Package leaflet: Information for the patient

Adimax® 200 mg/5 ml, powder for oral suspension

Azithromycin

adipharm

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Adimax® is and what it is used for

The active substance contained in this drug is the macrolide antibiotic azithromycin. It disrupts protein formation in the cells of different bacteria thus suppressing the growth and replication of the microorganisms causing common human diseases.
Adimax® is used for treatment of infections caused by bacteria susceptible to azithromycin, such as:
- upper respiratory tract infections: sore throat, tonsilitis, sinusitis, media ear infection
- lower respiratory tract infections: bronchitis, different types of pneumonia;
- skin and soft tissue infections: stage 1 of the Lyme disease (tick-transmitted disease), erysipelas, different bacterial skin infections;

2. What you need to know before you take Adimax®

Do not take Adimax®:
- if you are allergic (hypersensitive) to azithromycin or any of the other ingredients of this medicine;
- if you are allergic (hypersensitive) to other macrolide antibiotics;
- if you are taking ergot derivative-containing products because of possible ergotism manifesting with "blue limb" effect and limping;

Warnings and precautions

In some cases serious allergic reactions may occur, such as swelling of the face,lips, tongue and/or throat, wheezing (shortness of breath), etc. Some of them may reappear due to the prolonged drug retention in tissues which requires an extended period of observation and treatment. In case of appearance or suspicion of an allergic reaction, product administration should be discontinued.
This is a prescription product and should be used with caution in patients with significant weight loss, cardiac rhythm disorders (risk of cardiac adverse events) and patients with impaired immunity. Caution should be exercised in patients with severe renal and/or hepatic diseases (particularly in case of bile retention).
You should know that the doctor will assess if this product is appropriate for treatment of certain types of pneumonia.
Similar to the treatment with other antibacterial agents, superinfections may develop (antibiotic-associated additional infections) caused by fungi or other bacteria.
A pseudomembranous colitis (inflammation of the colon progressing with a severe and persistent diarrhea) of different severity may develop. Specific treatment is required in the moderate and severe forms of the disease.

Children

Use of this product is not recommended in new-born and preterm babies.

Other medicines and Adimax®

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This product may be co-administered with carbamazepine, methylprednisolone, theophylline, didanosine.
In coadministration of azithromycin with:
- digoxin: the levels of digoxin in the blood are elevated;
- rifabutin: white blood cell count may decrease;
- ergot derivatives: risk of ergotism;
- drugs that decrease blood clotting (e.g. warfarin, coumarin anticoagulants) & risk of haemorrhages. It is necessary to control some laboratory parameters such as prothrombin time;
- terfenadine: risk of heart rhythm disorders

The doctor should assess the benefit of coadministration of azithromycin with cyclosporin, and if required, the levels of cyclosporin in the blood should be monitored, and the dose adjusted if necessary.

Adimax® with food and drink

Adimax® may be taken with or without food.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

This product is intended for children but nevertheless you should know that:
- clinical data on the safe use of azithromycin in pregnant women are insufficient, therefore the product is subject to medical prescription;
- it is not known whether azithromycin is excreted in breast milk, therefore azithromycin may be used by breastfeeding women only if there is no alternative, or else breastfeeding should be discontinued during treatment with azithromycin.

Driving and using machines

No data exist about azithromycin affecting the ability to drive and use machines.

Important information about some ingredients in Adimax®

Adimax® contains as an excipient sucrose which should be taken into consideration in the treatment of patients with diabetes mellitus.
Each 5 ml of the reconstituted suspension contains 3.6 g sucrose.

3. How to take Adimax®

Always take Adimax® exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Upper or lower respiratory tract infections, skin and soft tissue infections

Recommended dose is: 10 mg/kg once daily for 3 days. In case the sore throat is caused by a certain type of bacteria, the so called streptococci, your doctor may consider it necessary to administer a higher dose (20 mg/kg once daily).

To achieve appropriate dosing of the product according to body weight, please use the following information:

Body weight	Daily dose Adimax® 200 mg/5 ml, powder for oral suspension
10 – 14 kg	2.5 ml (100 mg)
15 – 24 kg (3 – 7 years)	5 ml (200 mg)
25 – 34 kg (8 – 11 years)	7.5 ml (300 mg)
35 – 44 kg (12 – 14 years)	10 ml (400 mg)
≥ 45 kg	Dose as per adults 12.5 ml (500 mg)

In children up to 15 kg body weight (under 3 years of age): Determine the dose as accurately as possible using the oral dosing syringe provided with the pack.

Pneumonias

The recommended dose is 10 mg/kg once daily on the first day, and then 5 mg/kg once daily on days 2 to 5.

Lyme disease

Recommended dose: 20 mg/kg once daily on the first day and then 10 mg/kg once daily from day 2 to day 5. Total dose for the course of therapy: 60 mg/kg.

Kidney impairment
No dose adjustment is required in patients with mild renal function impairment. In case of severe renal impairment the doctor will assess if treatment with this product is possible, and the necessary dose adjustment.

Liver impairment
Since azithromycin is metabolized in the liver and excreted in the bile, the drug should not be used in patients with severe liver failure.

Method of administration
Adimax® powder for oral suspension should be used as a single daily dose. The precise dose should be measured after reconstitution of the suspension by using an oral dosing syringe provided with the pack.
The drug may be taken with or without food.

Instructions for reconstitution of the suspension

1. The bottle contains a dry powder which reconstitutes with water.
2. Turn the cap anticlockwise to open.
3. Fill the bottle with cold water. With oral dosing syringe provided with the pack you can measure the right amount of water. The right amount of water depends on the pack size:
   - For pack size for 20 ml reconstituted suspension - add 10,5 ml of water
   - For pack size for 30 ml reconstituted suspension - add 15 ml of water
4. Shake well until obtaining a homogeneous suspension.
5. Store reconstituted suspension below 30°C and discard when full dosing is completed.
6. Shake the suspension before each use.

Instructions for using the dosing syringe

1. Dip the tip of the dosing syringe in the suspension and use the plunger to withdraw the necessary amount .
2. Make sure the child is supported in a position for feeding, put the tip of the dosing syringe in the child's mouth and slowly squirt the suspension.
3. Upon the intake of the medicinal product, give the child a small amount of juice or water.
4. After use, rinse the dosing device with water and store in a dry and clean place.

If you take more Adimax® than you should
If you have used more than the prescribed dose, tell your doctor or go to the nearest hospital. The usual symptoms of this antibiotic overdose include reversible loss of hearing, severe nausea, vomiting and diarrhea. In case of overdose it is necessary to give activated charcoal and use appropriate drugs.

If you forget to take Adimax®
If you have missed a dose, take it as soon as you remember.
Do not take a double dose to make up for a forgotten dose. Take the next dose at the usual time.

If you stop taking Adimax®
Do not stop the drug administration even if your child feels better, unless your doctor tells you to do so.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects
Like all medicines, Adimax® can cause side effects, although not everybody gets them.
This product is usually well tolerated. The indicated frequency refers to the reported side effects:
Common: may affect more than 1 in 100 patients and less than one in 10 patients.
Uncommon: may affect up to 1 in 1000 patients and less than 1 in 100 patients
Rare: may affect up to 1 in 10,000 patients and less than 1 in 1000 patients
Very rare: affect less than 1 in 10,000 patients.

The drug-associated adverse reactions include the following:
Blood and lymphatic system disorders
Rare: Platelet or white blood cell count decreased
Heart disorders
Rare: heart palpitations, heart rhythm disorders of various severity
Ear and labyrinth disorders
Rare: dizziness, vertigo, poor hearing , ringing and noise in the ears (mostly transient; occur with higher doses for longer periods of time)
Gastrointestinal disorders
Common: nausea, vomiting, diarrhea, abdominal pain/spasms
Uncommon: loose stools, wind, indigestion, loss of appetite, gastric acidity increased
Rare: tongue discoloration, inflammation of the pancreas, blood in stools (black stools), pseudomembranous colitis
General disorders and administration site conditions
Rare: general discomfort, tiredness, chest pain
Hepatobiliary disorders
Common : liver enzymes increased
Rare : hepatitis and jaundice, severe liver function impairment
Immune system disorders
Rare: severe allergic reactions incl. allergic shock
Infections and infestations
Uncommon: bacterial inflammation or yeast infection of the vagina
Musculoskeletal system and connective tissue disorders
Rare: joint pains
Nervous system disorders
Uncommon: headache, dizziness, vertigo, numbness or pins and needles, altered taste or sense of smell, sleepiness
Rare: seizures, hyperactivity, short term loss of consciousness
Psychiatric disorders
Uncommon: nervousness
Rare: aggression, agitation, anxiety
Kidney and urinary tract disorders
Rare: nephritis (inflammation of the kidneys) and severe kidney failure
Skin and subcutaneous tissue disorders
Uncommon: itching, rash, hives (urticaria)
Rare: allergic reactions incl. swelling of the face, lips, tongue and throat, photosensitivity (skin reaction on exposure to sunlight), severe skin damage (e.g. Stevens-Johnson syndrome, toxic epidermal necrolysis).
Vascular disorders
Rare: hypotension (low blood pressure)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system.

5. How to store Adimax®.
Store dry powder below 30°C. Store constituted suspension below 30°C and discard when full dosing is completed.

Keep this medicine out of the sight and reach of children.

Do not use Adimax® after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information
What Adimax® powder for oral suspension contains
The active substance per 5 ml suspension is azithromycin dihydrate equivalent to azithromycin 200 mg.
The other ingredients are: sucrose, sodium phosphate anhydrous, hydroxypropylcellulose, xanthan gum, strawberry flavour, banana flavor, silica colloidal anhydrous.

What Adimax® 200 mg/5 ml powder for oral suspension looks like and contents of the pack
Appearance
Adimax® powder for oral suspension is a white to almost white powder which reconstitutes with water to give a suspension with vanilla flavor and slight banana odour.

Pack size
Adimax® 200 mg/5 ml powder for oral suspension is packed in a dark glass bottle, closed with a polyethylene screw cap and comes with the following pack sizes:
- bottle with powder for the preparation of 20 ml suspension.
- bottle with powder for the preparation of 30 ml suspension.

1 (one) bottle along with a leaflet and an oral dosing syringe in a single folding.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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