

PACKAGE LEAFLET: INFORMATION FOR THE USER

Minocycline Aurobindo 50 and 100 mg, film-coated tablets minocycline hydrochloride

Read carefully the entire leaflet before you take this medicine because it contains important information in for you.

Keep this leaflet. You may need it later again ..

you have questions ? Then contact your doctor or pharmacist.

Do not give this medicine to others because it is only prescribed to you . It can be harmful to others . others, also already have they the same complaints as you.

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

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

Minocycline is a semi-synthetic tetracycline derivative. It is an oral active antibiotic that is used for the treatment of infections ,sexually transmitted diseases and actinomycosis (actinomycosis infection with a certain type of fungus).

Minocycline is intended for the treatment of infections of the respiratory tract, the gastrointestinal tract, the urinary tract, the skin, as well as throat-, nose- and ear infections, caused by for minocycline sensitive micro-organisms. Minocycline can also be used in the treatment of sexually transmitted diseases, fungal infections or anthrax in patients who are allergic to penicillin penicillin.

2. should you not use this medicine ? of must you extra careful with be?

When may you this medicine not use?

Minocycline should not be applied applied at:

patients who allergic are to minocycline or to one of the substances in this medicine.

These substances can you find in section 6

at a serious deterioration of the liver function

during pregnancy and the giving of breastfeeding

in children under the 8 year.

When should you be extra careful with this medicine ? Minocycline

coated tablets should only under close medical supervision supervision to be administered to the following patient groups:

patients with liver and renal dysfunction
patients with disorders in the blood coagulation
patients who suffer to the syndrome of Ménière.

It is possible that there during the use of minocycline an infection occurs, which is caused by organisms that not sensitive are to minocycline.

In longer therapy duration it is advisable to recommend regularly checks of blood count, liver and kidney function out to perform, especially in patients with a poor liver or kidney function. In infections caused by organisms that are not sensitive are for minocycline and skin problems (manifests itself as sunburn), must the administration be discontinued ..

occurrence of from dizziness can the desired be the dosage to adjust ,in the occurrence of balance disorders and in symptoms symptoms, such as double vision, hallucinations and dark spots in the visual field, the treatment with minocycline should be discontinued .. is is offered, especially in patients suffering from the syndrome of Ménière (certain disorder of the vestibular system).

In the occurrence of severe diarrhea accompanied ongoing with fever during the therapy should the therapy be discontinued ..

can affect blood clotting blood coagulation influence. In connection with this should application of tetracyclines, in patients with disorder in the blood coagulation, cautiously be done. If one hypersensitive is for minocycline, appears one this often also to be for related compounds (e.g.. doxycycline).

Administration of isotretinoin should to be avoided before, during and after treatment with minocycline.

Extra caution is required in existing systemic lupus erythematosus (SLE, a certain auto-immune disease) or when this develops ;this is characterized by skin rash (especially on theface), face), hair loss, fever, a feeling of unwell being and illness and joint pain. The taking of minocycline can a deficiency of vitamin B, ascorbic acid and folic acid cause and can laboratory tests affect.

Minocycline can the function of the thyroid change; this is characterized by a swelling of the thyroid or pain in the neck or throat.

Consult your doctor if one of the above warnings applies you of application is or that in the past has been.

Do you still other medications?

Do you besides Minocycline Aurobindo still other medications, have you that recently done or is there the possibility that you in the near future other medications will take use? Tell that then your doctor or pharmacist. That applies also to medications for which no prescription is needed for.

A interaction can occur with simultaneous use of minocycline and a number of other medications, such as:

blood-thinning agents

penicillins

antacid agents for the stomach, these reduce the absorption of minocycline

iron supplements, these reduce the absorption of minocycline

activated charcoal en ion exchangers, these reduce the absorption of minocycline
isotretinoin.

Pregnancy, breastfeeding and fertility

Are you pregnant, do you think you pregnant to be, do you want to become pregnant or are you breastfeeding ? Then contact your doctor or pharmacist before you use medication .
Pregnancy medicines used.

Pregnancy

Minocycline should not be used during pregnancy pregnancy.

When

using minocycline no breastfeeding should be given ..

Driving ability in the use of machinery

Given the possible balance disorders and issues with vision, which minocycline can cause, caution is advised at the operating of vehicles or operating machines.

Minocycline Aurobindo contains lactose

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

Minocycline Aurobindo contains sodium

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

3. How do you use this medicine ?Use

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

doctor will will a personal, to your complaints adjusted, dosage prescribe.

Dosage

Start and maintenance therapy: 50 mg every 12 hours.

The therapy should be continued for 4-6 4-6 ..

severe infections Adults

: 200 mgas initial dose initial dose followed by 100 mg every 12 hours . In. In many cases can a dosage of 200 mg on the first day, followed by a daily dose of 100 mg, be sufficient .. :

In children children from 9 to 12 years is the usual initial dose 100 to 200 mg, followed by a dose of 50 to 100 mg, every 12 hours. This dosage corresponds to 2 to 4 mg/kg per day.

Minocycline should not be prescribed to children under the 8 years.

Infections to the urinary tract

In the treatment of infections to the urinary tract in the man the initial dose is 200 mg, followed by 100 mg every 12 hours ,, during minimum 4 days and followed by a check week 2-3 days after the treatment. A single dose of 200 to 300 mg proved in more than 90% of the cases effective to be. For convenience or in control difficulties can therefore this single-dose therapy be applied.

For adults women with acute urinary tract infections is sometimes a more prolonged therapy necessary (10 days).

Tetracyclines have the advantage simultaneously effective to are against the bacteria of “non specific urinary tract infections”, thereby the prevention of post-urinary tract infections is reduced. The dosage for these acute infections is 100 mg per day. The therapy should be continued for 1 1 3 3 ,after the the characteristic symptoms or the fever are disappeared. In patients with a reduced kidney function the dose must be adjusted .. Patients with a severely impaired liver function may, only if it cannot be otherwise, minocycline prescribed receive.

Method of administration

The tablets must with plenty of water be taken to prevent irritation of the esophagus to avoid. After the intake you should not immediately lie down lie. The tablets may during the meals and possibly also with milk be taken, if the intake stomach complaints causes.

Dosage adjustments

In case of balance problems or difficulties with the vision the dosage should be adjusted ..

happens if there is there suddenly stopped is with the use of the medicine

If you the by your doctor prescribed course do not complete, can it be that the infection not completely disappeared is and returns again.

Have you taken too much of this medicine?

If you suspect a serious overdose ,you should discontinue the use of Minocycline Aurobindo and contact your doctor. contact on tea take with your doctor.

Symptoms of overdose that can occur include :: with symptoms such as vomiting ,fever attacks fever attacksjaundice ,bruising bruises, blood containing pitch-black stools and fluid loss.

The treatment of an overdose consists of: having them drink water, inducing vomiting, gastric lavage (in case of large quantities), administer laxatives. Administer antacids to reduce absorption . Have you.

to take this medicine in to take?

Take the dose still in when you discover that you forgotten are this in to take, unless you just discovered when it time is for your next dose. In that last case you should missed dose not extra take, but just your schedule continue follow. It is important to tablets according to schedule in to take. Consult in case of doubt your doctor.

If you stop taking this medicine Your doctor

has indicated how long you should use minocycline indicated how long you minocycline must use. Stop the treatment not prematurely without with your doctor to consult.

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

4. Possible side effects

Like any medicine can also this medicine have side effects. Not everyone gets thereby to deal.

Stop immediately taking the tablets and seek direct medical help, if you experience any symptoms gets from the following:

allergic reactions (anaphylaxis, hypersensitivity): petechiae, bruising and discoloration of the skin (purpura), shock, mottled skin (exfoliative dermatitis), increase of the number white blood cells and one or more of the following symptoms: inflammation of the liver (hepatitis), pneumonia that is caused by an infection (pneumonitis), inflammation of the kidneys, inflammation of the heart muscle (myocarditis) or the pericardium (pericarditis), fever, swollen lymph nodes

lupus-like syndrome: the presence of antinuclear antibodies in the blood, joint pain (arthralgia), stiffness or swelling of the joints one or more of the following symptoms: fever, muscle pain (myalgia), liver inflammation (hepatitis), skin rash, inflammation of the blood vessels

serum sickness-like syndrome: fever, itchy skin rash, skin rash, joint pain (arthralgia), joint inflammation (arthritis), stiffness or swelling of the joints, increased number white blood cells in the blood

increased intracranial pressure: headache, problems with the vision, such as blurred vision, "blind" spots, double vision, permanent loss of sight. In children the skull may bulge

growth of bacteria that are resistant to tetracycline: inflammation of the intestines, inflammation of the tongue and the mouth, inflammation of the female genital organs (causes itching), pain during urination, irritation of the buttocks, upset stomach development

or of exacerbation of systemic lupus erythematosus (SLE), symptoms include large areas with red patches on the skin, hair loss, weight loss, painful joints and fever

symptoms of liver damage: fatigue, weakness, loss of appetite, weight loss, abdominal pain, fever

changed color of the skin, nails, teeth, mucous membranes of the mouth, bones, thyroid, eyes, breast milk, tears of sweat (hyperpigmentation).

Consult your doctor if the following side effects occur:

Side effects that sometimes occur (at 1 to 10 out of 1000 patients)

changes in the number and types blood cells
skin rash that may itch with or without pale or red lumps in the skin, swelling of the face, lips, tongue or throat
fever.

Side effects that rarely occur (in 1 to 10 in 10,000 patients)

more blue bruises, nosebleeds, throat infections, infections, extreme fatigue, shortness of breath with exertion or unusual paleness of the skin. Your doctor may ask you to a blood test to perform
dizziness, headache
nausea, diarrhea, vomiting, loss of appetite, underdevelopment of the tooth enamel, inflammation of the esophagus
fungal infection on your buttocks, genital organs or the mouth, inflammation of the male genital organs
increased urea levels in the blood
hair loss, skin reactions including red spots (erythema multiforme), severe skin reactions with redness, fever, blisters or ulcers (Stevens-Johnson syndrome), severe skin rash with redness, peeling and swelling of the skin, which resembles a burn (toxic

epidermal necrolysis), red bumps on the legs (erythema nodosum), sensitivity to sunlight or artificial light (for example sunbed)
joint pain (arthralgia), joint inflammation (arthritis), stiff or swollen joints, muscle pain (myalgia), systemic lupus erythematosus (SLE); if you already have suffer from SLE, then can Minocycline Aurobindo that worsen inflammation of the liver (hepatitis) or the kidneys.

Side effects that very rarely occur (in less than 1 in 10,000 patients)

inflammation of the tongue, mouth or intestines, difficulty with swallowing, indigestion
digestion of watery diarrhea, fever and cramps (pseudomembranous colitis)
acute renal failure
altered thyroid function. Tell your doctor when you notices that you experience gets from a swelling on the thyroid gland or if you pain in the neck or throat feels liver failure, jaundice (yellow become of the skin or the white of the eye), inflammation of the pancreas (pancreatitis), abnormal liver function tests.

Other side effects

Other side effects occurred in in a very small number of patients, the exact frequency is not known:

decreased levels of vitamin B, ascorbic acid and folic acid
delusions (hallucination), tingling or sharp pains in the hands and feet, feeling of dizziness and lightheadedness (vertigo), reduced sense of touch, seizures, drowsiness
vasculitis
reduced hearing, ringing in the ear
inflammation of the liver, because the immune system itself against the liver directs (auto-immune hepatitis)
bone pain, fragility or weakness of the bones
painful, bluish-red nodules in the skin (erythema nodosum).

The reporting of side effects

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

5. How do you store this medicine ?For

this medicine there are there no special storage conditions.

Keep out of sight and reach of children ..

this medicine after the expiry date on the packaging expiry date. It is to find on the packaging after "Exp.:". There is a month and a year. The last day of that month is the expiry date. Consult if in doubt about the shelf life your pharmacist.

Do not flush medications down the sink or the toilet and throw them away not in the trash can. Ask your pharmacist what to do with medications you should do not anymore needed are. If you medications in the right way disposes become they on 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 minocycline hydrochloride. Minocycline Aurobindo 50 and 100 mg, coated tablets contain per tablet respectively 50 and 100 mg minocycline base.

The other ingredients in this medicine are: povidone, lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, colloidal silicon dioxide, magnesium stearate, methylhydroxypropylcellulose, macrogol 6000, yellow iron oxide (E172), titanium dioxide (E171).

How does Minocycline Aurobindo look and what is in one packaging?

Minocycline Aurobindo 50 mg: round light yellow, biconvex tablets.

Minocycline Aurobindo 100 mg: oblong light yellow, biconvex tablets.

Minocycline Aurobindo 50 mg: 30 coated tablets in 3 blister packs (PVC/PVDC/Al) of 10 pieces.

Minocycline Aurobindo 100 mg: 30 coated tablets in 3 blister packs (PVC/PVDC/Al) of 10 pieces.

Holder of the license for in the trade bringing and manufacturer Marketing Authorization Holder

Aurobindo Pharma B.V.
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3741 LN Baarn

Manufacturer
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Minocycline Aurobindo 50 mg, coated tablets is registered in the register under RVG 22098.

Minocycline Aurobindo 100 mg, coated tablets is registered under RVG 22099. This

leaflet is last approved in September 2024 More September 2024

More information about this medicine can you find on the website of the Medicines Evaluation Board, Evaluation of medicines, www.cbg-meb.nl.