

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Metronidazole-ratiopharm® 400 mg Tablets

Metronidazole

Read the entire package leaflet carefully through, before you start taking this medicine begin , because because she contains important information.

- Keep the package leaflet on. Perhaps want you this later again read.
- If you further questions have, contact your doctor or pharmacist . This medicine was
- prescribed to you personally . Do not. to others . Third further. It can other people harm, even if they have the same symptoms as you. If you
- notice side effects ,, contact your doctor or pharmacist . This also applies to side effects. This applies also to side effects, which are not listed in this package leaflet indicated .. section 4. 4.

What is in this package leaflet contains

1. What is Metronidazole-ratiopharm® and what is it used for?
2. What should you know before taking from Metronidazole-ratiopharm® note?
3. How is Metronidazole-ratiopharm® to be taken?
4. What side effects are possible?
5. How is Metronidazole-ratiopharm® to store?
6. Contents the package and further information

1. What is Metronidazole-ratiopharm® and for what is it used?

Metronidazole-ratiopharm® is a medicinal product against parasites (parasites): against protozoa (protozoa) and without oxygen living (anaerobic) bacteria.

Metronidazole-ratiopharm® is used

- for Trichomoniasis
- for bacterial vaginosis (amine colpitis, nonspecific colpitis)
- for amoebiasis
- for giardiasis (Giardiasis)
- for infections (Transmissions, Infections) with involvement of bacteria, that without oxygen can live (anaerobes); especially infections, caused by the female genital organs, from gastrointestinal tract as well as ear, nose, throat, and dental-oralmaxillofacial area originate.
- in infections with *Helicobacter pylori* in the upper gastrointestinaltract
- for preventive Treatment for protection against infections in surgical procedures in the female genital area and in the gastrointestinaltract

Explanations:

Trichomoniasis is a Disease, caused by a flagellate, *Trichomonas vaginalis*, caused is. It occurs mainly in inflammations of the female vagina and the male urethra. The spread occurs almost exclusively through sexual intercourse. For the detection of the disease a secretion swab is made manufactured.

bacterial vaginosis is the bacterial composition , which, the naturally in the female vagina occurs, changes. It leads to an inflammation with a fish-like odor. Aminocolpitis and nonspecific Colpitis are other terms for bacterial vaginosis.

Amebiasis (amoebic dysentery) is a disease, caused by a rhizopod protozoan, *Entamoeba histolytica*, causes is. It leads mostly to abdominal pain and severe diarrhea due to an infection in the gastrointestinal tract. Furthermore it can lead to Infestation other organs occur, whereby the disease untreated often fatal . Fordiagnosis of amoebic dysentery the stool is examined.

Lambliasis (Giardiasis) is a disease, caused by a flagellate, *Giardia lamblia*, originates. Through an infection in the gastrointestinal tract it mainly leads to watery diarrhea. *Giardia lamblia* is in the stool detected.

2. What should you before taking Metronidazole-ratiopharm® consider? Metronidazole-ratiopharm®

must® may not taken be

- if you allergic to Metronidazole, other 5-nitroimidazoles (group, to which also Metronidazole belongs) or any of the Section 6. mentioned other components of this medication are. An exception exists, if a life-threatening infection is present and other medications ineffective are.

Warnings and Precautions

Please consult your doctor or pharmacist before you take Metronidazole-ratiopharm® ..

caution Caution during the intake of Metronidazole-ratiopharm® is necessary, if you have disorders of blood formation as well as disease of the brain, spinal cord and nerves suffer. Share this your doctor with.

In trichomoniasis is often the sexual partner also carrier of the trichomonads, even if so far no pathological changes noticed be should. To mutual infection to avoid, it is necessary, that the sexual partner also examined is and if necessary with treated is. During sexual intercourse should during the treatment be avoided should.

Cases with severe hepatotoxicity/acute liver failure including cases with fatal outcome were in patients with Cockaynesyndrome with medications observed, which contain metronidazole. If you have CockayneSyndrome suffer, should your doctor during the treatment with Metronidazole and after the treatment also your liver function Your Liver function frequently monitor.

Inform you your doctor immediately and discontinue the intake of Metronidazole if you develop the following symptoms:

- abdominal pain, Anorexia, nausea, vomiting, fever, malaise, fatigue, jaundice, dark urine, light gray or white stool or itching.

Patients with impaired liver function

If you suffer from severe liver damage, please consult before taking Metronidazole-ratiopharm® with your® with Your Doctor.

Intake of Metronidazole-ratiopharm® together with other medicines

Inform your doctor or pharmacist, if you are taking other medicines /apply recently other medicinal products taken /applied have or intend other medicinal products to take/to apply.

Which other medicinal products influence the effect of Metronidazol-ratiopharm® ?

Barbiturates, Phenytoin

A reduction in effect of Metronidazol-ratiopharm® occurs with administration of barbiturates (medications with with Active substances such as Hexobarbital or Phenobarbital, which against sleep disorders and seizures as well as for anesthesia used are) and with administration of medications with Phenytoin (Active ingredient against seizures).

Cimetidine

Medicinal product with Cimetidine (Active ingredient against gastritis [gastritis] as well as against stomach and intestinal ulcers) can very rarely the excretion of Metronidazole affect and thus the effect/side effects of Metronidazole-ratiopharm® enhance.

Disulfiram

The simultaneous administration of the alcohol withdrawal agent Disulfiram can lead to states of confusion and certain mental disorders (psychoses) lead.

Silymarin/Silibinin

With concurrent administration of Silymarin/Silibinin (medication for Treatment of liver diseases and digestive disorders) is the effect of Metronidazole-ratiopharm® reduced.

Diosmin

Diosmin (medication for treatment of venous leg disorders and hemorrhoids) can the metronidazole concentration in blood increase and thus the effect/side effects of Metronidazole-ratiopharm® enhance.

Which other medicines are in their effect by Metronidazole-ratiopharm® influenced?

Anticoagulant agents

Patients who with certain medications treated are, the the blood coagulation inhibit (anticoagulants of the coumarin type, such as e.g. phenprocoumon, warfarin), must if necessary be adjusted again, because through Metronidazole-ratiopharm® the anticoagulant effect of these medicines is enhanced ..

The

toxicity of busulfan (chemotherapeutic agent Chemotherapeutic agent can significantly increase enhanced become.

Ciclosporin

In concomitant administration of ciclosporin (a medication that suppresses the immune response suppresses or. weakens) and Metronidazole-ratiopharm® can the blood level of ciclosporin increased be. Therefore, let therefore your ciclosporin and creatinine blood levels frequently monitored.

5-fluorouracil

The toxicity of 5-fluorouracil (a chemotherapeutic agent for treatment of tumors) increases itself, as with simultaneous administration of Metronidazolratiopharm® the excretion of 5-fluorouracil reduced is.

Lithium

With administration of medications with lithium (medication for treatment of certain forms euphoric or depressive mood [manic-depressive states]) caution is advised, because thereafter a rise of the lithium in the blood observed was (risk of lithium toxicity with tremors and seizures). Have therefore your blood levels of lithium, creatinine and Electrolytes monitor.

Tacrolimus

The concomitant administration with Metronidazole-ratiopharm® leads to an increase in the blood level of tacrolimus (agent for modulation of the immune system). Let therefore your tacrolimus blood levels and the kidney function frequently monitored.

Amiodarone

The simultaneous use with metronidazole and amiodarone (agents for Treatment of arrhythmias) can lead to an influence of cardiac activity. Therefore should the cardiac activity be regularly monitored in the ECG become. Consult a doctor as soon as you notice any arrhythmia, such as dizziness, palpable changes in heartbeat or a temporary fainting episode.

Mycophenolate mofetil

In concurrent administration with antibiotics can the availability of mycophenolate mofetil (a drug that suppresses the immune system suppressed) in body reduced be. Therefore is a simultaneous frequent monitoring by laboratory tests recommended.

Intake of Metronidazole-ratiopharm® together with alcohol

The consumption of alcohol is during the treatment with metronidazole and for at least 48 hours afterwards to avoid, as otherwise intolerance reactions occur can, such as e.g. skin redness in the area of the head and neck as well as nausea, vomiting, headaches and dizziness.

Pregnancy, Lactation and Reproductive capability

If you are pregnant or breastfeeding ,or if you suspect that you are pregnant or intend to become pregnant intend, pregnant to become, ask your before taking this medicine consult your doctor or pharmacist for advice.

Pregnancy

If you are pregnant ,, will you your doctor only then with Metronidazole-ratiopharm® treat, if he considers this absolutely necessary ..

Metronidazole

passes goes into the breast milk over. Therefore should you during a treatment with Metronidazole-ratiopharm® and at least 2–3 days afterwards the breastfeeding interrupt interrupt.

Fertility

Animal studies show only a possible negative impact of metronidazole on the male reproductive organs, when high doses were administered were, the far above the maximum recommended dose for humans are.

Driving ability and ability to operate machinery

Especially at the start of treatment can Metronidazole-ratiopharm® Your reaction ability impair. You can then to unexpected and sudden events not anymore quickly and precisely enough react, so that e.g. the ability to active participation in road traffic or to operate machinery or working without secure support is reduced . This applies in. This applies in enhanced extent in interaction with alcohol.

Metronidazole-ratiopharm® contains lactose.

Please take Metronidazole-ratiopharm Metronidazole-ratiopharm^{only} after consulting with with your doctor a, if you know that, you suffer from an intolerance to certain sugars ..

3. How is Metronidazol-ratiopharm® to take?

Take this medicine always exactly according to agreement with your doctor take. Ask your with your doctor or Pharmacist after, if You are not sure are.

Dosage

The Dosage depends on after Type and Severity of the Disease.

The following information are average values and apply only, as far as Metronidazole-ratiopharm® by your doctor not otherwise prescribed was.

The daily dosage can ½ to at most 5 tablets Metronidazole-ratiopharm® (corresponding to 200-2,000 mg metronidazole) be. Usually are the Tablets 2 to 3 times daily taken.

Uncomplicated Infections (Infections, which with treatment usually quickly and without consequences heal)

In a low daily dose of 1½ tablets (corresponding to 600 mg metronidazole) or less is a multi-day treatment (5-7 days) required.

In the case of a higher dosage of 2½-5 tablets (corresponding to 1,000-2,000 mg metronidazole) per day a short treatment duration (13 days) may be sufficient. Bacterial

vaginosis Vaginosis and trichomoniasis in adults

Treatment by single dose of 5 tablets (equivalent to 2,000 mg metronidazole) possible.

Alternatively in

- bacterial vaginosis
2½ Tablets (corresponding to 1,000 mg Metronidazole) per day (divided into 2-3 single doses) for a total of 7 days.
- Trichomoniasis (especially in persistent cases)
2-2½-(4) tablets (corresponding 800-1,000-[1,600] mg Metronidazole) per day (divided into 2-3 single doses) for a total of 7 days.

To prevent mutual infection in Trichomoniasis trichomoniasis avoid, it is necessary that the sexual partner also be examined and if necessary treated with a metronidazole-containing preparation (see 2. "Warnings and Precautions").

Complicated Infections (Infections, which even with careful treatment often heal poorly) how

- inflammation of the uterine lining (endometritis)
- inflammation of the fallopian tubes or ovaries (adnexitis)
- inflammations in the area of teeth, mouth, and jaw
- inflammations in the area of throat, nose, and ears
- peritonitis (Peritonitis) and
- Abscesses (abscesses) in the abdominal cavity

Daily dosage at the beginning 4-5 tablets (corresponding to 1,600-2,000 mg metronidazole) and on the following days 2½ tablets (corresponding to 1,000 mg Metronidazole) for 5-7 days. Only in exceptional cases should the dosage be increased to 3½ tablets (corresponding to 1,400 mg Metronidazole) per day increased be.

In the context of combination therapy for eradication of *Helicobacter pylori* the official treatment recommendations should be considered before.

treatment preventive The should on a single dose of 1½ to a maximum of 5 tablets (corresponding to 600-2,000 mg Metronidazole) be limited remain.

Use in children and adolescents

Infections, the by anaerobic bacteria caused are

Children over 8 weeks to 12 years: 20 mg to 30 mg/kg body weight once per day as a single dose or divided into 7.5 mg/kg every 8 hours.

Dependent on severity can the dose to 40 mg/kg per day increased be. The duration of the treatment is usually 7 days. Children under 8 weeks: For these Age group is a medicinal product with lower strength required.

Bacterial vaginosis

Adolescents: twice daily 1 tablet (corresponding twice daily 400 mg Metronidazole) over 5 to 7 days or 5 tablets (corresponding to 2,000 mg Metronidazole) as a single dose.

Perioperative prophylaxis

Children under 12 years: once 20 mg to 30 mg/kg body weight one to two hours before the procedure.

Newborns under 40th week of gestation: For this age group is a medication with lower strength required

Urogenital trichomoniasis

Adolescents: 5 tablets (equivalent to 2,000 mg metronidazole) as a single dose or three times daily ½ tablet (corresponding to three times daily 200 mg Metronidazole) over 7 days or twice daily 1 tablet (corresponding to twice daily 400 mg Metronidazole) over 5 to 7 days.

Children under 10 years: 40 mg/kg body weight as a single dose (max. 2,000 mg Metronidazole) or 15 mg to 30 mg/kg body weight per day, divided on two to three doses daily. It must 2,000 mg per dose not exceeded be.

Lambliasis (Giardiasis)

Children over 10 years: 5 tablets (corresponding to 2,000 mg Metronidazole) once per day over 3 days or 1 tablet (corresponding to 400 mg Metronidazole) three times daily over 5 days.

Children from 7 to 10 years: 2½ tablets (corresponding to 1,000 mg metronidazole) once daily over 3 days.

Children from 3 to 7 years: 1½-2 tablets (corresponding to 600 mg to 800 mg metronidazole) once daily over 3 days. Children aged 1 to 3 years: For this age group a medication with lower strength is needed ..

expressed : Children receive 15 mg to 40 mg/kg body weight per day, per day, divided on two to three doses daily.

Amoebiasis

Children over 10 years: 1-2 tablets (corresponding to 400 mg to 800 mg Metronidazole) three times daily over 5 to 10 days.

Children from 7 to 10 years: ½-1 tablet (corresponding to 200 mg to 400 mg Metronidazole) three times daily over 5 to 10 days.

Children from 3 to 7 years: ½ tablet (corresponding to 200 mg Metronidazole) four times daily over 5 to 10 days.

Children aged 1 to 3 years: ½ tablet (corresponding to 200 mg Metronidazole) three times daily over 5 to 10 days.

Alternatively expressed: Children receive 35-50 mg/kg Body weight per day, divided into three doses daily, over 5 to 10 days. It must not exceed 2,400 mg per day exceeded be.

Combination therapy for eradication of Helicobacter pylori

In Framework of a combination therapy are 20 mg/kg body weight per day, divided into two doses daily (max. twice 500 mg/day), over 7 to 14 days applied. Before starting treatment are the official therapy recommendations to observe.

For children under 6 years are tablets, which must be swallowed whole are , not suitable ..

Type of Application

Take the tablets unchewed with sufficient liquid (e.g. 1 glass of water) during the meal or shortly afterwards take. The tablet can in some Doses divided are.

Duration of use

Your doctor decides on the duration of use . Warning

Warning:

treatment with Metronidazole-ratiopharm Metronidazole-ratiopharm® or a other nitroimidazole-containing medication should generally not exceed 10 days exceed. This period should only in individual cases in particularly strict indication (i.e. after careful consideration by your doctor in the presence of serious reasons) exceeded be. The treatment should as rarely as possible repeated be .. The limitation of the treatment duration is necessary, because a damage to human germ cells (possible damage to the genetic material) cannot be excluded exclude leaves and because in experimental series with animals an increase of certain tumors (growths) seen was.

If you an larger amount of Metronidazole-ratiopharm® taken have, than you should

If you a single dose of Metronidazole-ratiopharm® accidentally double take, this has no effects on the further intake, i.e. you take Metronidazole-ratiopharm® afterwards as one, as in the dosage instructions.

In case of intake considerably to high amounts of medication can it to nausea, vomiting, increased reflexes, ataxia (disorder in coordinated movement), accelerated Heartbeat, Shortness of breath and Disorientation (Lack of awareness of time and place) occur.

An antidote is not known. After medical treatment of the symptoms is with a complete recovery after a few days to expect.

If you have missed taking Metronidazole-ratiopharm® forgotten have

Do not take the double amount a, if you missed the previous dose forgotten have. If you your mistake still on the same day notice, take the too little taken medication amount still on the same day subsequently in.

Notice you your mistake only on the next day, then can it necessary to treatment by one day to extend. Consult your such a case please with your doctor.

If you Intake of Metronidazole-ratiopharm® discontinue

If you treatment prematurely end or it temporarily interrupt, jeopardize the treatment success!

In case of unpleasant Side effects will your doctor with you discuss, which countermeasures there are for this and whether other medications are suitable for you consider.

If you further questions about taking this medication have, contact your doctor or your doctor or pharmacist.

4. What side effects are possible?

Like all medicines can also this medicine side effects have, which however not in everyone occur must.

Some side effects can be serious be. Contact a doctor immediately if you experience any of the following side effects Side effects Occasionally:

can occur up to to to 1 in 100 treated patients affect)

- allergic reaction, often accompanied by drop in blood pressure, dizziness, nausea and possibly. shortness of breath (anaphylactic reaction)
- mucosal swelling in the area of the airways with shortness of breath (angioneurotic edema)
- Disorders in coordination of movements (ataxia), nerve disorders (peripheral neuropathies) and seizures

If you a numbness, tingling or prickling in arms and legs feel, must you immediately your doctor inform, even if these symptoms in you only in mild form occur!

Very rarely (can up to 1 in 10,000 treated affect)

- severely reduced number of certain white blood cells (agranulocytosis), of platelets (thrombocytopenia) or. of all blood cells (Pancytopenia). Symptoms are weakness, increased susceptibility to infections and increased bruising. It is necessary in these cases to quickly perform a blood count check become.
- severe cases of an allergic (anaphylactic shock). If it leads to a circulatory failure with consciousness disturbances, cold sweat as well as pale and cold hands and feet must immediately a doctor to assistance called be. Until the arrival are are the upper body of the patient flat and his legs elevated to position. To prevent from cooling is the patient with a blanket warm to keep. The doctor will the usual appropriate emergency measures initiate.
- Non- inflammatory diseases of the brain (encephalopathy with e.g. confusion, fever, headaches, hallucinations, paralysis, photosensitivity, disorders of vision and motor skills, neck stiffness), diseases of the cerebellum with e.g. Speech-, Movement- and Gait disorders, Tremors, Nystagmus (Nystagmus). These phenomena can regress after the end of treatment regress.
- of the the Pancreas (Pancreatitis), which leads to severe pain in the upper abdomen, nausea and vomiting leads to
- Occurrence severe persistent diarrhea during or in the first weeks after the treatment (pseudomembranous enterocolitis). This caused by an antibiotic treatment induced intestinal disease can be life-threatening and requires a immediate and appropriate medical treatment. Medicinal products that the bowel movement (peristalsis) inhibit, must not be taken .

Not known (Frequency on basis of available data not estimable)

- non- bacterial caused meningitis (aseptic meningitis)
- Disease/Inflammation of optic nerve
- In patients, who simultaneously with other antibiotics treated were, occurred cases of liver failure in which a liver transplantation necessary was was.
- acute inflammatory disease of the skin or mucous membrane (Erythema exudativum multiforme, Stevens-Johnson-syndrome, toxic epidermal necrolysis, fixed drug eruption); partly with Disorder of the general condition, fever and painful blistering
- Acute liver failure in patients with Cockaynesyndrome (see 2. "What should you before the Intake of Metronidazole-ratiopharm® observe?", „Warnings and Precautions“)

Further side effects

Please speak with your doctor about over the further treatment, if the following side effects occur:

Common (may affect up to 1 in 10 treated individuals)

Taste disturbances (e.g. metallic taste), bitter belching, tongue coating, inflammations in the mouth (glossitis, stomatitis), stomach pressure, nausea, vomiting, loss of appetite, diarrhea darkening of the Urine (caused by a metabolite, without clinical significance)

Occasionally (may affect up to 1 in 100 treated patients)

- Infections with a skin fungus (e.g. *Candida albicans*) in the genital area
- Reduction of white blood cells (leukopenia and granulocytopenia). With prolonged use therefore regular checks Blood count checks to perform.
- inflammatory Redness, allergic Rhinitis and allergic Conjunctivitis of the eye, Hives, Drug fever
- Headaches, Dizziness
- Drowsiness, Insomnia, Hallucination (Hallucination), Confusion states, Excitability, sad Mood disturbance (Depression)
- mostly temporary Visual disturbances such as Double vision and Myopia
- Disorders the liver function, increase of various liver enzyme levels
- skin reactions (e.g. rash with blister- and wheal formation [urticarial exanthem], pustular eruptions, itching, paroxysmal skin redness with sensation of heat [flush])
- painful urination (dysuria), cystitis (cystitis) and involuntary discharge of urine (urinary incontinence)
- feeling of weakness

Very rarely (can up to 1 in 10,000 treated affect)Jaundice

- ,hepatitis with cholestasis of the bile flow muscle pain
- Muscle painjoint pain Joint pain

Not known (Frequency based on available data not estimable) Hearing loss/

- Hearing impairment,Ringing in the earsor Tinnitus buzzing -buzzing (Tinnitus)

Children and Adolescents

Frequency, type and severity of side effects are in children and adults the same.

Reporting of side effects

If you side effects notice, contact your doctor or pharmacist . This also applies to side effects. This applies also to side effects, which are not listed in this package leaflet listed .You can Side effects also directly the Federal Institute for Drugs and Medical Devices, Dept. Pharmacovigilance, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, Website: www.bfarm.de report. By reporting side effects ,you can You contribute to, that more information about the safety of this medication made available . 5..

5. Metronidazole-ratiopharm ® be stored® to store?

Store this medicine out of the reach of children unreachable .

You must not use this medicine after the date on the carton and the blister packs after "Use by "/"Exp. to" indicated expiry date not use anymore. The expiry date refers to the last day of the indicated month.

Do not store above 30 °C store.

6. Contents of the package and further information

What Metronidazole-ratiopharm® contains

- The active ingredient is metronidazole.
Each tablet contains 400 mg Metronidazole.
- The other ingredients are:
Lactosemonohydrate, Microcrystalline cellulose, Corn starch, Povidone K30, Crospovidone, Macrogol 6000, Colloidal Silicon dioxide, Magnesium stearate (Ph.Eur.) [vegetable], Cellulose powder

How Metronidazole-ratiopharm® looks and contents of the package

Whitish, elongated Tablet with score line on both sides.

Metronidazole-ratiopharm® is in packages with 14 and 20 tablets available.

Pharmaceutical entrepreneur

ratiopharm GmbH
Graf-Arco-Str. 3
89079 Ulm

Manufacturer

Merckle GmbH
Ludwig-Merckle-Str. 3
89143 Blaubeuren

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