Fluconazol Injection, USP in INTRAVIA Plastic Container

**DESCRIPTION**
Fluconazol is the first of a new subclass of synthetic triazole antifungal agents, available as a sterile solution for intravenous use in INTRAVIA plastic container.

**Pharmacokinetics in Children**

<table>
<thead>
<tr>
<th>Age Studied</th>
<th>Single-Oral</th>
<th>Single-IV</th>
<th>Hours</th>
<th>Cmax (μg/mL)</th>
<th>Vdss (L/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>9 Months - 13 years</td>
<td>0.40 (38%)</td>
<td>0.51 (60%)</td>
<td>19.5</td>
<td>2.9 (22%)</td>
<td>91 (10%)</td>
</tr>
<tr>
<td>9 Months - 13 years</td>
<td>0.51 (60%)</td>
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<td>19.5</td>
<td>2.9 (22%)</td>
<td>91 (10%)</td>
</tr>
<tr>
<td>5 - 15 years</td>
<td>0.49 (40%)</td>
<td>0.59 (64%)</td>
<td>15.2</td>
<td>1.0 (8%)</td>
<td>43 (19%)</td>
</tr>
<tr>
<td>5 - 15 years</td>
<td>0.59 (64%)</td>
<td>0.66 (31%)</td>
<td>17.6</td>
<td>1.1 (8%)</td>
<td>43 (19%)</td>
</tr>
</tbody>
</table>

**Clearance corrected for body weight was not affected by age in these studies. Mean body clearance in adults is reported to be 0.23 (17%) mL/min/kg**

**PRECAUTIONS**

**Drug Interaction Studies**

Oral contraceptives: Oral contraceptives were administered as a single dose both before and after the oral administration of fluconazol 50 mg once daily for 10 days in 10 healthy women. There was no significant difference in ethinyl estradiol or levonorgestrel AUC after the administration of fluconazol 50 mg of fluconazol. The mean increase in ethinyl estradiol AUC was 12% (range: -47 to 108%) and levonorgestrel AUC increased 17% (range: -13 to 141%).

A second study evaluated the potential interaction of once weekly dosing of fluconazol 300 mg to 21 normal female volunteers. A pharmacokinetic study was conducted in 22 subjects, 65 years of age or older to receive 50 mg of fluconazol.
Cyclopertine: Cyclopertine AUC and Cmax were determined before and after the administration of fluconazole 200 mg daily for 14 days in eight renal transplant patients who had been on cyclopertine therapy for at least 6 months and in a stable cyclopertine dose for at least 6 weeks. There was a significant increase in cyclopertine AUC, Cmax, Cmin (24-hour concentration), and a significant reduction in apparent oral clearance following the administration of fluconazole 200 mg. The mean ± SD increase in AUC was 92% ± 43% (range: 18 to 274%); in Cmax, 157% ± 36% (range: 33 to 360%); the apparent oral clearance decreased 45% ± 15% (range: 15 to 60%). (See PRECAUTIONS.)

Zidovudine: Plasma steady-state concentrations were determined on two occasions (before and after fluconazole 200 mg daily for 15 days) in 13 volunteers with AIDS or ARC who were on a stable zidovudine dose for at least two weeks. There was a significant increase in zidovudine AUC following the administration of fluconazole. The mean ± SD increase in AUC was 20% ± 32% (range: -27 to 194%). The metabolite, G2VZ, was not parent drug ratio significantly decreased after the administration of fluconazole, from 7.6 ± 3.5 to 2.2 ± 4.5. (See PRECAUTIONS.)

Therapeutic: Six healthy volunteers received terfenadine 60 mg BID for 15 days. Fluconazole 200 mg was administered daily from days 9 through 15. Fluconazole did not affect terfenadine plasma concentrations. Terfenadine AUC increased by 53% (range: 18% to 170%) with concomitant administration of fluconazole. There was no change in cardiac repolarization as measured by Holter QT intervals. Another study at a 400-mg and 800-mg daily dose of fluconazole demonstrated that fluconazole taken in doses of 400 mg per day or greater significantly increases plasma levels of terfenadine when taken concomitantly. (See CONTRAINDICATIONS and PRECAUTIONS.)

Drug Interactions: Effects of fluconazole on the pharmacokinetics of the sulfonylurea oral hypoglycemic agents tolbutamide, glipizide, and glibenclamide were evaluated in three placebo-controlled studies in normal volunteers. All subjects received the sulfonylurea alone as a single dose and again as a single dose following the administration of fluconazole 100 mg daily for 7 days. In these three studies 22/24 (76%) of subjects treated with and 9/22 (40.1%) of placebo treated patients experienced symptoms consistent with hypoglycemia. (See PRECAUTIONS.)

In normal volunteers, there were significant increases in tolbutamide (500 mg single dose) AUC and Cmax following the administration of fluconazole. There was a mean ± SD increase in tolbutamide AUC of 26% ± 8% (range: 12 to 39%). Tolbutamide Cmax increased 11% ± 9% (range: -6 to 27%) following administration of fluconazole. (See PRECAUTIONS.)

Glipizide: The AUC and Cmax of glipizide (2.5 mg single dose) were significantly increased following the administration of fluconazole in 13 normal male volunteers. There was a mean ± SD increase in AUC of 44% ± 29% (range: -13 to 115%) and Cmax increased 19% ± 19% (range: -23 to 62%). Five subjects required oral glucose feeding following the ingestion of glipizide after 7 days of fluconazole administration. (See PRECAUTIONS.)

Rifabutin: There have been published reports that an interaction exists when fluconazole is administered concomitantly with rifabutin, leading to increased serum levels of rifabutin. (See PRECAUTIONS.)

Tacrolimus: There have been published reports that an interaction exists when fluconazole is administered concomitantly with tacrolimus, leading to increased serum levels of tacrolimus. (See PRECAUTIONS.)

Disulfani: In an open-label, placebo-controlled, randomized, double-blind study of 24 C. albicans meningitis patients treated with a 300 mg dose of fluconazole with cisapride. Two groups of 10 normal subjects were administered fluconazole 200 mg daily or placebo. Cisapride 20 mg four times daily was started after 7 days of fluconazole or placebo dosing. Following a single dose of fluconazole, there was a 101% increase in the cisapride AUC and a 154% increase in the cisapride Cmax. Fluconazole significantly increased the QT interval in subjects receiving cisapride by 50 to 60 ms daily from day 1 to 15. In subjects not receiving cisapride, there was a 25 ms increase in QT interval from day 1 to 15. (See PRECAUTIONS.)

Midazolam: The effect of fluconazole on the pharmacokinetics and pharmacodynamics of midazolam was examined in a randomized, cross-over study in 12 volunteers. In the study, subjects ingested placebo or 400 mg of fluconazole on Day 1. On Days 3 and 5, subjects received placebo, and on Day 7, 8, and 9, subjects received 200 mg of fluconazole in a single dose. Prior to fluconazole ingestion, the first dose of midazolam was orally ingested on the first day, 0.05 mg/kg was administered intravenously on the fourth day, and 7.5 mg orally on the fifth day. Following single doses of fluconazole, there was an 11% increase in the midazolam AUC and Cmax by 25% and 150%, respectively. On the fifth day of dosing, fluconazole increased the midazolam AUC and Cmax by 25% and 74%, respectively. The psychomotor effects of midazolam were significantly increased after oral administration of midazolam but not significantly affected following intravenous midazolam. A second randomized, double-blind, placebo-controlled, cross-over study in three phases was performed to determine the effect of fluconazole on the pharmacokinetics of midazolam. In phase 1, each subject was given oral midazolam 400 mg and intravenous saline; oral placebo and intravenous fluconazole in phase 2, and oral fluconazole and intravenous saline in phase 3. Oral fluconazole was administered after the clearance of IV midazolam by 51%. On Day 8, following oral dosing, fluconazole increased the midazolam AUC and Cmax by 25% and 150%, respectively. On the sixth day of dosing, fluconazole increased the midazolam AUC and Cmax by 25% and 74%, respectively. The psychomotor effects of midazolam were significantly increased after oral administration of midazolam but not significantly affected following intravenous midazolam.

Drug Interactions: Mechanism of Action

Fluconazole is a highly selective fungal cytochrome P-450 dependent lanosterol 14α-demethylase. The enzyme is responsible for the conversion of lanosterol (a normal sterol) to ergosterol, an essential fungal sterol. Fluconazole inhibits the enzyme competitively with a Ki of 131 μM. The Ki for 14α-demethylase, reduced access to the drug target, or some combination of these mechanisms.

Cyclosporine: Cyclosporine AUC and Cmax were determined before and after the administration of fluconazole 100 mg daily for 7 days. In these three studies 22/46 (47.8%) of fluconazole treated patients and 9/22 (40.1%) of placebo treated patients experienced symptoms consistent with hypoglycemia. (See PRECAUTIONS.)

Conclusion: In normal volunteers, there were significant increases in tolbutamide (500 mg single dose) AUC and Cmax following the administration of fluconazole. There was a mean ± SD increase in tolbutamide AUC of 26% ± 8% (range: 12 to 39%). Tolbutamide Cmax increased 11% ± 9% (range: -6 to 27%) following administration of fluconazole. (See PRECAUTIONS.)

Glipizide: The AUC and Cmax of glipizide (5 mg single dose) were significantly increased following the administration of fluconazole in 20 normal male volunteers. There was a mean ± SD increase in AUC of 44% ± 29% (range: -13 to 115%) and Cmax increased 19% ± 19% (range: -23 to 62%). Five subjects required oral glucose feeding following the ingestion of glipizide after 7 days of fluconazole administration. (See PRECAUTIONS.)

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**Pediatric Studies**

Oral cryptococcal candidiasis: An open-label, comparative study of the efficacy and safety of fluconazole (2-3 mg/kg/day) and oral nystatin (400,000 I.U. 4 times daily) in immunocompromised children with oral candidiasis. Demonstrable clinical and mycological response rates were higher in the children treated with fluconazole. Clinical cure at the end of treatment was reported for 86% of fluconazole treated patients compared to 46% of nystatin treated patients. The relapse rate of fluconazole treated patients had the infecting organism eradicated compared to 11% for nystatin treated patients.

**CONTRAINdications**

Fluconazole Injection, USP is contraindicated in patients who have shown hypersensitivity to fluconazole or to any of its excipients. There is a potential cross-sensitivity between fluconazole and other azole antifungal agents. Caution should be used when prescribing Fluconazole Injection, USP to patients who have shown hypersensitivity to other azoles. Coadministration of terfenadine is contraindicated in patients receiving Fluconazole Injection, USP on the basis of an investigational study. (See CLINICAL PHARMACOLOGY: Drug Interaction Studies and PRECAUTIONS.)

**WARNINGS**

(1) Hepatic injury: Fluconazole has been associated with rare cases of serious hepatic toxicity, including fatalities primarily in patients with serious underlying medical conditions. In cases of fluconazole-associated hepatotoxicity, no obvious relationship to total daily dose, duration of therapy, sex or age of the patient has been observed. Fluconazole hepatotoxicity usually occurs within 1 month of starting therapy; however, reactions have occurred as early as 4 days or as late as 45 days after drug administration. Fluconazole hepatotoxicity usually resolves or improves when the drug is discontinued. A potential risk factor for the development of hepatotoxicity with fluconazole therapy is the presence of liver disorders. In these instances, the risk-benefit ratio of fluconazole therapy should be carefully considered. Fluconazole Injection, USP should be discontinued if clinical signs and symptoms consistent with liver disease develop that may be attributable to fluconazole.

(2) Anaphylaxis: Anaphylaxis has been reported.

(3) Dermatologic: Patients have rarely developed exfoliative skin disorders during treatment with fluconazole. In patients with serious underlying diseases (predominantly AIDS and malignancy), these reactions have resulted in a fatal outcome. Patients who develop rashes during treatment with Fluconazole Injection, USP should be monitored closely and the drug discontinued if lesions progress.

**PRECAUTIONS**

General: Some azoles, including fluconazole, have been associated with prolongation of the QT interval on the electrocardiogram. During post-marketing surveillance, there have been rare cases of QT prolongation and torsade de pointes in patients taking fluconazole. Most of these reported episodes involved serendipitous patients with a predisposing risk factor, such as myocardial infarction, brady- or tachyarrhythmia, conduction defects, electrolyte abnormalities, and concomitant medications that may have contributed. Careful monitoring of patients in any of these circumstances should be given. Fluconazole Injection, USP should be discontinued if clinical signs and symptoms consistent with liver disease develop that may be attributable to fluconazole.

Drug Interactions: (See CLINICAL PHARMACOLOGY: Drug Interaction Studies and CONTRAINDICATIONS.) Clinically or potentially significant drug interactions between fluconazole and the following agents/classes have been observed. These are described in greater detail below:

- Oral hypoglycemics
  - Concomitant use of fluconazole and oral hypoglycemic agents; one fatality has been reported from hypoglycemia in association with combined oral contraceptive use. Clinical experience has not identified differences in responses between the elderly and younger patients.

- Ethinyl estradiol and levonorgestrel-containing oral contraceptives
  - Fluconazole tablets coadministered with ethinyl estradiol- and levonorgestrel-containing oral contraceptives produced an overall mean increase in ethinyl estradiol and levonorgestrel levels; however, in some patients there were decreases up to 47% and 33% of ethinyl estradiol and levonorgestrel levels. (See CLINICAL PHARMACOLOGY: Drug Interaction Studies.) There have been reports of uveitis in patients to whom fluconazole and rifabutin were coadministered. (See CONTRAINDICATIONS and CLINICAL PHARMACOLOGY: Drug Interaction Studies.) Fluconazole and rifabutin should be administered with caution to patients with these potentially proarrhythmic effects who are receiving concomitant medications that may contribute to QT prolongation. Fluconazole Injection, USP should be discontinued if clinical signs and symptoms consistent with liver disease develop that may be attributable to fluconazole.

- Antipsychotics
  - Fluconazole reduces the plasma concentrations of phenothiazines. Careful monitoring of patients receiving Fluconazole Injection, USP and phenothiazines is recommended. (See CLINICAL PHARMACOLOGY: Drug Interaction Studies.)

- Phenytoin
  - Fluconazole reduces the plasma concentrations of phenytoin. Careful monitoring of phenytoin concentrations in patients receiving Fluconazole Injection, USP and phenytoin is recommended. (See CLINICAL PHARMACOLOGY: Drug Interaction Studies.)

- Rifampin
  - Rifampin enhances the metabolism of concurrent antiretroviral drugs. Rifampin portion of the data indicate that the dose of rifampin should be increased in patients receiving fluconazole in combination with rifampin.

- Prochlorperazine
  - Prochlorperazine may increase the risk of QT prolongation. Prochlorperazine should be used with caution in patients receiving Fluconazole Injection, USP.

- Ethinyl estradiol
  - Fluconazole may reduce the contraceptive efficacy of oral contraceptives. Patients who take oral contraceptives should be carefully monitored and the dose of the oral contraceptive should be adjusted as necessary. (See CLINICAL PHARMACOLOGY: Drug Interaction Studies.)

**ADVERSE REACTIONS**

Ritabulin: There have been reports of uveitis in patients to whom fluconazole and ritabulin were coadministered. Patients receiving Fluconazole Injection, USP concomitantly should be carefully monitored. (See CLINICAL PHARMACOLOGY: Drug Interaction Studies.)

**TCARmolls:** There have been reports of nephrotic patients to whom fluconazole and tacrolimus were coadministered. Careful monitoring of tacrolimus and Fluconazole Injection, USP concomitantly should be carefully monitored. (See CLINICAL PHARMACOLOGY: Drug Interaction Studies.)

- Short-acting Benzodiazepines: Following oral administration of midazolam, fluconazole resulted in substantial increases in midazolam AUC and Cmax with no effect on clearance. Midazolam appears to be more pronounced following oral administration of Fluconazole Injection than with fluconazole administered intravenously. If short-acting benzodiazepines, which are metabolized by the cytochrome P450 system, are concurrently administered, the pharmacodynamic and pharmacokinetic effects exerted by the benzodiazepine and Fluconazole Injection, USP should be appropriately monitored. (See CLINICAL PHARMACOLOGY: Drug Interaction Studies.)

Fluconazole tablets coadministered with ethinyl estradiol- and levonorgestrel-containing oral contraceptives produced an overall mean increase in ethinyl estradiol and levonorgestrel levels; however, in some patients there were decreases up to 47% and 33% of ethinyl estradiol and levonorgestrel levels. (See CLINICAL PHARMACOLOGY: Drug Interaction Studies.)

**Clinical Pathology:**

**Drug Interaction Studies**

Fluconazole Injection, USP should be administered with caution to patients with these potentially proarrhythmic effects who are receiving concomitant medications that may contribute to QT prolongation. Fluconazole Injection, USP should be discontinued if clinical signs and symptoms consistent with liver disease develop that may be attributable to fluconazole.
The following treatment-related clinical adverse events occurred at an incidence of 1% or greater in 448 patients receiving fluconazole for 7 or more days in clinical trials: nausea 3.7%, headache 1.9%, skin rash 1.8%, vomiting 1.7%, abdominal pain 1.7%, and diarrhea 1.5%.

Hepatotoxicity: In combined clinical trials and marketing experience, there have been rare cases of serious hepatic reactions during treatment with fluconazole. (See WARNINGS.) The spectrum of these hepatic reactions has ranged from mild elevations of liver transaminases to hepatic cholestasis and fulminant hepatic failure, including fatalities. Instances of fatal hepatic reactions were noted to occur primarily in patients with pre-existing liver disease, particularly cirrhosis, and, in one case, hemochromatosis. Lipid lowering medications, usually taken simultaneously with fluconazole, may enhance the risk of hepatic reactions.

In two comparative trials evaluating the efficacy of fluconazole for the suppression of relapse of cryptococcal meningitis, a statistically significant increase was observed in median ASAT (SGOT) levels from a baseline value of 30 IU/L to 41 IU/L in one trial and 30 IU/L to 69 IU/L in the other. The overall rate of serum transaminase elevations of more than 8 times the upper limit of normal was approximately 1% in fluconazole-treated patients in whom relapse occurred as compared with placebo. In these trials, transient elevations with severe underlying disease (primary AIDS or malignancy), most of whom were receiving multiple concomitant medications, Transient hepatic reactions, including hepatitis and jaundice, have occurred in patients with no other identifiable risk factors. In each of these cases, liver function returned to baseline on discontinuation of fluconazole.

Adverse Reactions in Children:
In Phase II/III clinical trials conducted in the United States and in Europe, 577 pediatric patients, ages 1 day to 17 years, were treated with fluconazole at doses up to 15 mg/kg/day for up to 3.6 years. Dose-related increases in the percent of children experienced treatment related adverse events.

Overdose:
There have been reports of overdose with fluconazole. A 42-year-old patient infected with human immunodeficiency virus developed delirium and confusion, and, after ingesting 8200 mg of fluconazole, the patient was admitted to the hospital, and his condition resolved within 48 hours.

Fluconazole is largely excreted in urine. A three-hour hemodialysis session decreases plasma levels by approximately 50%.

DOSE AND ADMINISTRATION
Dosage in Patients With Impaired Renal Function:

Creatinine clearance (ml/min).

Females: 0.85 x above value

Males: Weight (kg) x (140 - age)

Serum creatinine (mg/100 mL)

K x serum creatinine (mg/100 mL)

Linear length or height (cm)

DO NOT ADD SUPPLEMENTARY MEDICATION.

The following dose equivalency scheme should generally provide equivalent exposure in pediatric and adult patients.

Dosage and Administration in Children:
The following dose equivalency scheme should generally provide equivalent exposure in pediatric and adult patients.

Experience with fluconazole in neonates is limited to pharmacokinetic studies in premature newborns. (See CLINICAL PHARMACOLOGY.) Based on the prolonged half-life seen in premature newborns (gestational age 26 to 29 weeks), these infants, in the first two weeks of life, should receive the same dosage (mg/kg) as in older children, but administered every 48 hours. After the first two weeks, these children should be dosed once daily if regimens for fluconazole are convenient.

Oral Fluconazole candidiasis: The recommended dosage of Fluconazole Injection, USP for oropharyngeal candidiasis in children is 6 mg/kg on the first day, followed by 3 mg/kg once daily. Treatment should be administered for a minimum of 7 days and for at least 2 weeks following the resolution of signs of infection.

Oral Fluconazole candidiasis: For the treatment of esophageal candidiasis, the recommended dosage of Fluconazole Injection, USP is 150 mg on the first day, followed by 100 mg on the second day. This dosage may be used for at least 14 days following the resolution of signs of infection. The recommended dosage for oral fluconazole in children with AIDS, the recommended dose of Fluconazole Injection, USP is 6 mg/kg on the first day.

Dose in Patients With Impaired Renal Function:

In the treatment of infections, daily doses of 6-12 mg/kg/day have been used in an open, noncomparative study of a small number of children.

Cryptococcal meningitis: For the treatment of acute cryptococcal meningitis, the recommended dosage is 12 mg/kg/day, followed by 6 mg/kg/day to a total of 4 weeks of therapy. Patients with esophageal candidiasis should be treated for a minimum of 3 weeks and for at least 2 weeks following the resolution of symptoms.

Candida infections: For the treatment of candidemia and disseminated Candida infections, daily doses of 6-12 mg/kg/day have been used in an open, noncomparative study of a small number of children.

In two comparative studies, fluconazole was as effective as the combination of amphotericin B and 5-fluorocytosine and had a lower incidence of adverse events.

Intravenous Fluconazole Injection, USP is administered by intravenous infusion. Fluconazole has been used safely for up to 4041 days (7 years) in clinical trials without evidence of accumulation or toxicity.

Intravenous Fluconazole Injection, USP is intended only for intravenous administration using sterile equipment.

Parenteral drug products should be inspected visually for particulate matter and discolored vials before administration.

Continuous intravenous infusion may be used for up to 14 days. Higher serum levels may be obtained by giving the daily dose in a single injection. The solution should be clear and colorless. If it is cloudy or discolored, it should not be used.

Intravenous Fluconazole Injection, USP is supplied in single-use containers, and should be stored at controlled room temperature (15°C to 30°C), protected from freezing and from light. Fluconazole is supplied as sterile iso-osmotic solutions containing 2 mg/mL of fluconazole. They are supplied in INTRAVIA plastic containers.

HOW SUPPLIED

Fluconazole Injections, USP: Fluconazole Injections, USP for intravenous infusion administration are formulated as sterile iso-osmotic solutions containing 2 mg/mL of fluconazole. They are supplied in INTRAVIA plastic containers containing volumes of 100 mL or 250 mL, affording dosages of 200 mg and 400 mg of Fluconazole, respectively.

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Fluconazole injections, USP in INTRAVIA Plastic Containers: 20 mg/mL NDC 0069-0045-03 Fluconazole in Sodium Chloride Diluent 100 mg/10 mL x 10 214J54 NDC 0069-0045-03 Fluconazole in Sodium Chloride Diluent 400 mg/20 mL x 10

Storage

Store between 77°F (25°C) and 41°F (5°C). Brief exposure up to 104°F (40°C) does not adversely affect the product. Protect from freezing. Avoid excessive heat.

Rx only

REFERENCES


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