concentrations are proportional to dose. Ninety percent steady-state levels are reached by day 4 – 5 with multiple once daily dosing.

The administration of a higher dose on the first day, double that of the normal daily dose, raises plasma levels to approximate to 90% steady-state levels by the second day.

The apparent volume of distribution approximates to total body water. Fluconazole achieves good penetration in all body fluids studied. The levels of fluconazole in saliva and sputum are similar to plasma levels. In patients with fungal meningitis, fluconazole levels in the CSF are approximately 80% of the corresponding plasma levels. High skin concentrations of fluconazole, above serum concentrations, are achieved in the stratum corneum, epidermis-dermis and eccrine sweat. Fluconazole accumulates in the stratum corneum. Plasma protein binding is low (11-12%).

The major route of excretion is renal, with approximately 80% of the administered dose appearing in the urine as unchanged drug. Fluconazole clearance is proportional to creatinine clearance. There is no evidence of circulating metabolites.

Its long clearance plasma elimination half-life makes it possible to administer a single dose in the treatment of genital candidiasis and a daily dose in the treatment of other indications.

5.3 Preclinical safety data

Reproductive toxicity Increases in foetal anatomical variants (supernumerary ribs, renal pelvis dilation) and delays in ossification were observed at 25 and 50 mg/kg and higher doses. At doses from 80 mg/kg to 320 mg/kg embryolethality in rats was increased and foetal abnormalities included wavy ribs, cleft palate and abnormal cranio-facial ossification.

Carcinogenesis Fluconazole showed no evidence of carcinogenic potential in mice and rats treated orally for 24 months at doses of 2.5, 5 or 10 mg/kg/day. Male rats treated with 5 and 10mg/kg/day had an increased incidence of hepatocellular adenomas.

Mutagenesis Fluconazole, with or without metabolic activation, was negative in tests for mutagenicity in 4 strains of *S. typhimurium* and in the mouse lymphoma L5178Y system. Cytogenetic studies *in vivo* (murine bone marrow cells, following oral administration of fluconazole) and *in vitro* (human lymphocytes exposed to fluconazole at 1000 µg/ml) showed no evidence of chromosomal mutations.

Impairment of fertility Fluconazole did not affect the fertility of male or female rats treated orally with daily doses of 5, 10 or 20 mg/kg or with parenteral doses of 5, 25 or 75 mg/kg, although the onset of parturition was slightly delayed at 20 mg/kg p.o. In an intravenous perinatal study in rats at 5, 20 and 40 mg/kg, dystocia and prolongation of parturition were observed in a few dams at 20 mg/kg and 40 mg/kg, but not at 5 mg/kg. The disturbances in parturition were reflected by a slight increase in the number of still-born pups and decrease of neonatal survival at these doses. The effects on parturition in rats are consistent with the species specific oestrogen-lowering property produced by high doses of fluconazole. Such a hormone change has not been observed in women treated with fluconazole.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections
Sodium chloride
Hydrochloric acid (for pH adjustment)
Sodium hydroxide (for pH adjustment)

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in *section 6.6.*

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Type I glass vials: 25ml, 50ml and 100ml.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

For single use only. Discard any remaining solution.

Although further dilution is unnecessary, fluconazole intravenous infusion is compatible with the following administration fluids:

a. Dextrose 20%
b. Ringer’s solution
c. Hartmann’s solution
d. Potassium chloride in dextrose
e. Sodium bicarbonate 4.2%
f. Normal saline (0.9%)

Recommended method of administration:
Fluconazole intravenous infusion does not require dilution prior to administration. If necessary, the solution may be infused through an existing administration set containing one of the compatible fluids listed above using a suitable ‘Y’ connection. Mixing with other drugs prior to infusion is not recommended.

Fluconazole intravenous infusion may be infused through an existing line with one of the above listed fluids. No specific incompatibilities have been noted, although mixing with any other drug prior to infusion is not recommended.

7 MARKETING AUTHORISATION HOLDER

Teva UK Limited
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Eastbourne
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8 MARKETING AUTHORISATION NUMBER

PA 0237/064/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8 October 2004
Date of last renewal: 13 March 2008

10 DATE OF REVISION OF THE TEXT

August 2010