

Package leaflet: information for the user

Metronidazole Aurobindo 250 mg, film-coated tablets
Metronidazole Aurobindo 500 mg, film-coated tablets
metronidazole

Read carefully the entire leaflet before you use this medicine, because there is important information for you.

Keep this leaflet. Maybe you need it later again necessary.

Do you still have questions? Then contact your doctor or pharmacist.

Do not let this medicine pass to others, because it is only for you prescribed. It can be harmful to others, even if they have the same symptoms as you. Do

you experience any side effects one of the side effects listed in section 4 are? Or do you experience a side effect that is not in this leaflet listed? Then contact your doctor or pharmacist.

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1. What is Metronidazole Aurobindo and what is this medicine used for?

Metronidazole Aurobindo belongs to the group of medicines that fight bacteria and single-celled organisms (protozoa).

Metronidazole Aurobindo is in adults and children used in the treatment of:

infections of the urethra or of the mucous membrane of the vagina, the so-called "white discharge" at women (Trichomoniasis, Gardnerella vaginalis).

intestine- and liver infections caused by a certain unicellular organism, amoeba (amoebiasis).

intestinal infections caused by a certain unicellular organism, giardia (giardiasis).

severe infections that are caused by micro-organisms that are sensitive to this medicine .. one certain form of severe gum inflammation (angina of Plaut-Vincent).

And to certain infections to prevent that can arise during and after a surgery.

2. When may you not use this medicine or must you be extra careful with it?

When may you not use this medicine?

Say it immediately to your doctor and stop taking metronidazole if you:

are allergic to any of the substances in this medicine. These substances can be found in section 6 of this leaflet.

If you an abnormal blood count is determined. This is assessed by your doctor.
You suffer from a condition of your brain , thespinal cord or the nerves nerves
(neurological disorder)

You suffer from abdominal pain ,lack of appetite (anorexia),nausea nauseavomiting ,fever
fever, malaise, fatigue, jaundice, dark urine, clay-colored (light gray)- or putty-colored
stools or itching.

When should you seek caution be with this medicine?

If there are during the treatment seizures or other neurological disorders (e.g.. numbness
of the arms and/or legs) occur, your treatment immediately to be adjusted ..
prolonged use of metronidazole metronidazole the hematopoiesis possible can harm (see
section 4, "Possible side effects"), can your blood count during the treatment be
monitored.

When you alcoholic drink use. You must not alcoholic drinks use during and up to 48 hours
after the treatment with Metronidazole Aurobindo.

When you this medicine longer than 10 days use. There may changes in your genetic
material (DNA) occur.

If your liver not well works. The active substance, metronidazole, can accumulate then
accumulate in your body (see "If your liver does not function properly" in section 3).

If you are allergic to other ,similar medications (ketoconazoleketoconazole, miconazole,
sulconazole). You can then also be allergic to Metronidazole Aurobindo. Go
to your doctor if you after the the treatment of the "white discharge" still symptoms has. It
may be that you suffer from another infection (gonorrhoea (gonorrhoea)).

Cases of severe hepatotoxicity/acute liver failure, including cases with a fatal outcome in
patients with Cockayne syndrome, of Cockayne, are reported with medications that
metronidazole contain.

If in you there is a case of syndrome of Cockayne, must your doctor also frequently your
liver function check as long as you are with metronidazole being treated and also
afterwards.

Cases of very serious skin reactions have been reported, such as the Stevens-Johnson
syndrome (SJS) with high fever, blisters on the skin, joint pain and/or eye inflammation, or
severe, sudden allergic reaction, with such as symptoms fever and blisters on the skin and
peeling of the skin (TEN (toxic epidermal necrolysis)), or sudden outbreak of dozens to
hundreds 1 to 2 mm large blisters filled with pus (AGEP (acute generalized exanthematous
pustulosis)). In case of symptoms or signs of SJS, TEN or AGEP should u immediately to
stop with the treatment.

If you experience vertigo (dizzy feeling) experience during the use of metronidazole.

If you a blood test must undergo, tell then to the doctor or nurse who is performing the
test that you use metronidazole .. can affect influence have on the results of some blood
tests.

Contact a doctor if one of the above warnings applies to you or that in the past is is been.

Used you still other medications?

Used you besides Metronidazole Aurobindo still other medications, do you that short ago done or
are you this perhaps soon do? Inform that then your doctor or pharmacist.

Contact your doctor if you use medications that a disturbance in the heart rhythm can cause (a so-called QT-prolongation that is visible on one ECG), such as certain antiarrhythmics (medications for arrhythmias), certain antibiotics and medications that are mainly used to treat psychosis (including delusions, hallucinations, paranoia or disorganized thoughts).

Simultaneous use with the following medications is not recommended:

Disulfiram, a medicine against alcohol addiction. You can experience symptoms of psychotic reactions. A psychosis is a serious mental illness in which the control about one's own behavior and actions is disturbed.

Phenobarbital, used in epilepsy. Phenobarbital can reduce the effectiveness of Metronidazole Aurobindo.

Phenytoin, a medicine for heart conditions or epilepsy. Phenytoin can reduce the effectiveness of Metronidazole Aurobindo.

Cimetidine, a medicine for stomach complaints. The side effects of Metronidazole Aurobindo may increase.

Certain medicines for blood clotting (anticoagulants of the coumarin type, such as acenocoumarol). Metronidazole Aurobindo can enhance the effect of these medications.

Medications containing lithium. Metronidazole Aurobindo can increase the level of lithium in the blood, causing the kidneys to be poisoned.

Ciclosporin, a medicine that is used after organ transplants and in certain skin diseases. Metronidazole Aurobindo can increase the level of this substance in the blood.

Medicines with as an ingredient 5-fluorouracil (treatment against cancer). Metronidazole Aurobindo can increase the level of 5-fluorouracil in the blood, thereby 5-fluorouracil can be extra harmful.

Busulfan, which is used in cancer. There is a greater chance that you experience side effects from busulfan.

What should you pay attention to with eating, drinking and alcohol?

You may not use alcoholic drinks during the treatment and up to 48 hours after the treatment with Metronidazole Aurobindo. This can lead to certain mental disorders, which are mentioned in section 4 "Possible side effects".

Pregnancy and breastfeeding

Are you pregnant, do you think you are pregnant to be, do you want to become pregnant or are you breastfeeding? Then contact your doctor or pharmacist before you use this medicine.

Pregnancy

If your doctor deems it necessary, you can use Metronidazole Aurobindo during the pregnancy.

Breastfeeding

Metronidazole Aurobindo enters in the breast milk. You may use Metronidazole Aurobindo once if you are breastfeeding. If you use Metronidazole Aurobindo for longer time, you must first consult with your doctor whether you must stop with the giving of breastfeeding.

Driving ability and the use of machines

Metronidazole can cause side effects such as temporary blurred or double vision, dizziness, lightheaded feeling (vertigo), confusion, hallucinations (seeing things or hearing that are not there), seizures (convulsions).

If this happens, you must not drive a vehicle, operate machines or use tools ..

Aurobindo tablets contain lactose

If your doctor has told you that you cannot tolerate certain sugars, please contact your doctor before you take this medicine ..

Metronidazole Aurobindo contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, which means that it is essentially "sodium-free".

do you use this medicine?

Use this medicine always exactly as your doctor or pharmacist has told you. Are you unsure about the correct dosage use? Then contact your doctor or pharmacist.

The dosage is per patient different and will by your doctor be determined. Unless your doctor something else prescribes is the usual dosage:

For giardiasis

10 years and older: 3x 400 mg per day for 5 days, of
2x 500 mg per day for 7-10 days, or
2000 mg once a per day for 3 days.

Children under 10 years: 1-3 years: 500 mg once a day for 3-7
3-7 : 600 to 800 mg once a day per day during 3 days
7-10 years: 1000 mg once a per day during 3 days

Alternative, expressed in mg per kg body weight: 15-40 mg/kg body weight per day in 2-3 doses.

In amoebiasis

10 years and older:: 400 800 mg 3 times per day for 5-10 days

Children younger than 10 years: 1-3 years: 100 to 200 mg 3 times per day for 5-10 days
3-7 years: 100 to 200 mg 4 times per day for 5-10 days
7-10 years: 200 to 400 mg 3 times per day for 5-10 days

Alternative can the dose expressed be per body weight

35-50 mg/kg body weight per day in 3 doses for 5-10 days; maximum 2400 mg per day.

In severe infections

Adults and children older than 12 years:

3 x 750 mg per day or

3-4 x 500 mg per day for 7 days or longer, if necessary

Children older than 8 weeks to 12 years: The usual dose is 20-30 mg/kg body weight per day, administered as one single dose or as 7.5 mg/kg body weight every 8 hours. The dose can be increased to 40 mg/kg body weight, per day dependent on the severity of the infection. The duration of the treatment is usually 7 days.

Babies younger than 8 weeks old: The usual dose is 15 mg/kg body weight per day, administered as a single dose or as 7.5 mg/kg body weight every 12 hours.

In newborns who are born at a gestational age less than 40 weeks metronidazole can accumulate during the first week of life. Therefore must after a few days treatment the amount metronidazole in the blood be monitored.

To prevent of infections that after a surgery can occur: (bowel surgery (colon surgery)): Usually will metronidazole 24 hours before the surgery be administered to at least 4 hours after the closure of the wound, or longer, depending on the risk of infection.

Adults and children older than 12 years: 1000 mg Metronidazole Aurobindo as a single dose, followed by 500 mg, 3 times daily for 24 hours until before the surgery not more may be eaten.

Children younger than 12 years: 20-30 mg/kg body weight, given as a single dose, 1-2 hour before the procedure.

Newborns born at a gestational age less than 40 weeks: 10 mg/kg body weight, administered as a single single dose, before the procedure.

In trichomoniasis
Both the patient and the partner must be treated.

Adults and children of 10 years and older:
3 x 200 mg per day for 7 days, or
2 x 400 mg per day for 5-7 days or
2000 mg as a single dose.

Children younger than 10 years: 15-30 mg/kg body weight per day in 2-3 doses over over 7 days, or 40 mg/kg body weight if single dose. Maximum 2000 mg per dose.

In infections with Gardnerella vaginalis
Both you and your female partner must be treated.

Adults: 1000 mg per day, in 2 doses, for 7 days
Adolescents up to 18 years old: 2x 400 mg per day for 5-7 days, or 2000 mg as single dose.

Adults

Gynecological procedures:

1000 mg Metronidazole Aurobindo as a single administration, followed by 500 mg 3 times daily until before the operation not more may be eaten. After the operation as necessary still 24 hours 3 x 500 mg.

Children

Prior to the operation is Metronidazole Aurobindo administered in combination with another drug that bacteria fights (neomycin).Metronidazole

Aurobindo tablets or or suspension (3 times daily for 2 days)	Neomycin tablets (4 times daily for 3 days)	
5 - 12 years: 100 mg		500 mg
1 - 5 year: 5 mg/kg body weight	250 mg	
Younger than 1 year: 5 mg/kg body weight		125 mg

After the surgery is the treatment continued, usually with a different dosage form.

Outbreak of Helicobacter pylori in children:

As part of a combination treatment, 20 mg/kg per day with a maximum of 500 mg in 2 doses during 7-14 days.

Dosage for angina of Plaut-Vincent:

Dosage as for severe infections.

Your doctor will tell you how long you Metronidazole Aurobindo must use.

If your liver does not function properly

If your liver does not function properly will your doctor of dosage reduce.

If you notice that this medicine too strong or just too little works, consult then your doctor.

Have you taken too much of this medicine taken?

If you have taken Metronidazole Aurobindo used , then immediately contact with your doctor or pharmacist.

Use of too much metronidazole can lead to among other nausea, vomiting and coordination problems, such as ataxia. After use of too much metronidazole, the mainly the symptoms treated. There is no specific antidote for overdose.

Are you forgotten this medicine in to take?

If you once a dose Metronidazole Aurobindo forget ,can you you this still take, except when it almost time is for the next dose. Just then simply the old schema.

Do you have any other questions about the use of this medicine? Please contact your doctor or pharmacist.

4. Possible side effects

Such as each medicine can also this medicine side effects have. Not everyone gets affected by it.

Rarely (occur in in less than 1 in 1000 users):

Severe hypersensitivity reactions (anaphylaxis).

Very rarely (occur in less than 1 in 10,000): less than 1 in 10,000):

very serious blood disorder blood disorder due to a deficiency of white blood cells with sudden high fever, severe sore throat and ulcers in the mouth (agranulocytosis).

A blood disorder due to a deficiency of white blood cells, making you more susceptible to infections (neutropenia).Deficiency

of to platelets, making you more susceptible to bruising bruises.

blood disorder that manifests as an increased sensitivity to infections for infections (transient leukopenia). This abnormality disappears again when you stop using

Metronidazole Aurobindo. Metronidazole condition

of the brain from the brain with for example confusion and convulsions

(encephalopathy), a condition of the brain with for example coordination problems,

speech disorders, difficulties with walking, convulsions of the eyeball and tremors (cerebellar syndrome). These side effects may recover after discontinuing the treatment

treatment.

A severe inflammation of the large intestine with symptoms fever and severe ,persistent or bloody diarrhea (pseudomembranouspseudomembranous colitis).

Increased amount liver enzymes in the blood. Damage of the liver, which may be accompanied by jaundice (yellow discoloration of the skin or eyes).

Disorders in the control over the actions and behavior (psychotic disorders).

Not known (can with the available data not become determined):

Headache, drowsiness, dizziness, coordination disorders.

A certain form of meningitis, which usually is caused by a virus (aseptic meningitis).

Nerve disorder (neuropathy) or seizures that resemble on epilepsy.

Disorders in vision, such as double vision, myopia, blurred vision, not able to see clearly or changes in color vision . Condition.

Condition of inflammation of the optic nerve.

Damage or loss of hearing, tinnitus.

Gastrointestinal complaints such as pain in the upper abdomen, nausea, vomiting and diarrhea.

Inflammation of the oral mucosa, coated tongue, discoloration of the tongue (possibly as result of a candida-infection).

Taste disorders, such as an unpleasant metallic taste.

Inflammation of the pancreas with as symptoms severe pain in the upper abdomen radiating to the back and nausea and vomiting.

Lack of appetite (anorexia).

Darkening of your urine.

Muscle pain, joint pain.

Sudden fluid retention in the skin and mucous membranes of for example the throat or tongue, breathing difficulties or itching and skin rash, often as allergic reaction (angioneurotic edema).

Transient skin rash in some infectious diseases, itching, flushing, skin rash with severe itching and formation of welts (hives).

Sharp demarcated area of the skin with redness and sometimes with blisters, that arises due to hypersensitivity to the medication (fixed-drug eruption).

Severe, sudden allergic reaction with high fever, blisters on the skin and peeling of the skin (toxic epidermal necrolysis).

Severe allergic reaction with high fever, blisters on the skin, joint pain and/or eye inflammation (Stevens-Johnsonsyndrome).

Severe skin rash with sudden eruption of dozens to hundreds 1 to 2 mm large vesicles filled with pus (acute generalized exanthematous pustulosis).

Liver failure, in which liver transplantation necessary was. This has been reported in patients who were treated with metronidazole together with another antibiotic . Acute.

Acute liver failure in patients with the syndrome of Cockayne (see section 2 "When should you be extra careful with this medicine ?"). Observations

of from things that are not there (hallucinations), confusion, depressive mood.

Fever.

Dizzy feeling (vertigo).

Arrhythmias (so-called QT-prolongation that can be seen on an ECG), especially when metronidazole was used with other medications that heart rhythm can disturb.

The frequency, nature and severity of side effects are in children the same as in adults.

The reporting of side effects

Do you experience side effects, please contact your doctor or pharmacist. This applies also to side effects that are not in this leaflet . You. You can side effects also report via the Dutch Side Effects Center Lareb, www.lareb.nl. By reporting side effects ,you help us to gain more information to obtain about the safety of this medicine.

5. How do you store this medicine ?Out of the

sight and reach range of children keep.

There is no special storage temperature required. Store in the original packaging.

Do not use this medicine any more after the expiry date. You find it on the label, the box or the bottle. It states a month and a year. The last day of that month is the expiry date.

Do not flush medications down the sink or the toilet and do not throw them in the trash can. Ask your pharmacist what to do with medications you should do not use anymore. If you medications

in the right way dispose, be they in a correct way destroyed and enter they not into the environment end up.

6. Contents of the package and other information

Which substances are in this medicine?

The active ingredient in this medicine is metronidazole. One tablet contains 250 or 500 mg metronidazole.

The other substances in this medicine are croscarmellose sodium, lactose monohydrate, povidone, magnesium stearate, corn starch, microcrystalline cellulose, hydroxypropylmethylcellulose, titanium dioxide (E171) and macrogol 400.

How does Metronidazole Aurobindo look and what is in a package?

Metronidazole Aurobindo 250 mg are white, rounded coated tablets with a score line.

Metronidazole Aurobindo 500 mg are white, rounded coated tablets with a score line with the letters "CLJ". The score line is not intended to divide the tablet into two equal doses. Packages

PVC/Al

strip packaging : 20 or 30pieces ..

tablet bottles with with one HDPE/LDPE or HDPE cap: 100 pieces.

It is possible that not all mentioned pack sizes in the market are introduced.

Holder of the license for in the market introduction and manufacturer
Marketing Authorization Holder
Aurobindo Pharma B.V., Baarnsche Dijk 1, 3741 LN Baarn

Manufacturer
Generis Farmacêutica, S.A., Rua João de Deus, 19, 2700-487 Amadora, Portugal

Registered in
Metronidazole Aurobindo 250 mg, film-coated tablets RVG 07074.
Metronidazole Aurobindo 500 mg, film-coated tablets RVG 08652.

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Transtoyou