Adimax® 500 mg film-coated tablets

Azithromycin

adipharm

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

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

ADIMAX® contains azithromycin which belongs to the group of antibacterial medicinal products for systemic use, macrolide.

ADIMAX® is indicatedi for the treatment of the following infections when known or likely to be due to one or more susceptible microorganisms:

Upper respiratory tract infections including pharyngitis/tonsilitis, sinusitis and otitis media.

Lower respiratory tract infections including bronchitis and community-acquired pneumonia

Skin and soft tissue infections including moderate acne vulgaris, erythema chronicum migrans (first stage of Lyme disease), erysipelas, impetigo and secondary pyoderma.

Sexually transmitted diseases including uncomplicated genital infections due to *Chlamydia trachomatis*

Gastric and duodenal infections caused by *Helicobacter pylori*.

2. Before you use ADIMAX®

Do not use ADIMAX®:

- if you are allergic (hypersensitive) to azithromycin, to any macrolide, or to any of the other ingredients of ADIMAX®
- concomitantly with ergot derivatives, because of the theoretical possibility of ergotism.

Take special care with ADIMAX®

In rare cases, azithromycin is reported to have caused serious allergic (rarely fatal) reactions, such as angioneurotic oedema and anaphylaxis. Some of these reactions have caused recurrent symptoms and have required longer observation and treatment.

Streptococcal infections: Penicillin is usually the first choice for treatment of pharyngitis/tonsillitis due to *Streptococcus pyogenes* and also for prophylaxis of acute rheumatic fever. Azithromycin is in general effective against streptococcus in the oropharynx, but no data are available that demonstrate the efficacy of azithromycin in preventing acute rheumatic fever.

Superinfections: As with any antibacterial agent, there is a possibility that superinfections could occur (e.g. fungal infections).

Taking other medicines

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

ADIMAX® should be taken at least 1 hour before or 2 hours after the antacid.

Administration of azithromycin does not affect the blood levels of carbamazepine, methylprednisolone, theophylline, didanosine and rifabutine.

Neutropenia was observed in subjects receiving concomitant azithromycin and rifabutin. Although neutropenia has been associated with the use of rifabutin, a causal relationship to combination with azithromycin has not been established.

The therapeutic situation should be carefully considered before azithromycin and cyclosporin are administered simultaneously. If combination treatment is considered justifiable, ciclosporin levels should be carefully monitored and the dose should be adjusted accordingly.

An increased tendency towards haemorrhage has been reported in connection with the concurrent use of azithromycin and warfarin or coumarin-like oral anticoagulants. Attention should be paid to the frequency of prothrombin time monitoring.

In patients receiving azithromycin and digoxin, the possibility of a rise in the digoxin concentrations should be borne in mind and digoxin levels monitored.

Because of theoretical possibility of ergotism, azithromycin and ergot derivates should not be concomitantly administered.

Azithromycin should be administered with caution in combination with terfenadine. However, there was no specific evidence that such an interaction had occurred. Occurrence of serious dysrhythmia secondary to prolongation of the QTc interval in patients receiving other anti-infectives in conjunction with terfenadine has been reported.

Zidovudine: 1000 mg single doses and 1200 mg or 600 mg multiple doses of azithromycin had no effect upon the plasma pharmacokinetics or urinary excretion of zidovudine or its glucuronide metabolite.

However, administration of azithromycin increased the concentrations of phosphorylated zidovudine, the clinically active metabolite, in mononuclear cells in the peripheral circulation. The clinical significance of these findings is unclear, but may be of benefit to patients.

Taking ADIMAX® with food and drink

ADIMAX® 500 mg tablets may be taken with or without food.

Pregnancy and breast-feeding

There are no adequate and well controlled studies in pregnant women. Azithromycin should be used during pregnancy only if adequate alternatives are not available.

There are no studies determining whether the drug passes into breast milk, so that azithromycin should only be used in lactating women where adequate alternatives are not available.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Azithromycin has not been found to affect on the ability to drive or operate machinery.

3. How to use ADIMAX®

Always take ADIMAX® exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure

Method of administration

ADIMAX® 500 mg tablets are taken as a single daily dose.

The usual dose is:

Adults, including elderly patients and children over 45 kg body weight

In the treatment of upper and lower respiratory tract infections and skin and soft tissue infections (with exception of erythema migrans): the total dose of azithromycin is 1500 mg which should be given over three days (one 500 mg film-coated tablet as single dose).

In the treatment of moderate acne vulgaris the total dose of 6 g

is recommended in following regimen: one 500 mg tablets once daily over 3 days followed by 500 mg tablet once weekly for the following 9 weeks. The second week dose should be taken seven days after the first taken tablet and the 8 following doses should be taken in 7 days intervals.
In the treatment of erythema migrans the total dose is 3 g: 1 g once daily (two 500 mg film-coated tablets as single dose) on the first day, followed by 500 mg once daily (one 500 mg film-coated tablet as single dose) from second to fifth day.
In the treatment of uncomplicated genital infections due to *Chlamydia trachomatis*: 1 g (two 500 mg film-coated tablets) as a single dose.
In the treatment of gastric and duodenal infections caused by *Helicobacter pylori*: 1 g once daily (two 500 mg film-coated tablets) for 3 days, in combination with antisecretory and other drugs, according to doctor's decision.
ADIMAX® 500 mg film-coated tablets are suitable only for children of at least 45 kg body weight for whom the adult dose may be used.
Renal failure
In patients whose renal function is slightly impaired (creatinine clearance >40 ml/min) adjustment of the dose is not necessary. No studies have been conducted in patients with a creatinine clearance of <40 ml/min. Consequently caution must be exercised in the use of azithromycin for these patients.
Hepatic failure
Since azithromycin is metabolised in the liver and excreted in the bile, the drug should not be given to patients suffering from severe liver disease. No studies have been conducted regarding treatment of such patients with azithromycin.

If you take more ADIMAX® than you should

The undesirable effects seen at doses in excess of recommended doses were similar to those after normal doses. The typical symptoms of an overdose with macrolide antibiotics include reversible loss of hearing, severe nausea, vomiting and diarrhoea. In cases of overdose, the administration of medicinal charcoal and general symptomatic treatment, as well as measures to support vital functions, are indicated where necessary.

If you forget to take ADIMAX®

Do not take a double dose to make up for a forgotten dose. Missed dose should be taken as soon as possible and the following ones in 24 hour intervals.
If you have any further questions to the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, ADIMAX® can cause side effects, although not everybody gets them. Frequencies of odverse drug reactions are defined as: very common (≥ 1/100, < 1/10); uncommon (≥ 1/1,000, < 1/100); rare (≥ 1/10,000, < 1/1,000). Azithromycin is well tollerated and with low frequency of adverse reactions.

Blood and lymphatic system disorders
- Rare: Thrombocytopenia, transient mild neutropenia, however, a causal relationship with the azithromycin treatment has not been confirmed.

Psychiatric disorders
- Rare: Aggressiveness, restlessness, anxiety, and nervousness

Nervous system disorders
- Uncommon: Dizziness/vertigo, somnolence, headache, convulsions(which have also been found to be caused by other macrolides), taste perversion.
- Rare: Paraesthesia and asthenia, Insomnia and hyperactivity

Ear and labyrinth disorders
- Rare: impaired hearing, deafness and ringing in the ears when azithromycin is used at large doses over prolonged periods. The majority of these problems however are reversible.

Cardiac disorders
- Rare: Palpitations, arrhythmias with associated ventricular tachycardia (which other macrolides have also been shown to cause) have been reported.

Gastrointestinal disorders
- Common: Nausea, vomiting, diarrhoea, abdominal discomfort (pain/cramps)
- Uncommon: Loose stools, flatulence, digestive disorders, anorexia
- Rare: Constipation, discoloration of tongue, Pseudomembranous colitis

Hepato-biliary disorders
- Rare: Hepatitis and cholestatic jaundice, including abnormal liver function test values, as well as rare instances of hepatic necrosis and hepatic dysfunction, which in rare instances have resulted in death.

Skin and subcutaneous tissue disorders
- Uncommon: Allergic reactions including pruritus and rash
- Rare: Allergic reactions including angioneurotic oedema, urticaria and photosensitivity; serious skin reactions such as erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis. You may experience pain at the time of injection or localirritatition on the site of injection.

Musculosceletal, connective tissue and bone disorders
- Uncommon: Arthralgia

Renal and urinary disorders
- Rare: Interstitial nephritis and acute renal failure

Reproductive system and breast disorders
- Uncommon: Vaginitis

General disorders
- Rare: Anaphylaxis including oedema (leads in rare cases to death); Candidiasis If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store ADIMAX®

Store at temperature below 30°C.
Keep out of the reach and sight of children!
Presription only medicine.
Do not use ADIMAX® after the expiry date which is stated on the outer packaging. The expiry date refers to the last day of that month.
Medicines should not be disposed of via waste-water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What ADIMAX® contains

The active substance is azithromycin (as dihydrate) Each film-coated tablet contains 500 mg azithromycin.
The other ingredients are:
- Tablet core: cellulose microcrystalline, sodium starch glycolate, hypromellose, sodium laurilsulfate, calcium hydrogen phosphate anhydrous, sodium stearyl fumarate.
- Tablet coating: hydroxypropylcellulose, hypromellose, titanium dioxide (E 171), polyethylen glycol, caprilic capric triglycerides

What ADIMAX® looks like and contents of the pack

ADIMAX® are white, oblong film-coated tablets.
3 film-coated tablets in a PVC/ Al blisters. 1 blister in a carton box.

Marketing authorization holder and manufacturer:
ADIPHARM EAD
130, Simeonovsko shosse Blvd.
Sofia 1700, Bulgaria

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