

LEAFLET: INFORMATION FOR THE  
USER  
Doxycycline Accord 100 mg Dispersible Tablets  
Doxycycline

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

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist, or nurse has told you.

Keep this leaflet. You may need to read it again.

Do you have any questions? Contact your doctor, pharmacist, or nurse.

Do not pass this medicine on to others, as it is prescribed only for you. It may harm others, even if their symptoms are the same as yours.

Do you experience any side effects mentioned in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor, pharmacist, or nurse.

In this leaflet:

1. What is Doxycycline Accord Dispersible Tablet and what is it used for?
2. When should you not use this medicine or be extra careful with it?
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## 1. WHAT IS Doxycycline Accord Dispersible Tablet AND WHAT IS IT USED FOR?

This medicine is indicated for the treatment of infections caused by bacteria that are sensitive to treatment with doxycycline, in adults and children from 8 years old.

This medicine can be prescribed by your doctor for infections of the respiratory tract, urinary tract, genital organs, eye, or gastrointestinal tract. This medicine can also be prescribed for infections with flu-like symptoms (Q fever, Rickettsiosis/Spotted fever), in the treatment of malaria or (youth) pimples (acne).

## 2. WHEN SHOULD YOU NOT USE THIS MEDICINE OR BE EXTRA CAUTIOUS?

When should you not use this medicine?

if you are allergic to doxycycline and other tetracyclines (similar antibiotics) or any of the other substances in this medicine. These substances can you find in section 6;

if you are pregnant or want to become pregnant;

if u breastfeeding gives.

This medicine should not be used during tooth development (pregnancy, in newborns, or in children under 8 years) as use can lead to permanent discoloration (yellow-gray-brown) or affect the proper growth of the teeth.

Under certain circumstances (e.g., in severe or life-threatening conditions), your doctor may decide that the benefits of treatment outweigh this risk in children under 8 years, and that Doxycycline Accord should be prescribed.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine.

if you expose your skin to strong sunlight or artificial sunlight, as more severe burning sometimes occurs in some people using doxycycline;

if you have a liver condition;

it is possible that other infections may occur while using doxycycline. The pathogens causing these infections are not sensitive to doxycycline. If new infections occur during treatment with this medicine, you should inform your doctor, discontinue use of this medicine, and start another treatment;

if severe diarrhea occurs during treatment with this medicine, accompanied by fever. If this is the case, you must immediately inform your doctor and discontinue use of this medicine;

if you do not notice a reduction in fever and inflammatory symptoms within a few days. This may indicate that the pathogens are insensitive (resistant) to this medicine, or that other bacteria, not sensitive to this medicine, have emerged;

if you use doxycycline for a long time, your doctor may have your blood checked to rule out side effects on the kidneys, liver, and the production of new blood cells. If your doctor detects certain abnormalities, the treatment with doxycycline will be discontinued

if you have esophageal irritation or ulcer;

if you have a blood clotting disorder and are being treated with medicines that inhibit blood clotting, you should be aware that doxycycline can affect blood clotting. It is important that the doctor who prescribed doxycycline is aware of the blood clotting disorder. If you are under treatment at the thrombosis service, you should also inform the thrombosis doctor about the use of doxycycline.

Children and adolescents up to 12 years

This medicine should not be used in infants or children under 8 years, as it can cause permanent discoloration of the teeth or problems with tooth development.

This medicine should only be used in children between 8 and 12 years if other medicines are not possible or do not work.

Are you using any other medicines?

Are you using any other medicines besides Doxycycline Accord, or have you recently done so, or is there a possibility that you will use other medicines in the near future? Tell that then your doctor or pharmacist.

medicines that inhibit blood clotting, such as acenocoumarol and phenprocoumon.

The effect of these medicines is enhanced;

penicillins (certain antibiotics). These medicines can reduce the bactericidal effect of doxycycline;

iron preparations and antacids (medicines containing aluminum, calcium, magnesium, or bismuth) (see the section "When should you be extra careful with this medicine?").

These agents reduce the effectiveness of doxycycline;

antiepileptic drugs (carbamazepine, phenytoin, barbiturates). These agents reduce the effectiveness of doxycycline;

ciclosporin (a drug used to suppress the body's immune system). The amount of ciclosporin in the blood can be increased;

the anesthetic methoxyflurane. The simultaneous use of doxycycline and methoxyflurane can lead to fatal kidney toxicity;

if you are being treated for diabetes, your doctor may need to change the dose of your diabetes treatment;  
when doxycycline is used simultaneously with isotretinoin or acitretin, increased pressure in the brain can occur.

#### Pregnancy, breastfeeding, and fertility

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

This medicine should not be used during pregnancy, as it can cause permanent discoloration of the unborn child's teeth and may delay bone growth.

This medicine should not be used by breastfeeding mothers as it can cause tooth discoloration and reduced bone growth in the infant.

#### Driving and using machines

This medicine has a moderate influence on the ability to drive and operate machines.

In case of dizziness, blurred vision, or double vision, driving vehicles and operating machines is discouraged.

### 3. HOW TO USE THIS MEDICINE?

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

Your doctor determines the dosage based on the condition. It is important to follow his instructions carefully. Below is the usual dosage, but a different dosing schedule is also possible, depending on the nature of the condition.

The usual dosage for adults is: Take 2 tablets of this medicine on the first day at the same time, followed by 1 tablet per day until the course is completed.

#### Children aged 8 to 12 years:

Doxycycline Accord may be used for the treatment of acute infections in children aged 8 to 12 years if no other medicines are available or if it is unlikely that other medicines will be effective. Under those circumstances, the usual doses are:

#### For children weighing 45 kg or less:

The first day: 4.4 mg per kilogram of body weight (in a single or two divided doses), and then 2.2 mg per kilogram of body weight (in a single or two divided doses) from the second day. The duration of treatment depends on the infection being treated. In more severe infections, up to 4.4 mg per kilogram of body weight can be given for the entire duration of treatment.

For children weighing more than 45 kg – the adult dose should be used; 200 mg on the first day and then 100 mg per day. The duration of treatment depends on the infection being treated. Have you used too much of this medicine? If you are concerned that you have received too much of this medicine, tell your doctor or nurse immediately. When you use more of this medicine than you should, the risk of known side effects may be higher.

If you have taken too much doxycycline, contact your doctor or pharmacist immediately. In severe cases, your doctor will have you drink plenty of water, use laxatives, and (in very large amounts) possibly perform gastric lavage.

Symptoms that may occur when you have taken too much doxycycline include vomiting, fever attacks, jaundice, bruising, black, thin stools, and abnormalities in blood composition.

Have you forgotten to use this medicine?

Do not take a double dose to make up for a forgotten dose.

Method of use

Take the tablets in a sitting or standing position with a generous amount of water or milk or with food.

Do not take the tablets just before going to bed, as this may cause irritation of the esophagus.

If you stop using this medicine

It is important that you complete the course prescribed by your doctor, even if the symptoms of the infection have already disappeared. This prevents the infection from returning. Completing the course means continuing until all the tablets prescribed by your doctor are finished.

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

#### 4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everyone gets them. Contact your doctor as soon as possible if you experience any of the following side effects:

- the Jarisch–Herxheimer reaction, which causes fever, chills, headache, muscle pain, and skin rash that usually resolves on its own. This reaction occurs shortly after starting treatment with doxycycline for spirochete infections such as Lyme disease.

Common (occur in 1 to 10 out of 100 users during treatment with the group of medicines to which this medicine belongs (tetracyclines)):

vaginal inflammation (vaginitis);  
candidiasis (certain fungal infection);  
nausea;  
itching (pruritus) around the anus;  
black tongue;  
inflammation in the mouth (stomatitis);  
inflammation of the genitals and/or the anus;  
bone development disorder;  
skin irritation.

Sometimes (occur in 1 to 10 out of 1000 users during treatment with the group of medicines to which this medicine belongs (tetracyclines)):

headache;  
vomiting;  
diarrhea;

glossitis;  
skin rash;  
photosensitivity.

Rare (occur in 1 to 10 out of 10,000 users during treatment with the group of medicines to which this medicine belongs (tetracyclines)):

anemia due to excessive breakdown of blood (hemolytic anemia), blood disorder with symptoms of bruising and bleeding tendency (thrombocytopenia), blood disorder (lack of white blood cells) accompanied by increased susceptibility to infections (neutropenia), excess of a certain type of white blood cells (eosinophilia);  
drug rash (DRESS)  
brown-black discoloration of the thyroid (with long-term administration);  
lack of appetite (anorexia);  
ringing in the ears (tinnitus);  
inflammation of the membrane around the heart;  
flushing;  
swallowing disorder (dysphagia), impaired digestion with a feeling of fullness or pain in the stomach area, belching, nausea, vomiting and heartburn (dyspepsia);  
inflammation of the intestines;  
inflammation of the pancreas, with symptoms of severe pain in the upper abdomen radiating to the back and nausea and vomiting (pancreatitis);  
altered liver function, liver poisoning (hepatotoxicity), liver inflammation (hepatitis), jaundice, liver failure;  
skin rash with irregular red spots (erythema multiforme), severe allergic reaction with high fever, blisters on the skin, joint pain and/or eye inflammation (Stevens-Johnson syndrome), severe, sudden allergic reaction, with symptoms of fever and blisters on the skin and peeling of the skin (toxic epidermal necrolysis), skin rash with intense itching (hives) and formation of welts (urticaria), scaling skin;  
exacerbation of a certain condition that can affect various organs in the body, including skin, lungs, heart, kidneys, brain and nerves, eyes, joints, and intestines (systemic lupus erythematosus);  
joint pain, muscle pain, abdominal pain.

Very rare (occur in less than 1 in 10,000 users during treatment with the group of medicines to which this medicine belongs (tetracyclines)):

hypersensitivity reactions;  
increased fontanelle in babies, increased pressure in the brain. This may be accompanied by symptoms such as headache, blurred vision, double vision, nausea, vomiting, ringing in the ears, eye pain, and seeing stars. These symptoms disappear within a few days or weeks after treatment;  
severe inflammation of the colon accompanied by fever and the secretion of mucus sometimes mixed with pus and blood (pseudomembranous colitis).

Unknown (occur during treatment with the group of medicines to which this medicine belongs (tetracyclines) and based on known data, the frequency cannot be determined):

bleeding tendency, (prolongation of clotting time);  
disorder in the production of red blood pigment (porphyria);  
accelerated heartbeat (tachycardia);  
discoloration of the teeth or tooth development disorder

reduced development of tooth enamel;  
detachment of the nail, which sometimes leads to the loss of the nail, after exposure to the sun (photo-onycholysis).  
skin lesion caused by hypersensitivity to a certain medication characterized by a sharply defined, raised area with redness, and sometimes blistering (fixed drug eruption)

#### Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to any side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb (website [www.lareb.nl](http://www.lareb.nl)). By reporting side effects, you can help us obtain more information about the safety of this medicine.

#### 5. HOW TO STORE THIS MEDICINE?

Keep out of the sight and reach of children.  
Store below 25°C.  
Store in the original packaging.  
Do not take the tablets after the expiry date which is stated clearly on the packaging. The expiry date refers to the last day of that month.  
Medicines should not be disposed of via wastewater or with household waste. Ask your pharmacist how to dispose of medicines you no longer need. These measures will help protect the environment.

#### 6. CONTENTS OF THE PACK AND OTHER INFORMATION

What substances are in this medicine?

The active substance in this medicine is doxycycline. Each tablet contains 100 mg doxycycline. The other substances (excipients) in this medicine are: Maize starch, microcrystalline cellulose, polyvinylpyrrolidone (Povidone K30), sodium starch glycolate, purified talc, magnesium stearate, glyceryl palmitostearate, colloidal anhydrous silica.

What do Doxycycline Accord Dispersible Tablets look like and what is in a pack?

Yellow-green to yellow-grey round, biconvex tablets with the imprint 'AO' on one side and a score line on the other side Blister pack of PVC/Alu – 8 tablets per box The tablets are also packed in polypropylene containers with 100, 250, 500, 1000, and 5000 tablets Not all pack sizes may be marketed

Marketing authorization holder

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