Fungican®

fluconazole 150 mg

Broad Spectrum Antifungal

1. Name of the medicinal product
Fungican® 150 mg hard gelatin Capsules.
2. Qualitative and quantitative composition
Active ingredient:
Each capsule contains fluconazole 150 mg
Excipients:
Microcrystalline cellulose, Dibasic Calcium phosphate, Povidone K30, Croscarmellose Sodium, Magnesium stearate, Purified Talc
Composition of capsule shell:
Gelatin, Titanium Dioxide, Indigotine (Carmine FD&C Blue 2)
3. Pharmaceutical form
Hard Gelatin capsule
4. Clinical particulars
4.1 **Therapeutic indications**
Fungican® is indicated in the following fungal infections:
Fungican® is indicated in adults for the treatment of:
• Cryptococcal meningitis.
• Coccidioidomycosis.
• Invasive candidiasis.
• Mucosal candidiasis including oropharyngeal, oesophageal candidiasis, candiduria and chronic mucocutaneous candidiasis.
• Chronic oral atrophic candidiasis (denture sore mouth) if dental hygiene or topical treatment are insufficient.
• Vaginal candidiasis, acute or recurrent; when local therapy is not appropriate.
• Candidal balanitis when local therapy is not appropriate.
• Dermatomycosis including tinea pedis, tinea corporis, tinea cruris, tinea versicolor and dermal candida infections when systemic therapy is indicated.
• Tinea unguarium (onychomycosis) when other agents are not considered appropriate.
Fungican® is indicated 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.
• To reduce the incidence of recurrent vaginal candidiasis (4 or more episodes a year).
• Prophylaxis of candidal infections in patients with prolonged neutropenia (such as patients with haematological malignancies receiving chemotherapy or patients receiving Hematopoietic Stem Cell Transplantation.
Fungican® is indicated in term newborn infants, infants, toddlers, children, and adolescents aged from 0 to 17 years old:
Fungican® is used for the treatment of mucosal candidiasis (oropharyngeal, oesophageal) invasive candidiasis, cryptococcal meningitis and the prophylaxis of candidal infections in immunocompromised patients. Fungican can be used as maintenance therapy to prevent relapse of cryptococcal meningitis in children with high risk of recurrence.
Therapy may be initiated 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.
4.2 **Posology and method of administration**
Posology:
The dose should be based on the nature and severity of the fungal infection. Treatment of infections requiring multiple dosing should be continued until clinical parameters or laboratory tests indicate that active fungal infection has subsided. An inadequate period of treatment may lead to recurrence of active infection.

Adults:			
Indication		**Posology**	**Duration of treatment**
Cryptococcosis	– Treatment of cryptococcal meningitis	Loading dose: 400 mg on Day 1 Subsequent dose: 200 mg	Usually at least 6 to 8 weeks. In life-threatening infections the daily dose can be increased to 400 mg.
	– Maintenance therapy to prevent relapse of cryptococca meningitis in patients with high risk of recurrence	200 mg to 400 mg once daily	Indefinitely at a daily dose of 200 mg
Coccidioidomycosis		200 mg to 400 mg once daily	11 months up to 24 months or longer depending on the patient. 800 mg daily may be considered for some infections and especially for meningal disease.
Invasive candidiasis		Loading dose: 800 mg on Day 1 Subsequent dose: 400 mg once daily	In general, the recommended duration of therapy for candidemia is for 2 weeks after first negative blood culture result and resolution of signs and symptoms attributable to candidemia.
Treatment of mucosal candidiasis	– Oropharyngeal candidiasis	Loading dose: 200 mg to 400 mg on Day 1 Subsequent dose: 200 mg to 400 mg once daily	7 to 21 days (until oropharyngeal candidiasis is in remission). Longer periods may be used in patients with severely compromised immune function.
	– Oesophageal candidiasis	Loading dose: 200 mg to 400 mg on Day 1 Subsequent dose: 100 mg to 200 mg once daily	14 to 30 days (until oesophageal candidiasis is in remission). Longer periods may be used in patients with severely compromised immune function.
	– Candiduria	200 mg to 400 mg once daily	7 to 21 days. Longer periods may be used in patients with severely compromised immune function.
	– Chronic atrophic candidiasis	50 mg once daily	14 days
	– Chronic mucocutaneous candidiasis	50 mg to 100 mg once daily	Up to 28 days. Longer periods depending on both the severity of infection or underlying immune compromisation and response
Prevention of relapse of mucosal candidiasis in patients infected with HIV who are at high risk of experiencing relapse.	– Oropharyngeal candidiasis	100 mg to 200 mg once daily or 200 mg 3 times per week	As indefinite period for patients with chronic immune suppression
	– Oesophageal candidiasis	100 mg to 200 mg once daily or 200 mg 3 times per week	As indefinite period for patients with chronic immune suppression
Genital candidiasis	– Acute vaginal candidiasis – Candidal balanitis	150 mg	Single dose
	~~– Treatment and prophylaxis~~ of recurrent vaginal candidiasis (4 or more episodes a year).	~~150 mg every third day~~ for a total of 3 doses (day 1, 4, and 7) followed by 150 mg once weekly ~~Maintenance dose:~~	~~maintenance dose: 6 months.~~
Dermatomycosis	- *tinea pedis,* - *tinea corporis,* - *tinea cruris,* ~~- candida infections~~	150 mg once weekly or 50mg once daily	2 to 4 weeks, tinea pedis may require treatment for up to 6 weeks
	- tinea versicolor	300 mg to 400 mg once weekly, 50 mg once daily	1 to 3 weeks
	- tinea unguium	150 mg once weekly	2 to 3 months. Treatment should be continued until infected nail is replaced (uninfected nail grows in). Regrowth of fingernails and toenails normally requires 3 to 6 months, and 6 to 12 months, respectively. However, growth rates may vary widely in individuals, and by age. After successful treatment of long-term chronic infections, nails occasionally remain dishapted.
	(onychomycosis)		
Prophylaxis of candidal infections in patients with prolonged neutropenia		200 mg to 400 mg once daily	Treatment should start several days before the anticipated onset of neutropenia and continue for 7 days after recovery from neutropenia after the neutrophil count rises above 1000 cells per mm³.

Special populations
Elderly
Dosage should be adjusted based on the renal function.
Renal impairment
Fluconazole is predominantly excreted in the urine as unchanged active substance. No adjustments in single dose therapy are necessary. In patients (including paediatric population) with impaired renal function who will receive multiple doses of fluconazole, an initial dose of 50 mg to 400 mg should be given, based on the recommended daily dose for the indication. After this initial loading dose, the daily dose (according to indication) should be based on the following table:

Creatinine clearance (ml/min)	Percent of recommended dose
>50	100%
5-50 mg haemodialysis	50%
Haemodialysis	100% after each haemodialysis.

Patients on haemodialysis should receive 100% of the recommended dose after each haemodialysis, on non-dialysis days, patients should receive a reduced dose according to their creatinine clearance.
Hepatic impairment
Limited data are available in patients with hepatic impairment, therefore fluconazole should be administered with caution to patients with liver dysfunction.
Paediatric population
A maximum dose of 400 mg daily should not be exceeded in paediatric population.
As with similar infections in adults, the duration of treatment is based on the clinical and mycological response. Fungican is administered as a single daily dose.
For paediatric patients with impaired renal function, see dosing in "Renal impairment". The pharmacokinetics of fluconazole has not been studied in paediatric population with renal insufficiency (for "Term newborn infants" who often exhibit primarily renal immaturity please see below).
Infants, toddlers and children (from 28 days to 11 years old):

Indication	Posology	Recommendations
- Mucosal candidiasis	Initial dose: 6 mg/kg Subsequent dose: 3 mg/kg once daily	Initial dose may be used on the first day to achieve steady state levels more rapidly
- Invasive candidiasis - Cryptococcal meningitis	dose: 6 to 12 mg/kg once daily	Depending on the severity of the disease
- Maintenance therapy to prevent relapse of cryptococcal meningitis in children with high risk of recurrence	Dose: 6 mg/kg once daily	Depending on the severity of the disease
- Prophylaxis of Candida in immunocompromised patients	Dose: 3 to 12 mg/kg once daily	Depending on the extent and duration of the induced neutropenia (see Adults posology)

Adolescents (from 12 to 17 years old):
Depending on the weight and pubertal development, the prescriber would need to assess which posology (adults or children) is the most appropriate. Clinical data indicate that children have a higher fluconazole clearance than observed for adults. A dose of 100, 200 and 400 mg in adults corresponds to a 3, 6 and 12 mg/kg dose in children to obtain a comparable systemic exposure.
Safety and efficacy for genital candidiasis indication in paediatric population has not been established. Current available safety data for other paediatric indications are described in section 4.8. If treatment for genital candidiasis is imperative in adolescents (from 12 to 17 years old), the posology should be the same as adults posology.
Term newborn infants (0 to 27 days):
Neonates excrete fluconazole slowly. There are few pharmacokinetic data to support this posology in term newborn infants.

Age group	Posology	Recommendations
term newborn infants (0 to 14 days)	The same mg/kg dose as for infants, toddlers and children should be given every 72 hours	A maximum dose of 12 mg/kg every 72 hours should not be exceeded
term newborn infants (from 15 to 27 days)	The same mg/kg dose as for infants, toddlers and children should be given every 48 hours	A maximum dose of 12 mg/kg every 48 hours should not be exceeded

Method of administration
Fluconazole may be administered either orally (Capsules and Powder for Oral Suspension) or by intravenous infusion (Solution for Infusion), the route being dependent on the clinical state of the patient. On transferring from the intravenous to the oral route, or vice versa, there is no need to change the daily dose.
The fungican capsules should be swallowed whole and independent of food intake.
4.3 **Contraindications**
Hypersensitivity to the active substance, to related azole substances, or to any of the excipients.
Coadministration of terfenadine is contraindicated in patients receiving fluconazole at multiple doses of 400 mg per day or higher based upon results of a multiple dose interaction study. Coadministration 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.
4.4 **Special warnings and precautions for use**
Tinea capitis
Fluconazole has been studied for treatment of tinea capitis in children. It was shown not to be superior to griseofulvin and the overall success rate was less than 20%. Therefore, fungican should not be used for tinea capitis.
Cryptococcosis
The evidence for efficacy of fluconazole in the treatment of cryptococcosis of other sites (e.g. pulmonary and cutaneous cryptococcosis) is limited, which prevents dosing recommendations.
Deep endemic mycoses
The evidence for efficacy of fluconazole in the treatment of other forms of endemic mycoses such as paracoccidioidomycosis, lymphocutaneous sporotrichosis and histoplasmosis is limited, which prevents specific dosing recommendations.
Renal system
Fluconazole should be administered with caution to patients with renal dysfunction.
Adrenal insufficiency
Ketoconazole is known to cause adrenal insufficiency, and this could also although rarely seen be applicable to fluconazole. Adrenal insufficiency relating to concomitant treatment with prednisone, see section 4.5 'The effect of fluconazole on other medicinal products'.
Hepatobiliary system
Fluconazole should be administered with caution to patients with liver dysfunction.
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 patient has been observed. Fluconazole hepatotoxicity has usually been reversible on discontinuation of therapy.
Patients who develop abnormal liver function tests during fluconazole therapy must be monitored closely for the development of more serious hepatic injury.
The patient should be informed of suggestive symptoms of serious hepatic effect (important asthenia, anorexia, persistent nausea, vomiting and jaundice). Treatment of fluconazole should be immediately discontinued and the patient should consult a physician.
Cardiovascular system
Some azoles, including fluconazole, have been associated with prolongation of the QT interval on the electrocardiogram. Fluconazole causes QT prolongation via the inhibition of Rectifier Potassium Channel current (IKr). The QT prolongation caused by other medicinal products (such as amiodarone) may be amplified via the inhibition of cytochrome P450 (CYP) 3A4. During post-marketing surveillance, there have been very rare cases of QT prolongation and torsades de pointes in patients taking fluconazole. These reports included seriously ill patients with multiple confounding risk factors, such as structural heart disease, electrolyte abnormalities and concomitant treatment that may have been contributory. Patients with hypokalemia and advanced cardiac failure are at an increased risk for the occurrence of life-threatening ventricular arrhythmias and torsades de pointes.
Fluconazole should be administered with caution to patients with potentially proarrhythmic conditions.
Coadministration of other medicinal products known to prolong the QT interval and which are metabolised via the cytochrome P450 (CYP) 3A4 are contraindicated.
Halofantrine
Halofantrine has been shown to prolong QTc interval at the recommended therapeutic dose and is a substrate of CYP3A4. The concomitant use of fluconazole and halofantrine is therefore not recommended.
Dermatological reactions
Patients have rarely 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 severe cutaneous reactions to many medicinal products. If a rash, which is considered attributable to fluconazole, develops in a patient treated for a superficial fungal infection, further therapy with this medicinal product 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.
Hypersensitivity
In rare cases anaphylaxis has been reported.
Cytochrome P450
Fluconazole is a moderate CYP2C9 and CYP3A4 inhibitor. Fluconazole is also a strong inhibitor of CYP2C19. Fluconazole treated patients who are concomitantly treated with medicinal products with a narrow therapeutic window metabolised through CYP2C9, CYP2C19 and CYP3A4, should be monitored.
Terfenadine
The coadministration of fluconazole at doses lower than 400 mg per day with terfenadine should be carefully monitored.
4.5 **Interaction with other medicinal products and other forms of interaction**
Concomitant use of the following other medicinal products is contraindicated:
Cisapride: There have been reports of cardiac events including torsades de pointes in patients to whom fluconazole and cisapride were coadministered. A controlled study found that concomitant fluconazole 200 mg once daily and cisapride 20 mg four times a day yielded a significant increase in cisapride plasma levels and prolongation of QTc interval. Concomitant treatment with fluconazole and cisapride is contraindicated.
Terfenadine: Because of the occurrence of serious cardiac dysrhythmias secondary to prolongation of the QTc interval in patients receiving azole antifungals in conjunction with terfenadine, interaction studies have been performed. One study at a 200 mg daily dose of fluconazole failed to demonstrate a prolongation in QTc interval. 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. The combined use of fluconazole at doses of 400 mg or greater with terfenadine is contraindicated. The coadministration of fluconazole at doses lower than 400 mg per day with terfenadine should be carefully monitored.
Astemizole: Concomitant administration of fluconazole with astemizole may decrease the clearance of astemizole. Resulting increased plasma concentrations of astemizole can lead to QT prolongation and rare occurrences of torsades de pointes. Coadministration of fluconazole and astemizole is contraindicated.
Pimozide: Although not studied in vitro or in vivo, concomitant administration of fluconazole with pimozide may result in inhibition of pimozide metabolism. Increased pimozide plasma concentrations can lead to QT prolongation and rare occurrences of torsades de pointes. Coadministration of fluconazole and pimozide is contraindicated.
Quinidine: Although not studied in vitro or in vivo, concomitant administration of fluconazole with quinidine may result in inhibition of quinidine metabolism. Use of quinidine has been associated with QT prolongation and rare occurrences of torsades de pointes. Coadministration of fluconazole and quinidine is contraindicated.
Erythromycin: Concomitant use of fluconazole and erythromycin has the potential to increase the risk of cardiotoxicity (prolonged QT interval, torsades de pointes) and consequently sudden heart death. Coadministration of fluconazole and erythromycin is contraindicated.
Concomitant use of the following other medicinal products cannot be recommended:
Halofantrine: Fluconazole can increase halofantrine plasma concentration due to an inhibitory effect on CYP3A4. Concomitant use of fluconazole and halofantrine has the potential to increase the risk of cardiotoxicity (prolonged QT interval, torsades de pointes) and consequently sudden heart death. This combination should be avoided.
Concomitant use that should be used with caution:
Amiodarone: Concomitant administration of fluconazole with amiodarone may increase QT prolongation. Caution must be exercised if the concomitant use of fluconazole and amiodarone is necessary, notably with high dose fluconazole (800 mg).
Concomitant use of the following other medicinal products lead to precautions and dose adjustments:
The effect of other medicinal products on fluconazole:
Rifampicin: Concomitant administration of fluconazole and rifampicin resulted in a 25% decrease in the AUC and a 20% shorter half-life of fluconazole. In patients receiving concomitant rifampicin, an increase of the fluconazole dose should be considered.
Interaction studies have shown that when oral fluconazole is coadministered with food, cimetidine, antacids or following total body irradiation for bone marrow transplantation, no clinically significant impairment of fluconazole absorption occurs.
Hydrochlorothiazide: In a pharmacokinetic interaction study, coadministration of multiple-dose hydrochlorothiazide to healthy volunteers receiving fluconazole increased plasma concentration of fluconazole by 40%. An effect of this magnitude should not necessitate a change in the fluconazole dose regimen in subjects receiving concomitant diuretics.

The effect of fluconazole on other medicinal products:
Fluconazole is a moderate inhibitor of cytochrome P450 (CYP) isoenzymes 2C9 and 3A4. Fluconazole is also a strong inhibitor of the isoezyme CYP2C19. In addition to the observed/documented interactions mentioned below, there is a risk of increased plasma concentration of other compounds metabolised by CYP2C9, CYP2C19 and CYP3A4 coadministered with fluconazole. Therefore, caution should be exercised when using these combinations and the patients should be carefully monitored. The enzyme inhibiting effect of fluconazole persists 4-5 days after discontinuation of fluconazole treatment due to the long half-life of fluconazole.
Alfentanil: During concomitant treatment with fluconazole (400 mg) and intravenous alfentanil (20 µg/kg) in healthy volunteers the alfentanil AUC 10 increased 2-fold, probably through inhibition of CYP3A4.Dose adjustment of alfentanil may be necessary.
Amitriptyline, nortriptyline: Fluconazole increases the effect of amitriptyline and nortriptyline. 5-nortriptyline and/or 5-amitriptyline may be measured at initiation of the combination therapy and after one week. Dose of amitriptyline/nortriptyline should be adjusted, if necessary
Amphotericin B: Concurrent administration of fluconazole and amphotericin B in infected normal and immunosuppressed mice showed the following results: a small additive antifungal effect in systemic infection with C. albicans, no interaction in intracranial infection with Cryptococcus neoformans, and antagonism of the two medicinal products in systemic infection with Aspergillus fumigatus. The clinical significance of results obtained in these studies is unknown.
Anticoagulants: In post-marketing experience, as with other azole antifungals, bleeding events (bruising, epistaxis, gastrointestinal bleeding, hematuria, and melena) have been reported, in association with increases in prothrombin time in patients receiving fluconazole concurrently with warfarin. During concomitant treatment with fluconazole and warfarin the prothrombin time was prolonged up to 2-fold, probably due to an inhibition of the warfarin metabolism through CYP2C9. In patients receiving coumarin-type or indanedione anticoagulants concurrently with fluconazole the prothrombin time should be carefully monitored. Dose adjustment of the anticoagulant may be necessary.
Benzodiazepines (short acting), i.e. midazolam, triazolam: Following oral administration of midazolam, fluconazole resulted in substantial increases in midazolam concentrations and psychomotor effects. Concomitant intake of fluconazole 200 mg and midazolam 7.5 mg orally increased the midazolam AUC and half-life 3.7-fold and 2.2-fold, respectively. Fluconazole 200 mg daily given concurrently with triazolam 0.25 mg orally increased the triazolam AUC and half-life 4.4-fold and 2.5-fold, respectively. Potentiated and prolonged effects of triazolam have been observed at concomitant treatment with fluconazole. If concomitant benzodiazepine therapy is necessary in patients being treated with fluconazole, consideration should be given to decreasing the benzodiazepine dose, and the patients should be appropriately monitored.
Carbamazepine: Fluconazole inhibits the metabolism of carbamazepine and an increase in serum carbamazepine of 30% has been observed. There is a risk of developing carbamazepine toxicity. Dose adjustment of carbamazepine may be necessary depending on concentration measurements/effect.
Calcium channel blockers: Certain calcium channel antagonists (nifedipine, isradipine, amlodipine, verapamil and felodipine) are metabolised by CYP3A4. Fluconazole has the potential to increase the systemic exposure of the calcium channel antagonists. Frequent monitoring for adverse events is recommended.
Celecoxib: During concomitant treatment with fluconazole (200 mg daily) and celecoxib (200 mg) the celecoxib Cmax and AUC increased by 68% and 134%, respectively. Half of the celecoxib dose may be necessary when combined with fluconazole.
Cyclophosphamide: Combination therapy with cyclophosphamide and fluconazole results in an increase in serum bilirubin and serum creatinine. The combination may be used while taking increased consideration to the risk of increased serum bilirubin and serum creatinine.
Fentanyl: One fatal case of fentanyl intoxication due to possible fentanyl fluconazole interaction was reported. Furthermore, it was shown in healthy volunteers that fluconazole delayed the elimination of fentanyl significantly. Elevated fentanyl concentration may lead to respiratory depression. Patients should be monitored closely for the potential risk of respiratory depression. Dosage adjustment of fentanyl may be necessary.
HMG CoA reductase inhibitors: The risk of myopathy and rhabdomyolysis increases when fluconazole is coadministered with HMG-CoA reductase inhibitors metabolised through CYP3A4, such as atorvastatin and simvastatin, or through CYP2C9, such as fluvastatin. If concomitant therapy is necessary, the patient should be observed for symptoms of myopathy and rhabdomyolysis and creatine kinase should be monitored. HMG-CoA reductase inhibitors should be discontinued if a marked increase in creatine kinase is observed or myopathy/rhabdomyolysis is diagnosed or suspected.
Olaparib: Moderate inhibitors of CYP3A4 such as fluconazole increase olaparib plasma concentrations, concomitant use is not recommended. If the combination cannot be avoided, limit the dose of olaparib to 200 mg twice daily.
Immunosuppressors (i.e. ciclosporin, everolimus, sirolimus and tacrolimus):
Ciclosporin: Fluconazole significantly increases the concentration and AUC of ciclosporin. During concomitant treatment with fluconazole 200 mg daily and ciclosporin (2.7 mg/kg/day) there was a 1.8-fold increase in ciclosporin AUC. This combination may be used by reducing the dose of ciclosporin depending on ciclosporin concentration.
Everolimus: Although not studied in vivo or in vitro, fluconazole may increase serum concentrations of everolimus through inhibition of CYP3A4.
Sirolimus: Fluconazole increases plasma concentrations of sirolimus presumably by inhibiting the metabolism of sirolimus via CYP3A4 and P-glycoprotein. This combination may be used with a dose adjustment of sirolimus depending on the effect/concentration measurements.
Tacrolimus: Fluconazole may increase the serum concentrations of orally administered tacrolimus up to 5 times due to inhibition of tacrolimus metabolism through CYP3A4 in the intestines. No significant pharmacokinetic changes have been observed when tacrolimus is given intravenously. Increased tacrolimus levels have been associated with nephrotoxicity. Dose of orally administered tacrolimus should be decreased depending on tacrolimus concentration.
Losartan: Fluconazole inhibits the metabolism of losartan to its active metabolite (E-31 74) which is responsible for most of the angiotensin II-receptor antagonism which occurs during treatment with losartan. Patients should have their blood pressure monitored continuously.
Methadone: Fluconazole may enhance the serum concentration of methadone. Dose adjustment of methadone may be necessary.
Non-steroidal anti-inflammatory drugs: The Cmax and AUC of flurbiprofen was increased by 23% and 81%, respectively, when coadministered with fluconazole compared to administration of flurbiprofen alone. Similarly, the Cmax and AUC of the pharmacologically active isomer [S-(+)-ibuprofen] was increased by 15% and 82%, respectively, when fluconazole was coadministered with racemic ibuprofen (400 mg) compared to administration of racemic ibuprofen alone.
Although not specifically studied, fluconazole has the potential to increase the systemic exposure of other NSAIDs that are metabolised by CYP2C9 (e.g. naproxen, lornoxicam, meloxicam, diclofenac). Frequent monitoring for adverse events and toxicity related to NSAIDs is recommended. Adjustment of dose of NSAIDs may be needed.
Phenytoin: Fluconazole inhibits the hepatic metabolism of phenytoin. Concomitant repeated administration of 200 mg fluconazole and 250 mg phenytoin intravenously, caused an increase of the phenytoin AUC24 by 75% and Cmin by 128%. With coadministration, serum phenytoin concentration levels should be monitored in order to avoid phenytoin toxicity.
Prednisone: There was a case report that a liver-transplanted patient treated with prednisone developed acute adrenal cortex insufficiency when a three month therapy with fluconazole was discontinued. The discontinuation of fluconazole presumably caused an enhanced CYP3A4 activity which led to increased metabolism of prednisone. Patients on long-term treatment with fluconazole and prednisone should be carefully monitored for adrenal cortex insufficiency when fluconazole is discontinued.
Rifabutin: Fluconazole increases serum concentrations of rifabutin, leading to increase in the AUC of rifabutin up to 80%. There have been reports of uveitis in patients to whom fluconazole and rifabutin were coadministered. In combination therapy, symptoms of rifabutin toxicity should be taken into consideration.
Saquinavir: Fluconazole increases the AUC and Cmax of saquinavir with approximately 50% and 55% respectively, due to inhibition of saquinavir's hepatic metabolism by CYP3A4 and inhibition of P-glycoprotein. Interaction with saquinavir/ritonavir has not been studied and might be more marked. Dose adjustment of saquinavir may be necessary.
Sulfonylureas: Fluconazole has been shown to prolong the serum half-life of concomitantly administered oral sulfonylureas (e.g., chlorpropamide, glibenclamide, glipizide, tolbutamide) in healthy volunteers. Frequent monitoring of blood glucose and appropriate reduction of sulfonylurea dose is recommended during coadministration.
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 rate of theophylline. Patients who are receiving high dose theophylline or who are otherwise at increased risk for theophylline toxicity should be observed for signs of theophylline toxicity while receiving fluconazole. Therapy should be modified if signs of toxicity develop.
Vinca alkaloids: Although not studied, fluconazole may increase the plasma levels of the vinca alkaloids (e.g. vincristine and vinblastine) and lead to neurotoxicity, which is possibly due to an inhibitory effect on CYP3A4.
Vitamin A: Based on a case-report in one patient receiving combination therapy with all-trans-retinoid acid (an acid form of vitamin A) and fluconazole, CNS related undesirable effects have developed in the form of pseudotumor cerebri, which disappeared after discontinuation of fluconazole treatment. This combination may be used but the incidence of CNS related undesirable effects should be borne in mind.
Voriconazole: (CYP2C9, CYP2C19 and CYP3A4 inhibitor): Coadministration of oral voriconazole (400 mg Q12h for 1 day, then 200 mg Q12h for 2.5 days) and oral fluconazole (400 mg on day 1, then 200 mg Q24h for 4 days) to 8 healthy male subjects resulted in an increase in Cmax and AUC of voriconazole by an average of 57% (90% CI: 20%, 107%) and 79% (90% CI: 40%, 128%), respectively. The reduced dose and/or frequency of voriconazole and fluconazole that would eliminate this effect have not been established. Monitoring for voriconazole associated adverse events is recommended if voriconazole is used sequentially after fluconazole.
Zidovudine: Fluconazole increases Cmax and AUC of zidovudine by 84% and 74%, respectively, due to an approx. 45% decrease in oral zidovudine clearance. The half-life of zidovudine was likewise prolonged by approximately 128% following combination therapy with fluconazole. Patients receiving this combination should be monitored for the development of zidovudine-related adverse reactions. Dose reduction of zidovudine may be considered.
Azithromycin: An open-label, randomized, three-way crossover study in 18 healthy subjects assessed the effect of a single 1200 mg oral dose of azithromycin on the pharmacokinetics of a single 800 mg oral dose of fluconazole as well as the effects of fluconazole on the pharmacokinetics of azithromycin. There was no significant pharmacokinetic interaction between fluconazole and azithromycin.
Oral contraceptives: Two pharmacokinetic studies with a combined oral contraceptive have been performed using multiple doses of fluconazole. There were no relevant effects on hormone level in the 50 mg fluconazole study, while at 200 mg daily, the AUCs of ethinyl estradiol and levonorgestrel were increased 40% and 24%, respectively. Thus, multiple dose use of fluconazole at these doses is unlikely to have an effect on the efficacy of the combined oral contraceptive.
Ivacaftor: Co-administration with ivacaftor, a cystic fibrosis transmembrane conductance regulator (CFTR) potentiator, increased ivacaftor exposure by 5-fold and hydroxymethyl-ivacaftor (M1) exposure by 1.9-fold. A reduction of the ivacaftor dose to 150 mg once daily is recommended for patients taking concomitant moderate CYP3A inhibitors, such as fluconazole and erythromycin.
4.6 Fertility, pregnancy and lactation
Pregnancy
An observational study has suggested an increased risk of spontaneous abortion in women treated with fluconazole during the first trimester.
There have been reports of multiple congenital abnormalities (including brachycephalia, ears dysplasia, giant anterior fontanelle, femoral bowing and radio-humeral synostosis) in infants whose mothers were treated for at least three or more months with high doses (400 - 800 mg daily) of fluconazole for coccidioidomycosis. The relationship between fluconazole use and these events is unclear.
Fluconazole in standard doses and short-term treatments should not be used in pregnancy unless clearly necessary.
Fluconazole in high dose and/or in prolonged regimens should not be used during pregnancy except for potentially life-threatening infections.
Breast-feeding
Fluconazole passes into breast milk to reach concentrations similar to those in plasma. Breast-feeding may be maintained after a single dose of 150 mg fluconazole. Breast-feeding is not recommended after repeated use or after high dose fluconazole. The developmental and health benefits of breast-feeding should be considered along with the mother's clinical need for Fungican and any potential adverse effects on the breast-fed child from Fungican or from the underlying maternal condition.
4.7 **Effects on ability to drive and use machines**
No studies have been performed on the effects of fluconazole on the ability to drive or use machines.
Patients should be warned about the potential for dizziness or seizures while taking fluconazole and should be advised not to drive or operate machines if any of these symptoms occur.
4.8 Undesirable effects
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.
The following adverse reactions have been observed and reported during treatment with fluconazole with the following frequencies: Very common (≥ 1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000), not known (cannot be estimated from the available data).

System Organ Class	Common	Uncommon	Rare	Not known
Blood and the lymphatic system disorders		Anaemia	Agranulocytosis, leukopenia, thrombocytopenia, neutropenia	
Immune system disorders			Anaphylaxis	
Metabolism and nutrition disorders	Decreased appetite	Hypercholesterolaemia, hypokalemia	hypertriglyceridemia, hypoalbuminemia	
Psychiatric disorders		Sleeplessness, drowsiness		
Nervous system disorders	Headache	Seizures, paresthesia, 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		
Hepatobiliary 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, pruritus, increased sweating	Toxic epidermal necrolysis, Stevens-Johnson syndrome, acute generalised exanthematous pustulosis, dermatitis exfoliative, 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, excluding the genital candidiasis indication, are comparable to those seen in adults.
Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
4.9 Overdose
There have been reports of overdose with fluconazole. Hallucination and paranoid behaviour have been concomitantly reported.
In the event of overdose, symptomatic treatment (with supportive measures and gastric lavage if necessary) may be adequate.
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
Mechanism of action
Fluconazole is a triazole antifungal agent. Its primary mode of action is the inhibition of fungal cytochrome P-450-mediated 14 alpha-lanosterol demethylation, an essential step in fungal ergosterol biosynthesis. The accumulation of 14 alpha-methyl sterols correlates with the subsequent loss of ergosterol in the fungal cell membrane and may be responsible for the antifungal activity of fluconazole. Fluconazole has been shown to be more selective for fungal cytochrome P-450 enzymes than for various mammalian cytochrome P-450 enzyme systems.
Fluconazole 50 mg daily given up to 28 days has been shown not to effect testosterone plasma concentrations in males or steroid concentration in females of child-bearing age. Fluconazole 200 mg to 400 mg 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 50 mg do not affect its metabolism.
Susceptibility in vitro:
In vitro, fluconazole displays antifungal activity against most clinically common Candida species (including *C. albicans, C. parapsilosis, C. tropicalis*). *C. glabrata* shows a wide range of susceptibility while *C. krusei* is resistant to fluconazole.
Fluconazole also exhibits activity *in vitro* against *Cryptococcus neoformans* and *Cryptococcus. gattii* as well as the endemic moulds *Blastomyces dermatitidis, Coccidioides immitis, Histoplasma capsulatum* and *Paracoccidioides brasiliensis.*
5.2 Pharmacokinetic properties
The pharmacokinetic properties of fluconazole are similar following administration by the intravenous or oral route.
Absorption
After oral administration fluconazole is well absorbed, and plasma levels (and systemic bioavailability) are over 90% of the levels achieved after intravenous administration. Oral absorption is not affected by concomitant food intake. Peak plasma concentrations in the fasting state occur between 0.5 and 1.5 hours post-dose. Plasma concentrations are proportional to dose. Ninety percent steady state levels are reached by day 4-5 with multiple once daily dosing. Administration of a loading dose (on day 1) of twice the usual daily dose enables plasma levels to approximate to 90% steady-state levels by day 2.
Distribution
The apparent volume of distribution approximates to total body water. Plasma protein binding is low (11-12%).
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% the corresponding plasma levels. High skin concentration of fluconazole, above serum concentrations, are achieved in the stratum corneum, epidermis-dermis and excrine sweat. Fluconazole accumulates in the stratum corneum. At a dose of 50 mg once daily, the concentration of fluconazole after 12 days was 73 µg/g and 7 days after cessation of treatment the concentration was still 5.8 µg/g. At the 150 mg once-a-week dose, the concentration of fluconazole in stratum corneum on day 7 was 23.4 µg/g and 7 days after the second dose was still 7.1 µg/g.
Concentration of fluconazole in nails after 4 months of 150 mg once-a-week dosing was 4.05 µg/g in healthy and 1.8 µg/g in diseased nails; and fluconazole was still measurable in nail samples 6 months after the end of therapy.
Biotransformation
Fluconazole is metabolised only to a minor extent. Of a radioactive dose, only 11% is excreted in a changed form in the urine. Fluconazole is a moderate inhibitor of the isozymes CYP2C9 and CYP3A4. Fluconazole is also a strong inhibitor of the isozyme CYP2C19.
Elimination
Plasma elimination half-life for fluconazole is approximately 30 hours. The major route of excretion is renal, with approximately 80% of the administered dose appearing in the urine as unchanged medicinal product. Flu

فَنچيكان®

فلوكونازول ١٥٠ مجم

مضاد للفطريات واسع المدى

اقرأ هذه النشرة بعناية قبل البدء في تناول هذا الدواء لأنه يحتوي على معلومات مهمة بالنسبة لك.
– احتفظ بهذه النشرة. قد تحتاج لقراءتها مرة أخرى.
– إذا كان لديك أي أسئلة أخرى، اسأل طبيبك أو الصيدلي.
– تم وصف هذا الدواء لك فقط، فلا تصفه للآخرين لانه قد يؤذيهم، حتى لو كانت لديهم نفس اعراض المرض الذى تعانى منه.
– إذا حدث لك أي آثار جانبية، فأخبر طبيبك أو الصيدلي. يتضمن ذلك أي آثار جانبية أخرى غير مدرجة في هذه النشرة.

ماذا في هذه النشرة:

١. ما هو فنچيكان® و ما هو استخداماته
٢. ما تحتاج إلى معرفته قبل أن تأخذ فنچيكان®
٣. كيف تأخذ فنچيكان®
٤. الآثار الجانبية المحتملة
٥. كيفية تخزين فنچيكان®
٦. محتويات العبوة وغيرها من المعلومات

١ - ما هو فنچيكان® و ما هو استخداماته

ينتمى **فنچيكان®** الى مجموعة من الأدوية تسمى "مضادات الفطريات". المادة الفعالة فى **فنچيكان®** هى فلوكونازول. يستخدم **فنچيكان®** لعلاج التهابات الفطريات ويمكن أيضا أن يستخدم للوقاية من الإصابة بالعدوي الفطريه الكانديدا. السبب الأكثر شيوعا للإصابات الفطرية هو خميرة تسمى الكانديدا.

الكبار / البالغين

يستخدم هذا الدواء من قبل طبيبك لعلاج الانواع التاليه من العدوي الفطريه او الالتهابات الفطريه:
– التهاب السحايا الفطرية وهو التهاب فطري يصيب المخ.
– كوكيديود ميكوزيس – مرض فطرى يصيب الجهاز الرئوي.
– عدوى الكانديدا التى تصيب مجرى الدم ، أعضاء الجسم (مثل القلب والرئتين) او المسالك البولية.
– اصابات الاغشية المخاطية (الفلاع المخاطي) ، التي تصيب بطانة الفم والحلق وقرح تركيبات الاسنان.
– الفطريات التناسلية التى تصيب المهبل و القضيب.
– الالتهابات الفطرية الجلدية، مثل قدم الرياضي، القوباء الحلقية، الحكة، فطريات الأظافر

قد يتم وصف فنچيكان® ايضا فى:
– منع تكرار الاصابة بالتهاب السحايا الفطرية.
– منع عودة عدوى الفلاع المخاطي.
– الحد من تكرار الاصابة بالفطريات المهبلية.
– الوقاية من الاصابة بالكانديدا (فى حالة ضعف الجهاز المناعى).

الأطفال والمراهقون (من ٠ إلى ١٧ سنة)

قد يصف الطبيب هذا الدواء لعلاج الأنواع التالية من الفطريات :
– الفلاع المخاطي ، العدوى التي تصيب بطانة الفم والحنجرة
– الفطريات التي تسببها الكانديدا في مجرى الدم ، أعضاء الجسم (مثل القلب، الرئتين) أو المسالك البولية
– التهاب السحايا الفطرى، وهو التهاب فطري يصيب المخ.

قد يتم وصف فنچيكان® ايضا فى:
– الوقاية من الفطريات التي تسببها الكانديدا (فى حالة ضعف الجهاز المناعي).
– منع تكرار الاصابة بالتهاب السحايا الفطرى.

٢ - ما تحتاج إلى معرفته قبل أن تأخذ فنچيكان®

يجب ان لا تأخذ **فنچيكان®** فى الحالات الاتية:
– إذا كان لديك حساسية من فلوكونازول، او من أدوية أخرى قمت بتناولها لعلاج الفطريات أو لأي من المكونات الأخرى لهذا الدواء. قد تشمل أعراض الحساسية: حكة ، احمرار في الجلد أو صعوبة في التنفس
– إذا كنت تأخذ استميزول، تيرفينادين (أدوية مضادة للحساسية).
– إذا كنت تأخذ سيزابرايد (يستخدم لإضطرابات المعدة).
– إذا كنت تتناول بيمازيد (يستخدم لعلاج الأمراض العقلية).
– إذا كنت تتناول الكينيدين (يستخدم لعلاج عدم انتظام ضربات القلب).
– إذا كنت تتناول الاريثروميسين (مضاد حيوي).

التحذيرات و الاحتياطات

يجب استشارة طبيبك أو الصيدلي قبل تناول **فنچيكان®** فى الحالات الاتية :
– إذا كنت تعاني من قصور في الكبد أو الكلى.
– إذا كنت تعاني من مرض بالقلب، مثل عدم انتظام ضربات القلب.
– إذا كان لديك مستويات غير طبيعية من البوتاسيوم أو الكالسيوم أو المغنيسيوم في الدم.
– إذا كان لديك حساسية جلدية شديدة (حكة أو احمرار في الجلد أو صعوبة في التنفس).
– إذا كان لديك قصور فى الغدة الكظرية حيث لا تنتج الغدة الكظرية كميات كافية من الكورتيزول (تعب مزمن، ضعف العضلات، فقدان الشهية، فقدان الوزن، آلام في البطن).

تناول ادوية اخرى مع فنچيكان®

يجب أن تخبر طبيبك أو الصيدلي في الحال إذا كنت تأخذ ، أو اخذت مؤخرا اى أدوية اخرى مثل :
– استيميزول ، تيرفينادين (مضادات حساسية).
– سيزابرايد (لعلاج اضطرابات المعدة).
– البيموزيد (يستخدم لعلاج بعض الامراض العقلية).
– الكينيدين (يستخدم لعلاج عدم انتظام ضربات القلب).
– الاريثروميسين (مضاد حيوي).

حيث لا ينبغي أن تؤخذ اى من هذه الادوية مع **فنچيكان®**.

هناك بعض الأدوية التي قد تتفاعل مع فلوكونازول. تأكد من اخبار طبيبك إذا كنت تأخذ أي من الأدوية التالية:
– ريفاميسين أو ريفابوتين(مضادات حيوية).
– الفنتانيل، فينتانيل (يستخدم كمخدر).
– اميتريبيتلين، نورتريبيتلين (مضادات للاكتئاب).
– الأمفوتريسين B، فوريكونازول (مضادات للفطريات).
– الأدوية التي تستخدم لمنع تجلط الدم (وارفارين و الأدوية المماثلة).
– البنزوديازيبينات (ميدازولام، تريازولام و الأدوية المماثلة) التى تستخدم للمساعدة على النوم أو لعلاج القلق.
– كاربامازيبين، فينيتوين (لعلاج نوبات الصرع).
– نيفيديبين، اسراديبين، أملوديبين، فيلوديبين ولوسارتان (لعلاج ارتفاع الضغط).
– اولابارب (يستخدم لعلاج سرطان المبيض).
– سيكلوسبورين، أيفيموليموس، سيروليموس أو تاكروليماس (لمنع رفض الاعضاء المزروعة).
– سيكلوز فوسفاميد، قلويات فينكا (فينكريستين، فينبلاستين أو أدوية مماثلة) لعلاج السرطان.
– هالوفانترين (يستخدم لعلاج الملاريا).
– استاتينات (أتورفاستاتين، سيمفاستاتين، فلوفاستاتين أو أدوية مماثلة) تستخدم للحد من ارتفاع مستويات الكوليسترول.
– الميثادون (لعلاج الألم).
– سيليكوكسيب، فلوربيبروفين، نابروكسين، ايبوبروفين، لورنوكسيكام، ميلوكسيكام، ديكلوفيناك (مضادات الالتهابات غير الستيرويدية) (NSAID).
– حبوب منع الحمل.
– بريدنيزون (ستيرويد).
– زيدوفودين، المعروف أيضًا باسم AZT، ساكينافير (يستخدم في علاج المرضى المصابين بفيروس نقص المناعة البشرية).
– أدوية علاج مرض السكري مثل كلوربروباميد، جليبينكلاميد، جليبيزيد أو تولبوتاميد.
– الثيوفيلين (يستخدم لعلاج الربو).
– فيتامين أ (مكمل غذائي).
– ايباكاهتور (يستخدم لعلاج تكيسات المبيض).
– أميودارون (يستخدم لعلاج عدم انتظام ضربات القلب).
– هيدروكلوروثيازيد (مدر للبول)

تناول فنچيكان® مع الطعام والشراب

يمكنك تناول فنچيكان مع أو بدون وجبة الطعام.

الحمل والرضاعة الطبيعية والخصوبة

إذا كنت حاملاً أو ترضعين رضاعة طبيعية، او تشكين أنك حامل أو تخططين لذلك، فاطلبى من طبيبك أو الصيدلي النصيحة قبل تناول هذا الدواء. يجب أن لا يؤخذ فلوكونازول أثناء الحمل ما لم يسمح طبيبك بذلك. يمكنك الاستمرار في الرضاعة الطبيعية بعد تناول جرعة واحدة من فلوكونازول ١٥٠ مجم، ولكن يجب عليك وقف الرضاعة إذا كنت تأخذين جرعات متكررة من فلوكونازول.

القيادة واستخدام الآلات

عند قيادة المركبات أو استخدام الآلات، يجب أن يؤخذ بعين الاعتبار انه قد يسبب تناول فلوكونازول فى بعض الاحيان دوخة أو نوبات صرع.

٣. كيف تأخذ فنچيكان®

يجب ان تتناول الدواء تمامًا حسب ارشادات طبيبك. راجع طبيبك أو الصيدلي إذا كنت غير متأكد من اى معلومة.
ابتلع الكبسولة كاملة مع كوب من الماء، من الأفضل أخذ الكبسولة في نفس الوقت كل يوم.
الجرعات الموصى بها من هذا الدواء للاستخدامات المختلفة هي :

البالغين

الحالة	الجرعة
لعلاج التهاب السحايا الفطرية	٤٠٠ مجم فى اليوم الاول ثم ٢٠٠ – ٤٠٠ مجم يوميا لمدة ٦ – ٨ اسابيع و ممكن زيادة مدة العلاج حسب الحاجة. كما يمكن زيادة الجرعة حتى ٨٠٠ مجم
لمنع تكرار الاصابة بالتهاب السحايا الفطرية	٢٠٠ مجم يوميا حتى يطلب منك الطبيب وقف العلاج
لعلاج كوكيديود ميكوزيس	٢٠٠ مجم – ٤٠٠ مجم يوميا لمدة ١١ – ٢٤ شهر أو أكثر حسب الاحتياج. يمكن زيادة الجرعة حتى ٨٠٠ مجم
لعلاج الالتهابات الفطرية الداخلية التي تسببها الكانديدا	٨٠٠ مجم اول يوم ثم ٤٠٠ مجم يوميا حتى يطلب منك طبيبك وقف العلاج
لعلاج التهابات الاغشية المخاطية المبطنة للفم	٢٠٠ مجم – ٤٠٠ مجم اول يوم ثم ١٠٠ – ٢٠٠ مجم والحلق و
قرح تركيبات الاسنان	يوميا حتى يطلب طبيبك وقف العلاج
لعلاج مرض القلاع المخاطي – تتوقف الجرعة على مكان الاصابة	٥٠ مجم – ٤٠٠ مجم يوميا لمدة ٧ – ٣٠ يوم ، حتى يطلب طبيبك وقف العلاج
لمنع تكرار الاصابة بالتهابات الاغشية المخاطية المبطنة للفم والحلق	١٠٠ مجم – ٢٠٠ مجم يوميا أو ٢٠٠ مجم ٣ مرات اسبوعيا، اذا كنت اكثر عرضة للاصابة بالفطريات
لعلاج الفطريات التناسلية	جرعة واحدة ١٥٠ مجم
للحد من تكرار الاصابة بالفطريات التناسلية	١٥٠ مجم كل ثلاثة ايام ٣ جرعات (يوم ١،٤،٧) ثم مرة واحدة اسبوعيا لمدة ٦ شهور ، اذا كنت اكثر عرضة للاصابة
لعلاج الفطريات الجلدية و فطريات الاظافر	تعتمد الجرعة حسب مكان الاصابة: ٥٠ مجم يوميا ، ١٥٠ مجم اسبوعيا، ٢٠٠ مجم – ٤٠٠ مجم اسبوعيا لمدة ١ – ٤ اسابيع (قد تحتاج فطريات القدم الى العلاج لمد ٦ اسابيع. أما فطريات الاظافر فيستمر العلاج حتى ينمو الظافر الجديد)
لمنع الاصابة بالفطريات التى يسببها فطر الكانديدا (فى حالة قصور جهازك المناعى)	٢٠٠ مجم – ٤٠٠ مجم يوميا، اذا كنت اكثر عرضة للاصابة

المراهقين من سن ١٢ – ١٧ عام

يجب تناول الجرعة الموصوفة من قبل طبيبك (سواء الكبار أو الأطفال حسب رؤيته)

الاطفال حتى سن ١١ عام

الجرعة القصوى للاطفال هى ٤٠٠ مجم يوميا. تتوقف جرعة الاطفال على وزن الطفل.

الحالة	الجرعة اليومية
فطريات الاغشية المخاطية المبطنة للفم والحلق الناجمة عن الكانديدا– تعتمد الجرعة ومدة العلاج على شدة و مكان الاصابة	٣ مجم / كجم يوميا (يمكن ان يعطى ٦ مجم / كجم فى اول يوم)
التهاب السحايا الفطرية أو الالتهابات الفطرية الداخلية التى تسببها الكانديدا	٦ مجم – ١٢ مجم / كجم يوميا
لمنع تكرار الاصابة بالتهاب السحايا الفطرية	٦ مجم / كجم يوميا
لوقاية الاطفال من الاصابات الفطرية بواسطة فطر الكانديدا (فى حالة قصور الجهاز المناعى)	٣ مجم – ١٢ مجم / كجم يوميا

الأطفال من عمر ٠ إلى ٤ أسابيع من العمر

•الأطفال من ٣ إلى ٤ أسابيع من العمر:
تعطى نفس الجرعة المذكورة أعلاه ولكنها تعطى مرة كل يومين. الجرعة القصوى هي ١٢ مجم لكل كيلوجرام من وزن الجسم كل ٤٨ ساعة.

•الأطفال أقل من أسبوعين:
تعطى نفس الجرعة المذكورة أعلاه ولكن تعطى مرة واحدة كل ٣ أيام. الجرعة القصوى هي ١٢ مجم لكل كيلوجرام من وزن الجسم كل ٧٢ ساعة.

كبار السن

يعطى جرعة البالغين المعتادة إلا إذا كان لديه قصور في الكلى.

المرضى الذين يعانون من قصور في الكلى

قد يقوم طبيبك بتغيير الجرعة ، اعتمادا على وظائف الكلى.

إذا كنت قد أخذت جرعة اكبر من الموصوفة لك

أخذ الكثير من الكبسولات مرة واحدة قد يعرضك للمرض. اتصل بطبيبك أو توجه الى قسم الطوارئ فى أقرب مستشفى. تشمل أعراض تناول جرعة زائدة : هلاوس فى السمع والرؤية والشعور والتفكير. يجب اخذ علاج للأعراض وغسيل المعدة إذا لزم الأمر.

إذا كنت قد نسيت أن تأخذ جرعة من فنچيكان®

لا تأخذ جرعة مضاعفة لتعويض الجرعة المنسية. إذا نسيت أخذ جرعة، خذها حالما تتذكرها. إذا كان الوقت قد حان للجرعة التى تليها ، فلا تأخذ الجرعة التي فاتك.
إذا كان لديك أي أسئلة أخرى حول استخدام هذا الدواء ، فاسأل طبيبك أو الصيدلي.

٤. الآثار الجانبية المحتملة

مثل جميع الأدوية، يمكن أن يسبب **فنچيكان®** آثارا جانبية، على الرغم من عدم حدوثها للجميع.
قد تحدث بعض اعراض الحساسية لدى قلة من الناس مع ندرة احتمال حدوث تفاعلات حساسية خطيرة.
اذا كان لديك أي من الأعراض التالية ، أخبر طبيبك فورا.
• حدوث صفير مفاجئ بالصدر، صعوبة في التنفس أو ضيق في الصدر.
• تورم في الوجه والجفون أو الشفاه.
•حكة في جميع أنحاء الجسم، احمرار الجلد أو ظهور بقع حمراء به.
•طفح جلدي.
•تفاعلات جلدية شديدة مثل الطفح الجلدي الذي يسبب فقاعات (بالاخص الفم واللسان).

قد يؤثر فلوكونازول على الكبد. تشمل اعراض متاعب الكبد الاتى:
–الوهن.
–فقدان الشهية.
–القيئ.
–اصفرار الجلد او بياض العين (اليرقان).
اذا شكوت من هذه الاعراض فاستشر طبيبك فورا.

الاعراض الجانبية الاخرى

اذا لاحظت ان الاعراض الجانبية الاتية تزداد سوءا او اذا شكوت من حدوث اعراض جانبية اخرى غير مدرجة فى هذه النشرة، فاخبر طبيبك او الصيدلي.

الآثار الجانبية الشائعة (تؤثر على ١ من كل ١٠ أشخاص) هي:
– الصداع.
– اضطراب في المعدة، اسهال، الشعور بالغثيان، والتقيؤ.
– ارتفاع انزيمات وظائف الكبد فى الدم.
– طفح جلدى.

الآثار الجانبية غير الشائعة (تؤثر على ١ من كل ١٠٠ شخص) هي:
– انخفاض في عدد خلايا الدم الحمراء التي تؤدى الى شحوب البشرة وتسبب ضعف أوضيق التنفس.
– ضعف الشهية.
– الارق، الشعور بالنعاس.
– دوخة، دوار، شعور بالوخز، خدر، تغييرات في حاسة التذوق.
– الإمساك، صعوبة الهضم، انتفاخ، جفاف الفم.
– ألم عضلي
– قصور الكبد واصفرار الجلد والعينين (اليرقان)
– طفح جلدى ، تقرحات ، حكة ، زيادة التعرق
– التعب والشعور العام بعدم الارتياح ، حمى

الآثار الجانبية النادرة (تؤثر على ١ من كل ١٠٠٠ شخص) هي:
•عدد اقل من المعتاد من خلايا الدم البيضاء (التي تساعد في الدفاع ضد الالتهابات) و كذلك الصفائح الدموية التي تساعد على وقف النزيف.
• يتغير لون الجلد الي اللون الأحمر أو الأرجواني الناتج عن انخفاض عدد الصفائح الدموية وخلايا الدم الأخرى
• ارتفاع مستويات الدهون والكولسترول في الدم
• انخفاض البوتاسيوم في الدم
• اهتزاز
• تغير فى رسم القلب الكهربى (ECG)، تغير في معدل او ايقاع ضربات القلب
• قصور الكبد
• تفاعلات حساسية (قد تكون شديدة) مثل تقرحات ، تنشير بالجلد ، تورم الشفتين و الوجه
• تساقط الشعر

آثار جانبية ذات معدلات غير معروفة ، ولكن قد تحدث (لا يمكن تقديرها من البيانات المتاحة):
– فرط الحساسية مع طفح جلدي، حمى، تورم فى بعض الغدد، زيادة عدد نوع من خلايا الدم البيضاء، التهاب فى الأعضاء الداخلية مثل (الكبد، الرئتين، القلب، الكليتين، الأمعاء الغليظة)و (تفاعلات دوائية أو الطفح الجلدي مع فرط الحمضات والأعراض العامه)

الابلاغ عن الاثار الجانبية

إذا حدث لك أي آثار جانبية، فأخبر طبيبك أو الصيدلي أو الممرضة، بما فى ذلك أي آثار جانبية غير مدرجة في هذه النشرة. من خلال الابلاغ عن الآثار الجانبية ، يمكنك المساعدة في تقديم مزيد من المعلومات حول سلامة هذا الدواء.

٥ - كيفية تخزين فنچيكان®

• يحفظ فى مكان آمن بعيد آ عن متناول أيدى الأطفال.
• يحفظ فى مكان جاف و درجة حرارة لا تزيد على ٣٠ درجة مئوية و في مكان جاف.
• لا تستخدم فنچيكان بعد تاريخ انتهاء الصلاحية المدونة. تاريخ الانتهاء يشيرالى اليوم الأخير من ذلك الشهر.

لا ينبغي أن يتم التخلص من الأدوية عن طريق مياه الصرف الصحي أو النفايات المنزلية. اسأل الصيدلي عن كيفية التخلص من الأدوية التي لم تعد مطلوبة. سوف تساعد هذه التدابير على حماية البيئة.

٦- مزيد من المعلومات

• ماذا يحتوي **فنچيكان®**
– مزيد من المعلومات
– المادة الفعالة هي ١٥٠ مجم فلوكونازول.
– المكونات الأخرى هي :
ميكروكريستالين سيلليلوز، ثنائى القاعدة فوسفات الكالسيوم، اليوفيدون ك ٣٠، كروسكارميلوز الصوديوم، استيارات المغنيسيوم، التلك النقى.
– كل كبسولة تحتوى على: جيلاتين ، ثانى اكسيد التيتانيوم، انديجو كاريمين اف د و سى بلو .

العبوة

علبة كارتون تحتوى على ١ ، ٢ ، ٣ (الومنيوم / بى فى سى شفاف) شرائط ، بكل شريط كبسولة جيلاتينية صلبة واحدة + نشرة داخلية.

تحفظ جميع الأدوية بعيداً عن متناول الأطفال

انتاج
شركة آمون للأدوية ش.م.م
مدينة العبور، القليوبية، مصر.
V09-24/1/2021
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