Package leaflet: Information for the user

Zedbac 500 mg powder for concentrate for solution for infusion

Azithromycin (as dihydrate)

Read all of this leaflet carefully before you start using 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, pharmacist or nurse.
- If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4

What is in this leaflet:

1. What Zedbac is and what it is used for

Zedbac belongs to a group of antibiotics called macrolides. It is used to treat localized infections caused by bacteria in many different parts of the body.

Which diseases are treated with Zedbac?
Zedbac is indicated for treatment of serious infections or when oral treatment cannot be used. It is used for treatment of pneumonia (lungs infection), and pelvic infections (infection of the reproductive organs) caused by susceptible organisms.

2. What you need to know before you are given Zedbac

Do not use Zedbac
- if you are allergic to azithromycin or any of the ingredients of this medicine (listed in section 6)
- if you are allergic (hypersensitive) to any other macrolide antibiotic (such as erythromycin or clarithromycin) or ketolide (macrolide derivatives)
- if you are taking any ergot derivatives such as ergotamine (used to treat migraine) as these medicines should not be taken together with azithromycin.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using Zedbac
- if you have an allergic reaction such as red or white spots on the skin, itching and skin irritation, swelling of the skin, larynx (throat) or tongue, and difficulty in breathing, in which case you should stop treatment with Zedbac
- if you have or have had kidney problems
- if you have or have had liver problems: your doctor may need to monitor your liver function or stop the treatment
- if you have or have had an abnormal heart rhythm in particular problems such as long QT syndrome (shown on an electro-cardiogram or ECG machine)
- if you feel heart palpitations or have an abnormal heartbeat, or get dizzy or faint when taking Zedbac, in which case you should inform your doctor immediately
- if you develop diarrhoea or loose stools during or after treatment. In some cases, there is the

possibility of developing a serious intestinal inflammation known as pseudomembranous colitis. Do not take any medicine to treat your diarrhoea without first checking with your doctor.

Other important precautions:
- Fungal infections may occur while you take azithromycin
- In rare cases severe allergic reactions may occur
- Medicines known as ergot derivatives e.g. ergotamine or dihydroergotamine (medicines used for migraines or reducing blood flow) should not be taken together with Zedbac
- Care must be also taken if you suffer from neurological or psychiatric diseases
- This medicine shall not be used to treat infected burn wounds
- Worsening of symptoms has been observed in patients with myasthenia gravis receiving azithromycin.

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

Medicines can interact with each other or with other substances causing unexpected drug reactions or in some cases may cause a decrease or increase of the expected effect. Therefore, you should inform your doctor about all the medicines you are taking or have taken, in particular:
- ergot derivatives such as ergotamine (used to treat migraine)
- digoxin (used to treat heart failure)
- colchicine (used for gout and familial Mediterranean fever)
- warfarin or any similar medicine to prevent blood clots
- ciclosporin (used to suppress the immune system to prevent and treat rejection of a transplanted organ or bone marrow)
- terfenadine (for hay fever or a skin allergy)
- nelfinavir (used for the treatment of HIV infection (AIDS))
- zidovudine (for HIV). Zedbac may reduce the blood levels of zidovudine and should therefore be taken at least 1-2 hours before or after zidovudine
- rifabutin (for HIV or tuberculosis)
- theophylline (for breathing problems).

You should not take Zedbac with antacids (used for indigestion).

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

Driving and using machines
Side effects could occur which may influence your ability to drive or use machines (see section 4).
You are advised not to drive or use machines whilst taking Zedbac.

Zedbac contains sodium
This medicine contains 168.2 mg (7.31 mmol) sodium (main component of cooking/table salt) in each 500 mg vial. This is equivalent to 8.41% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Zedbac

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will determine the dose and treatment duration which are suitable for you.

The following information describes the doses most commonly used in adults for the treatment of pneumonia (lung infection) and pelvic infections.

Pneumonia
500 mg administered as a single intravenous daily dose for at least **two days**, followed by oral administration of azithromycin. The appropriate timing of the switch to oral therapy should be done at the discretion of your doctor.

Pelvic infections
500 mg administered as a single intravenous daily dose for **one or two days**, followed by oral administration of azithromycin. The appropriate timing of the switch to oral therapy should be done at the discretion of your doctor.

Method and route of administration
Zedbac is intended to be administered by intravenous infusion.
This medicine should be reconstituted and diluted according to the instructions, and should be administered as an intravenous infusion over at least 60 minutes.

Average duration of treatment
The duration of your treatment will depend on the severity of your infection. Your doctor will inform you about it.

Special patient groups

Zedbac is not recommended for use in children and growing adolescents.

Patients with kidney or liver problems:
- You should tell your doctor if you have kidney or liver problems as your doctor may need to alter the normal dose.

No dose adjustment is needed for elderly patients.

If you have any further questions about the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately if you experience any of the following symptoms after receiving this medicine as the symptoms can be severe.

- allergic reactions which may cause sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body)
- severe or prolonged diarrhoea, which may have blood or mucus in it, during or after treatment with Zedbac as this may be a sign of serious bowel inflammation
- severe skin rash causing redness and flaking
- rapid or irregular heartbeat
- low blood pressure
- Serious skin reactions:
    - blistering of the skin, mouth, eyes and genitals (Stevens-Johnson Syndrome (SJS))

- blistering of the skin, severe skin reaction (Toxic Epidermal Necrosis (TEN))
- skin rash accompanied by other symptoms such as fever, swollen glands and an increase of eosinophils (a type of white blood cell). A rash appears as small, itchy red bumps (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS))
- skin eruption that is characterised by the rapid appearance of areas of red skin studded with small pustules (small blisters filled with white/yellow fluid) (Acute Generalized Exanthematous Pustulosis (AGEP)).

Stop taking azithromycin if you develop these skin symptoms and contact your doctor or seek medical attention immediately.

Other side effects that may occur when taking Zedbac are listed below. These may go away during treatment as your body adjusts to the medicine. Tell your doctor if any of these side effects continue to bother you.

Very common (may affect more than 1 in 10 people) side effects are:
- stomach cramps, feeling sick, diarrhoea, wind

Common (may affect up to 1 in 10 people) side effects are:
- dizziness, headache
- numbness or pins and needles
- being sick, indigestion
- loss of appetite, taste disturbance
- visual disturbances, deafness
- joint pain
- low numbers of lymphocytes (a type of white blood cell), higher number of eosinophils (a type of white blood cell)
- low blood bicarbonate
- tiredness or weakness

Uncommon (may affect up to 1 in 100 people) side effects are:
- yeast infections of the mouth and vagina (thrush)
- low numbers of leukocytes (a type of white blood cell), low number of neutrophils (a type of white blood cell)
- skin more sensitive to sunlight than normal
- feeling nervous
- reduced sense of touch or sensation (hypoesthesia)
- sleepiness or sleeplessness (insomnia)
- poor hearing or ringing in the ears
- heart palpitations, chest pain
- constipation, stomach pain associated with diarrhoea and fever
- inflammation of the liver (hepatitis), changes in liver enzymes
- general loss of strength
- swelling
- general discomfort
- abnormal laboratory test values (e.g. blood or liver tests)

Rare (may affect up to 1 in 1,000 people) side effects are:
- agitation
- vertigo
- changes in liver function

Not known (frequency cannot be estimated from the available data) side effects are:

- fits or fainting
- aggression or anxiety
- feeling hyperactive
- localised muscle weakness
- loss of smell or altered sense of smell, loss of taste
- tongue discolouration
- inflammation of the pancreas (pancreatitis)
- inflammation of the kidney or kidney failure
- yellowing of the skin or eyes (jaundice) or liver failure (rarely life-threatening)
- bruising or prolonged bleeding after injury
- abnormal electrocardiogram (ECG)
- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness.

Local injection site reactions (inflammation/pain) have been reported with the intravenous administration of azithromycin.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA.

Address: HPRA Pharmacovigilance, Earlsfont Terrace, IRL – Dublin 2.
Tel: +353 1 6764971.
Fax: +353 1 6762517
Website: www.hpra.ie
E-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zedbac

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

Do not use this medicine after the expiry date, which is stated on the carton and the vial after EXP. The expiry date refers to the last day of that month.

Keep the vial in the outer carton in order to protect from light.

Concentrated solution after reconstitution (according to the instructions): azithromycin as powder for solution for infusion is chemically and physically stable during 24 hours, when stored below 25 ºC.

Diluted solutions, prepared according to the instructions, are chemically and physically stable for 24 hours at or below 25°C, or for 7 days if stored under refrigeration (5°C).

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2°C to 8ºC, unless the reconstitution/dilution has taken place in controlled and validated aseptic conditions.

Do not use this medicine if you notice that the visual appearance has changed (e.g. the solution is not free from visible particles).
Any unused medicine must be discarded.

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 Zedbac contains
- The active substance is azithromycin (as dihydrate). Each vial contains 500 mg of azithromycin (equivalent to 524.03 mg azithromycin dihydrate).
- The other ingredients are: citric acid and sodium hydroxide 30% (for pH adjustment).

What Zedbac looks like and contents of the pack
Zedbac is a free white powder, with small aggregates, for solution for infusion. It comes in a 10 ml glass single dose vial, colourless with rubber stopper and sealed with aluminium/plastic flip-off cap.

The appearance of the product after reconstitution is a colourless and clear solution and leaves no visible undissolved matter.

Zedbac is available in the following pack sizes:

Pack with 1 vial.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Aspire Pharma (Malta) Limited
Trident Park, Notabile Gardens
No. 2, Level 3, Mdina Road
Central Business District
Birkirkara CBD2010, Malta

Manufacturer

Laboratório Reig Jofré, S.A.
Gran Capitán 10, 08970 Sant Joan Despí
Barcelona
Spain

Tecnimede – Sociedade Técnico-Medicinal S.A.
Quinta da Cerca - Caixaria
2565 - 187 Dois Portos
Portugal

This leaflet was last revised in 04/2024

The following information is intended for healthcare professionals only:

Zedbac should be reconstituted and diluted according to the instructions and should be administered

as an intravenous infusion over at least 60 minutes.
It should not be administered as an intravenous bolus or an intramuscular injection.

Zedbac as powder for solution for infusion is supplied in single dose vials.

Phase 1: Preparation of reconstituted solution

This medicinal product should be prepared under aseptic conditions.
The initial reconstituted solution is prepared by adding 4.8 ml of sterile water for injections to the 10 ml vial initial content using a standard 5 ml syringe (non-automated) and shaking the vial until all the drug is dissolved. Each ml reconstituted solution contains azithromycin dihydrate equivalent to 100 mg azithromycin (100 mg/ml).

The reconstituted solution must be further diluted prior to administration.

Phase 2: Dilution of reconstituted solution

To provide azithromycin at a concentration of 1.0 mg/ml:
Transfer 5 ml of the azithromycin solution prepared in phase 1 (100 mg/ml) to 500 ml of the appropriate diluents described below.

To provide azithromycin at a concentration of 2.0 mg/ml:
Transfer 5 ml of the azithromycin solution prepared in phase 1 (100 mg/ml) to 250 ml of the appropriate diluents described below.

The reconstituted solution can be diluted with:

0.9 % sodium chloride
0.45 % sodium chloride
5% dextrose in water
Lactated Ringer's solution

5% dextrose in 0.3% sodium chloride
5% dextrose in 0.45% sodium chloride

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From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2°C to 8ºC, unless the reconstitution / dilution has taken place in controlled and validated aseptic conditions.

Parenteral administration drugs should be inspected visually for particulate in suspension prior to administration. If particulate in suspension is evident in the reconstituted solution, it should be discarded.

Any unused medicine must be discarded.

Other intravenous substances, additives or other medications should not be added to Zedbac or infused simultaneously through the same intravenous line.