Package leaflet: Information for the user

Fluconazole-ratiopharm® 150 mg hard capsules
Active substance: Fluconazole

Read the entire package leaflet carefully before you start taking this medicine.
- Keep the package leaflet. You may want to read it again later.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you personally. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this package leaflet, please tell your doctor or pharmacist.

This package leaflet contains:

1. WHAT IS Fluconazole-ratiopharm® 150 mg AND WHAT IS IT USED FOR?

Fluconazole is a medicine used to treat a variety of fungal infections. Fluconazole, the active substance in Fluconazole-ratiopharm® 150 mg,
belongs to a group of medicines called triazole derivatives.
Fluconazole-ratiopharm 150 mg is used in the treatment of fungal infections that are known or likely to respond to
fluconazole:
- Acute or recurrent vaginal candidiasis (fungal infection of the vagina caused by the yeast Candida) that does not respond adequately to a local treatment.
- Fungal infections of the mucous membranes caused by Candida, such as oropharyngeal (mouth and throat), esophageal (esophagus), mucocutaneous (skin and mucous membrane), and non-invasive bronchopulmonary (upper respiratory tract involvement without lung involvement) candidiasis as well as candiduria (Candida pathogens in the urine) in immunocompromised patients.
- Fungal infections caused by yeasts of the genus Candida with involvement of internal organs (systemic candidiasis), including proven yeasts in the blood (candidemia), one or more organs affected (disseminated) deep Candida-infections and infections of the peritoneum (peritonitis).
- For the prevention of fungal infections (Candida infections) in patients with reduced white blood cells (neutropenic patients; e.g., due to AIDS or bone marrow transplantation).
- Treatment and preventive treatment (relapse prophylaxis) of cryptococcal-Meningitis (infection of the meninges with the yeast fungus Cryptococcus neoformans) in immunocompromised patients.
- Proven fungal infections of the skin caused by certain fungi (dermatophytes, Candida, or other species) (fungal skin diseases of the body [Tinea corporis] and the lower legs [Tinea

cruris], athlete's foot [Tinea pedis], and pityriasis versicolor), when a topical treatment has not responded or is considered unsuitable. In pityriasis versicolor only if the pathogens are resistant to first-line therapy or the infection occurs in immunocompromised patients.
- Proven nail fungal infections (onychomycoses).

Not all the mentioned indications apply to children. For more details, see section 3.

2. WHAT SHOULD YOU CONSIDER BEFORE TAKING Fluconazole-ratiopharm® 150 mg?

Fluconazole-ratiopharm® 150 mg must not be taken
- if you are hypersensitive (allergic) to fluconazole or any of the other ingredients of Fluconazole-ratiopharm® 150 mg.
- if you are being treated simultaneously with cisapride (a medicine for treating intestinal disorders), astemizole (a medicine for treating allergies), terfenadine (a medicine for treating allergies), pimozide (a medicine for treating schizophrenia), and quinidine (a medicine for treating heart rhythm disorders) (see also "Taking Fluconazole-ratiopharm® 150 mg with other medicines").

Special caution is required when taking Fluconazole-ratiopharm® 150 mg
- In rare cases, Fluconazole-ratiopharm® 150 mg can cause severe skin reactions with blistering and detachment of the skin (Stevens-Johnson syndrome, toxic epidermal necrolysis). If you develop a rash while being treated with Fluconazole-ratiopharm® 150 mg, you must inform your doctor immediately, who will decide on any necessary measures. AIDS patients tend to have severe skin reactions when taking many medications.
- if you are being treated simultaneously with halofantrine (a medicine for treating malaria) or terfenadine (a medicine for treating allergies) treated. Please inform your doctor about this before starting treatment with Fluconazole-ratiopharm® 150 mg.
- if you suffer from a congenital or acquired change in your heart activity (QT prolongation, which shows in the ECG).
- if you are simultaneously receiving medications that also prolong the QT interval in the ECG, e.g., medications for the treatment of heart rhythm disorders (antiarrhythmics) of class IA or III.
- if you suffer from an electrolyte imbalance and especially from low potassium and magnesium levels.
- if you suffer from a low heart rate requiring treatment (bradycardia), heart rhythm disorders, or severe heart failure.

During treatment with Fluconazole-ratiopharm® 150 mg, changes in liver and kidney values as well as blood counts, such as a reduced number of white blood cells (leukocytopenia) and a reduced number of blood platelets (thrombocytopenia) were observed in some patients, especially those with severe underlying conditions such as AIDS and malignant diseases.

Rarely, in patients who died from severe underlying conditions and had received multiple doses of fluconazole, autopsy findings included liver cell necrosis. These patients had simultaneously received several medications, some of which have a hepatotoxic effect, and/or had underlying conditions that could have caused the liver cell necrosis.

Since a possible connection with fluconazole cannot be ruled out, patients who develop abnormal liver function values during treatment with fluconazole must be carefully monitored for the development of more severe liver damage. If signs or symptoms occur during treatment with fluconazole that indicate liver disease (such as yellowing of the skin and eyes, dark urine, itching, loss of appetite, or abdominal pain), fluconazole must be discontinued.

Elderly people
In elderly patients without evidence of impaired kidney function, the usual dosage recommendations should be followed. In patients with impaired kidney function (creatinine clearance below 50 ml/min), the dosage should be adjusted according to the guidelines for patients with impaired kidney function.

Patients with impaired liver function
If you suffer from severely impaired liver function, you should only use Fluconazole-ratiopharm® 150 mg with appropriate precautions until more extensive experience is available. Please discuss this with your doctor. Patients with impaired kidney function

Patients with impaired renal function
When taking Fluconazole-ratiopharm® 150 mg with other medicines Please inform your doctor or pharmacist if you are taking/using or have recently taken/used other medicines, even if they are non-prescription medicines. to take?").

Astemizole (medicine for the treatment of allergies)
Cisapride (medicine for the treatment of intestinal disorders) Terfenadine (medicine for the treatment of allergies)

Pimozide (medicine for the treatment of schizophrenia)
- Quinidine (medicine for the treatment of heart rhythm disorders)
- The effect of Fluconazole-ratiopharm® 150 mg can be influenced by simultaneous treatment with the following medicines or groups of medicines:
- Please inform your doctor before taking any of these medicines simultaneously with Fluconazole-ratiopharm® 150 mg.
- Hydrochlorothiazide (water tablets)
- Rifampicin (medicine for the treatment of tuberculosis)

The effect of Fluconazole-ratiopharm® 150 mg can be influenced by concurrent treatment with the following medications or groups of medications
be influenced:
Please inform your doctor before taking any of these medications simultaneously with Fluconazole-ratiopharm® 150 mg.
- Hydrochlorothiazide (water tablets)
- Rifampicin (medication for the treatment of tuberculosis)

Fluconazole-ratiopharm® 150 mg can affect the action of the following medicines when used simultaneously:
When used simultaneously, Fluconazole-ratiopharm® 150 mg can significantly affect the breakdown of the following medicines, which can impair their effect or lead to an increase in side

effects. Please inform your doctor before taking any of these medicines simultaneously with Fluconazole-ratiopharm® 150 mg.

- Alfentanil (anesthetic)
- Amitriptyline (medicine for the treatment of depression)
- Oral medicines for diabetes of the sulfonylurea type (e.g. Glimepiride, Glibenclamide, Glipizide, Tolbutamide)
- Anticoagulants of the coumarin type (e.g. Warfarin)
- Benzodiazepines (mood-enhancing medicines, e.g. sedatives like Midazolam, Triazolam)
- Calcium antagonists
- Carbamazepine (medicine for the treatment of epilepsy)
- Celecoxib (medicine against inflammation)
- Didanosine (antiviral, medicine for the treatment of HIV infections)
- Ergot alkaloids (medicines for constricting blood vessels)
- Fluvastatin (medicine for lowering elevated cholesterol levels)
- Halofantrine (medicine for the treatment of malaria)
- Medicines for suppressing the immune response: Ciclosporin, Sirolimus, Tacrolimus
- Isoniazid (medicine for the treatment of tuberculosis)
- Phenytoin (medicine for the treatment of epilepsy)
- Rifabutin (antibiotic, drug for the treatment of tuberculosis)
- Theophylline
- Trimetrexate (cytostatic)
- Xanthine (additional agents for the treatment of epileptic seizures)
- Zidovudine (antiviral, drug for the treatment of HIV infections)

- HMG-CoA reductase inhibitors

If you notice symptoms such as muscle pain, weakness, or fatigue during concurrent treatment with Fluconazole-ratiopharm® 150 mg and drugs that lower blood lipid levels (HMG-CoA reductase inhibitors) such as atorvastatin, please inform your doctor immediately. These may be signs of changes in skeletal muscles (myopathy) or a loss of muscle cells (rhabdomyolysis). Your doctor will decide whether further concurrent treatment is possible.

- Oral contraceptives (birth control pills)

Fluconazole-ratiopharm® 150 mg is unlikely to negatively affect the effectiveness of oral contraceptives (birth control pills).

- Losartan (drug for the treatment of high blood pressure)

The concurrent administration of losartan and Fluconazole-ratiopharm® 150 mg impairs the conversion of losartan into its active form, which is responsible for its effects. This may lead to a decrease in the effectiveness of losartan. Please inform your doctor before taking these medications concurrently.

- Methadone

There have been reports of an interaction following concurrent administration of methadone and Fluconazole-ratiopharm® 150 mg. If you If you are taking methadone, please inform your doctor before starting treatment with Fluconazole-ratiopharm® 150 mg. doctor about it.

- Prednisone

Fluconazole inhibits the breakdown of glucocorticosteroids. After discontinuation of fluconazole, there may be an increased breakdown of prednisone which triggers adrenal insufficiency (Addison's crisis). Patients undergoing long-term treatment with fluconazole must be closely monitored for signs of adrenal insufficiency after discontinuation of fluconazole.

Pregnancy and breastfeeding
Fluconazole in standard doses and as short-term treatment should only be used during pregnancy if absolutely necessary. Fluconazole in high doses or over a long period should only be used during pregnancy for life-threatening infections. applied.

Fluconazole passes into breast milk and reaches lower concentrations there than in plasma. After a single dose of 200 mg fluconazole or less, breastfeeding can be continued. With repeated use or after taking fluconazole in high doses, breastfeeding is not recommended.

Ability to drive and use machines
Fluconazole-ratiopharm® 150 mg has little or no effect on the ability to drive or use machines. However, it should be noted that dizziness, drowsiness, and seizures may occur (see 4. "What side effects are possible?"). Important information about certain other ingredients of Fluconazole-ratiopharm® 150 mg

This medicine contains lactose. Please only take Fluconazole-ratiopharm® 150 mg after consulting your doctor if
This medicine contains lactose. Please take Fluconazole-ratiopharm® 150 mg only after consulting your doctor if You are aware that you have an intolerance to certain sugars.

3. HOW TO TAKE Fluconazole-ratiopharm® 150 mg?

Always take Fluconazole-ratiopharm® 150 mg exactly as your doctor has instructed. Please consult your doctor or pharmacist if you are not entirely sure.

Unless otherwise prescribed by the doctor, the usual dose is

Adults:
- Vaginal candidiasis:

1 capsule of Fluconazole-ratiopharm® 150 mg (= 150 mg fluconazole) as a single dose.

- Candidiasis of the mucous membranes in immunocompromised patients:

Daily dose: 50 mg fluconazole for 2–4 weeks. In difficult cases, the dose can be increased to 100 mg fluconazole daily. To prevent a recurrence of the infection, fluconazole can be taken over a longer period (6–8 weeks).

- Systemic candidiasis (fungal infections caused by yeast fungi of the genus Candida involving internal organs):

In general, treatment should begin on the 1st day with a single dose of 400 mg fluconazole, followed by 200 mg fluconazole once daily. If necessary, the dose can be increased to 400 mg once daily. In invasive and therefore potentially life-threatening fungal diseases caused by Candida species, a daily dose of 800 mg may be required. The duration of treatment depends on

the clinical A daily dose of 800 mg may be required. The duration of treatment depends on the clinical Course dependent.

- Prevention of Candida infections in patients with a reduction in the number of white blood cells (neutropenic patients):

Once daily 50–400 mg fluconazole depending on the risk of recurrence of the infection. In patients with a high risk of systemic infection, such as patients at risk of developing severe or persistent neutropenia, a dose of 400 mg fluconazole once daily is recommended. The treatment should begin a few days before the onset of neutropenia and continue for 7 days after the neutrophil count rises above 1000/mm3. Treatment and preventive treatment of cryptococcal meningitis in immunocompromised patients:

- Start therapy with 400 mg fluconazole daily, followed by 200–400 mg fluconazole for at least 6–8 weeks. In invasive and potentially life-threatening

fungal infections caused by Cryptococcus neoformans, a daily dose of 800 mg fluconazole may be necessary, especially in high-risk patients. To prevent the recurrence of cryptococcal meningitis, 100–200 mg fluconazole daily is recommended. In AIDS patients, the duration of preventive treatment should be carefully considered due to the increased risk of resistance to fluconazole.
Proven fungal infections of the skin: be reconsidered.

- Once daily 50 mg fluconazole or once weekly 150 mg fluconazole.
- Duration of treatment: 2–4 weeks.

Athlete's foot (tinea pedis):
Once daily 50 mg fluconazole.

- Duration of treatment: Treatment may be required for up to 6 weeks.

Nail fungal infections (onychomycosis):
Once weekly 1 capsule of Fluconazole-ratiopharm® 150 mg (= 150 mg fluconazole). The treatment must be continued until the

- affected nail has regrown. The regrowth of a fingernail can take 3–6 months, that of a toenail 6–12 months.

1 capsule of Fluconazole-ratiopharm® 150 mg (= 150 mg fluconazole) once weekly. The treatment must be continued until the affected nail has regrown. The regrowth of a fingernail can take 3–6 months, that of a toenail 6–12 months.
In the case of onychomycosis, a positive fungal culture or the visible regrowth of a healthy, non-infected nail can guide the treatment.
The clinical improvement of onychomycosis may only be noticeable several months after a negative fungal finding, as the regrowth of a non-infected nail can occur very slowly.

For dosages that cannot be achieved with this strength, preparations with a different active ingredient content are available.

Use in children:
The duration of treatment, as in adults with similar infections, depends on the clinical and mycological course.

Fluconazole-ratiopharm® 150 mg is administered once daily as a single dose.

For dosing in children with impaired renal function, see under "Patients (Adults and Children) with impaired renal function."

Children from 4 weeks:
The recommended dose of Fluconazole-ratiopharm® 150 mg for mucosal candidiasis is 3 mg/kg daily. To achieve steady-state levels more quickly, a loading dose of 6 mg/kg can be administered on the first day of treatment.
For the treatment of systemic candidiasis and cryptococcal infections, the recommended dose is 6–12 mg/kg daily, depending on the severity of the disease.

To prevent Candida infections in immunocompromised patients with increased risk due to neutropenia (reduction in the number of white blood cells) following cytotoxic chemotherapy or radiotherapy, the daily dose should be 3–12 mg/kg, depending on the extent and duration of the induced neutropenia (see dosing under "Adults").
A maximum daily dose of 400 mg of fluconazole should not be exceeded in children.

Children aged 4 weeks and younger:
Newborns excrete fluconazole slowly. In the first two weeks of life, the same mg/kg dosages as in older However, in children, it should be applied every 72 hours. During the 3rd and 4th week of life, the same dose should be administered every 48 hours. be.
In children in the first two weeks of life, a maximum dose of 12 mg/kg every 72 hours should not be exceeded. In children between the 3rd and 4th week of life, 12 mg/kg every 48 hours should not be exceeded.

The pharmacokinetics of fluconazole have not been studied in children with impaired renal function.

The capsules are not suitable for children under 5–6 years who cannot take solid medicines like tablets or capsules.
The required dose in mg/kg can often not be achieved with the administration of capsules.

For dosages that cannot be achieved with this dosage strength, other preparations with a lower active ingredient content are
available.

Elderly people:
Elderly patients without renal impairment generally receive the usual adult dosage. For dosing in patients with impaired renal function (creatinine clearance below 50 ml/min), see the following section.

Patients (adults and children) with impaired renal function:
Fluconazole is predominantly excreted unchanged in the urine. No dose adjustment is required when treated with a single dose. If you suffer from severely impaired renal function (creatinine clearance below 50 ml/min), please consult your doctor before starting treatment. In this case, the dosage must be adjusted.

Method of administration
The capsules must be swallowed whole with sufficient liquid (a glass of water). They can be taken independently of meals. If you have taken more Fluconazole-ratiopharm® 150 mg than you should

If you have taken a larger amount of Fluconazole-ratiopharm® 150 mg than you should
Please talk to your doctor if you have taken a larger amount of Fluconazole-ratiopharm® 150 mg than you should.
He will decide on any necessary measures.

If you forget to take Fluconazole-ratiopharm® 150 mg
If you have taken a smaller amount of Fluconazole-ratiopharm® 150 mg than you should, you can take the missing amount on the same day. Do not take a double dose if you have forgotten the previous dose.

If you stop taking Fluconazole-ratiopharm® 150 mg
If you end or interrupt your treatment too early, your fungal infection may recur.
If you have further questions about the use of the medication, ask your doctor or pharmacist.

4. WHAT SIDE EFFECTS ARE POSSIBLE?

Like all medicines, Fluconazole-ratiopharm® 150 mg can have side effects, but not everyone will experience them.
The most frequently reported side effects observed during clinical studies and associated with Fluconazole are headaches, rash, abdominal pain, bloating, diarrhea, and nausea.

The following frequency categories are used to evaluate side effects:

very common	more than 1 in 10 treated
common	less than 1 in 10, but more than 1 in 100 treated
occasional	less than 1 in 100, but more than 1 in 1,000 treated
rare	less than 1 in 1,000 but more than 1 in 10,000 treated
very rare	less than 1 in 10,000 treated
unknown	cannot be estimated from the available data

Blood and lymphatic system disorders
Occasionally: Anemia
Rare: Changes in blood count such as a reduced number of white blood cells (including neutropenia and agranulocytosis) and a reduced number of platelets (thrombocytopenia) (see 2. under “Special caution when taking Fluconazole-ratiopharm® 150 mg is required”).

Immune system disorders
Very rare: severe hypersensitivity reactions (anaphylactic reactions including swelling of skin and mucous membranes (angioedema) and of the face (facial edema).

Metabolism and nutrition disorders
Rare: Increased cholesterol and triglyceride levels in the blood, decreased potassium levels in the blood.

Psychiatric disorders
Occasionally: Insomnia, drowsiness with slight clouding of consciousness (somnolence).

Nervous system disorders
Common: Headaches.
Occasionally: cramps, dizziness, tingling (paresthesia), tremor, Taste disturbances, dry mouth.
Rare: seizures.

Heart diseases
Rare: changes in heart activity (QT prolongation, Torsade de pointes).

Gastrointestinal disorders
Common: nausea, vomiting, abdominal pain, diarrhea.
Occasionally: loss of appetite, constipation, indigestion, flatulence.

Liver and biliary diseases
Common: changes in liver enzyme levels (increase in alkaline phosphatase, ASAT, and ALAT).
Occasionally: cholestasis, clinically relevant increase in total bilirubin, jaundice, liver cell damage.
Rare: hepatitis, liver cell necrosis, liver failure with individual fatalities (see 2. under "Special caution when taking Fluconazole-ratiopharm® 150 mg is required").

Skin and subcutaneous tissue disorders
Common: rash.
Occasionally: itching, increased sweating.
Rare: hair loss.
Very rare: severe skin disorder with peeling of the skin (exfoliation), detachment of the skin (Stevens-Johnson syndrome and toxic epidermal necrolysis).
AIDS patients are particularly prone to developing skin reactions after taking many medications (see 2. under "Special Caution is required when taking Fluconazole-ratiopharm® 150 mg.
Unknown frequency: (fixed) drug rash, hives, acute generalized exanthematous pustulosis.

Musculoskeletal, connective tissue, and bone disorders
Occasionally: Muscle pain.

Renal and urinary disorders
Very rare: Changes in kidney values have been observed (see 2. under "Special caution is required when taking Fluconazole-ratiopharm® 150 mg is required").

General disorders and administration site conditions
Occasionally: Fatigue, malaise, general weakness (fatigue, feeling of weakness, lack of strength), fever.
Side effects were observed more frequently in HIV-infected patients than in non-HIV-infected patients. However, the pattern of side effects was very similar in these patients.

Children
Compared to all patients, side effects were reported more frequently in children.
Additionally, irritability and anemia were specifically reported in children.

Countermeasures
If you experience severe side effects, you should inform your doctor, who will decide whether the treatment can be continued or if any other measures are necessary. This particularly concerns all signs of a hypersensitivity reaction. If these occur, Fluconazole-ratiopharm® 150 mg may only be taken again if the doctor has expressly allowed it. If you develop a rash during treatment with Fluconazole-ratiopharm® 150 mg, you must inform your doctor immediately, who will decide on any necessary measures.

Please inform your doctor or pharmacist if any of the listed side effects significantly affect you or if you notice side effects that are not listed in this leaflet.

5. HOW SHOULD Fluconazole-ratiopharm® 150 mg BE STORED?

Keep medicines out of the reach of children.

Do not use the medicine after the expiry date stated on the carton and container. The expiry date refers to the last day of the month.

Storage conditions:
Do not store above 30 °C.

The medicine must not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of the medicine if you no longer need it. This measure helps protect the environment.

6. FURTHER INFORMATION

What Fluconazole-ratiopharm® 150 mg contains
The active substance is fluconazole.

Each hard capsule contains 150 mg of fluconazole.

The other ingredients are:

Capsule content
Colloidal anhydrous silica, magnesium stearate, talc, corn starch, povidone K 30, lactose.

Capsule shell:
Gelatin, titanium dioxide (E 171), indigotine (E 132).

What Fluconazole-ratiopharm® 150 mg looks like and contents of the pack
Capsule cap: medium blue; capsule body: white

Fluconazole-ratiopharm® 150 mg is available in packs containing 1 hard capsule.

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