NAME OF THE MEDICINAL PRODUCT

Fluconazole B. Braun 2 mg/ml solution for infusion

COMPOSITION

1 ml solution for infusion contains 2 mg of fluconazole.
50 ml solution for infusion contain 100 mg of fluconazole.
100 ml solution for infusion contain 200 mg of fluconazole.
200 ml solution for infusion contain 400 mg of fluconazole.

Excipient with known effect: 1 ml solution contains 0.15 mmol (3.5 mg) sodium.
Excipients: Sodium chloride, water for injection.

THERAPEUTIC INDICATIONS

Fluconazole B. Braun is indicated in the following fungal infections:

In adults for treatment of:
Cryptococcal meningitis; coccidioidomycosis, invasive candidiasis; mucosal candidiasis (including oropharyngeal candidiasis, oesophageal candidiasis, candiduria and chronic mucocutaneous candidiasis); chronic oral atrophic candidiasis (denture sore mouth) if dental hygiene or topical treatment are insufficient.

In adults for the prophylaxis of:
Relapse of cryptococcal meningitis in patients with high risk of recurrence; relapse of oropharyngeal or oesophageal candidiasis in patients infected with HIV who are at high risk of experiencing relapse; prophylaxis of candidal infections in patients with prolonged neutropenia (such as patients with haematological malignancies receiving chemotherapy or patients receiving Haematopoetic Stem Cell Transplantation).

In term newborn infants, infants, toddlers, children and adolescents aged from 0 to 17 years old:
Fluconazole B. Braun is used for the treatment of mucosal candidiasis (oropharyngeal, oesophageal), invasive candidiasis, cryptococcal meningitis and the prophylaxis of candidal infections in immunocompromised patients. Fluconazole B. Braun can be used as maintenance therapy to prevent relapse of cryptococcal meningitis in children with high risk of reoccurrence.

Therapy may be instituted before the results of the cultures and other laboratory studies are known; however, once these results become available, anti-infective therapy should be adjusted accordingly. Consideration should be given to official guidance on the appropriate use of antifungals.

CONTRAINDICATIONS

Hypersensitivity to the active substance, to related azole substances, or to any of the excipients.

Co-administration of terfenadine is contraindicated in patients receiving Fluconazole B. Braun at multiple doses of 400 mg per day or higher based upon results of a multiple dose interaction study. Co-administration of other medicinal products known to prolong the QT interval and which are metabolised via the cytochrome P450 (CYP) 3A4, such as cisapride, astemizole, pimozide, quinidine and erythromycin are contraindicated in patients receiving fluconazole.

UNDESIRABLE EFFECTS

Summary of safety profile:

Drug reaction with eosinophilia and systemic symptoms (DRESS) has been reported in association with fluconazole treatment.

The most frequently (>1/10) reported adverse reactions are headache, abdominal pain, diarrhoea, nausea, vomiting, alanine aminotransferase increased, aspartate aminotransferase increased, blood alkaline phosphatase increased and rash.

Undesirable effects are listed according to their frequencies as follows:

Common: (≥ 1/100 to < 1/10)
Uncommon: (≥ 1/1 000 to < 1/100)
Rare: (≥ 1/10 000 to < 1/1000)
Not known: (Can not be estimated from the available data)

System Organ Class	Common	Uncommon	Rare	Not known
Blood and lymphatic system disorders		Anaemia	Agranulocytosis, leukopenia, neutropenia, thrombocytopenia	

Immune system disorders			Anaphylaxis	
Metabolism and nutrition disorders		Decreased appetite	Hypercholesterolemia, hypertriglyceridemia, hypokalaemia	
Psychiatric disorders		Somnolence, insomnia		
Nervous system disorders	Headache	Seizures, paraesthesia, dizziness, taste perversion,	Tremor	
Ear and labyrinth disorders		Vertigo		
Cardiac disorders			Torsade de pointes, QT prolongation	
Gastrointestinal disorders	Abdominal pain, vomiting, diarrhoea, nausea	Constipation, dyspepsia, flatulence, dry mouth		
Hepato-biliary disorders	Alanine aminotransferase increased, aspartate aminotransferase increased, blood alkaline phosphatase increased	Cholestasis, jaundice, bilirubin increased	Hepatic failure, hepatocellular necrosis, hepatitis, hepatocellular damage	
Skin and subcutaneous tissue disorders	Rash	Drug eruption*, urticaria~~l~~, pruritus, increased sweating	Toxic epidermal necrolysis, Stevens-Johnson syndrome, acute generalised exanthematous-pustulosis, exfoliative dermatitis, angioedema, face oedema, alopecia	Drug reaction with eosinophilia and systemic symptoms (DRESS)
Musculoskeletal and connective tissue disorders		Myalgia		

General disorders and administration site conditions		Fatigue, malaise, asthenia, fever		

*including Fixed Drug Eruption

Paediatric population
The pattern and incidence of adverse reactions and laboratory abnormalities recorded during paediatric clinical trials are comparable to those seen in adults.

WARNINGS

Keep out of sight and reach of children.

NOTE *Prescription only*
Not all products are registered and approved for sale in all countries or regions. Indications of use may also vary by country and region. Please contact your country representative for product availability and information

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