

## ZEDD®

contains the active ingredient azithromycin (as monohydrate)

### Consumer Medicine Information

#### What is in this leaflet

This leaflet answers some common questions about ZEDD.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking ZEDD against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, talk to your doctor or pharmacist.**

Keep this leaflet with your medicine. You may need to read it again.

#### What ZEDD is used for

ZEDD is used to treat bacterial infection including the following:

- respiratory infections such as sinusitis, sore throat, tonsillitis, bronchitis and pneumonia
- skin and underlying tissue infections
- genital infections such as Chlamydia
- an uncommon eye infection (Chlamydia trachomatis conjunctivitis and trachoma).

ZEDD may also be used to prevent infections by bacterium called Mycobacterium avium-intracellulare Complex.

ZEDD is an antibiotic which belongs to a group of medicines called azalides, a subclass of the macolide antibiotics. It works by killing or stopping the growth of bacteria causing your infection.

ZEDD does not work against viral infections such as colds or flu.

Your doctor may have prescribed ZEDD for another reason. Ask your doctor if you have any questions about why ZEDD has been prescribed for you.

ZEDD is available only with a doctor's prescription.

#### Before you take ZEDD

##### When you must not take it

**Do not take ZEDD if you are allergic to:**

- **azithromycin**
- **any other macrolide antibiotics such as clarithromycin, erythromycin and roxithromycin**
- **any of the ingredients listed at the end of this leaflet.**

Some of the symptoms of an allergic reaction may include skin rash, itchiness or hives, swelling of the face, lips or tongue (which may cause difficulty in swallowing), shortness of breath, wheezing or difficulty breathing.

**Do not take ZEDD if the expiry date (Exp.) printed on the pack has passed.**

If you take this medicine after the expiry date has passed, it may not work as well.

**Do not take ZEDD if the packaging shows signs of tampering or the tablets do not look quite right.**

##### Before you start to take it

**Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.**

**Tell your doctor if you are pregnant or plan to become pregnant.**

Your doctor will discuss the risks and benefits of taking ZEDD during pregnancy.

**Tell your doctor if you are breastfeeding.**

Your doctor will discuss the risks and benefits of taking ZEDD while breastfeeding.

**Tell your doctor if you have liver or kidney problems or any other medical conditions.**

**If you have not told your doctor about any of the above, tell them before you start taking ZEDD.**

##### Taking other medicines

**Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.**

Some medicines may be affected by ZEDD or may affect how well it works. These include:

- some medicines for migraine or headache such as ergotamine or dihydroergotamine
- oral contraceptives
- antacids, medicines used to treat indigestion
- coumarin-type Oral Anticoagulants (a medicine used to prevent blood clots)
- digoxin, a medicine used to treat heart failure
- cyclosporin, a medicine used to treat certain problems with the immune system
- terfenadine or astemizole, medicines used to treat hayfever and allergies
- zidovudine, a medicine used to treat patients with AIDS.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines. They also have more information on medicines to be careful with or avoid while taking ZEDD.

**If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.**

#### How to take ZEDD

##### How much to take

Your doctor will tell you how many tablets you need to take and when to take them. This depends on the type of your infection.

It is recommended that you take the tablet on an empty stomach.

**Follow all directions given to you by your doctor and pharmacist carefully.**

##### If you forget to take ZEDD

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.**

**Do not take two doses at a time to make up for the dose you missed.**

**If you are not sure what to do, ask your doctor or pharmacist.**

##### How long to take ZEDD

**Do not stop taking ZEDD until you finish the pack unless recommended by your doctor. Do not stop taking it just because you are feeling better.**

If you do not take the full course prescribed by your doctor, your infection may not clear completely or your symptoms may return.

*If you take too much ZEDD (overdose)*

**Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much ZEDD. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

If you take too many tablets, you may get an upset stomach, diarrhoea or skin rashes.

#### While you are taking ZEDD

##### Things you must do

**Before starting any new medicine, tell your doctor or pharmacist that you are taking ZEDD.**

**Tell all the doctors, dentists and pharmacists who are treating you that you are taking ZEDD.**

**If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.**

**If you get a sore, white mouth or tongue while taking, or soon after stopping ZEDD, tell your doctor. Also tell your doctor if you get vaginal itching or discharge.**

This may mean you have a yeast infection called thrush. Sometimes the use of ZEDD allows yeast to grow and the above symptoms to occur. ZEDD does not work against yeast.

##### Things you must not do

**Do not use ZEDD to treat any other conditions unless your doctor tells you to.**

**Do not give ZEDD to anyone else, even if they have the same condition as you.**

##### Things to be careful of

**Protect your skin when you are in the sun, especially between 10am and 3pm.**

Some azalide antibiotics may cause your skin to be more sensitive to sunlight than it is normally. Exposure to sunlight may cause a skin rash, itching, redness or a severe sunburn.

**If outdoors, wear protective clothing and use a 30+ sunscreen. If your skin does appear to be burning, stop taking ZEDD and tell your doctor immediately.**

**Talk to your doctor about the need for additional contraception while taking ZEDD.**

Some antibiotics may decrease the effectiveness of some birth control pills, although this has not been shown with ZEDD.

#### Side effects

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ZEDD.**

Like all other medicines, ZEDD may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

**Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor if you notice any of the following and they worry you:**

- white, furry sore tongue and mouth
- sore, itchy vagina with a white discharge
- nausea, vomiting
- loss of appetite
- stomach pain, indigestion
- wind, constipation, loose bowel motions
- unusual weight gain or swelling of the arms and legs
- dizziness
- headache
- muscle or joint aches
- hearing loss or ringing in the ears.

These are generally mild side effects.

**If any of the following happen, stop taking ZEDD and tell your doctor immediately:**

- diarrhoea (loose bowel motions)
- palpitations (fast or irregular heart beat)
- chest pain
- asthma, wheezing or shortness of breath
- symptoms of sunburn such as redness, itching, swelling or blistering which may occur more quickly than normal
- swelling of the face, lips or tongue which may lead to difficulty swallowing or breathing
- hives, itching or skin rash
- fainting
- yellowing of the eyes or skin, also called jaundice
- bleeding or bruising more easily than normal, reddish or purplish blotches under the skin
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- blood in the urine or bowel motions
- severe blistering or peeling of the skin
- convulsions (fits).

These are serious but rare side effects.

**Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.**

**Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after stopping treatment with ZEDD:**

- severe stomach cramps
- watery and severe diarrhoea, which may be bloody
- fever, in combination with one or both of the above.

These are rare but serious side effects. ZEDD can cause some bacteria, which are normally present in the bowel and normally harmless to multiply and therefore cause the above symptoms. You may need urgent medical attention. Do not take any medicine for this diarrhoea without first checking with your doctor.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

**Keep your tablets in a cool dry place where the temperature stays below 25°C.**

**Do not store ZEDD or any other medicine in the bathroom or near a sink.**

**Do not leave ZEDD in the car or on window sills.**

Heat and dampness can destroy some medicines.

#### *Disposal*

**If your doctor tells you to stop taking ZEDD, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.**

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#### Product description

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##### *What it looks like*

ZEDD comes as:

- ZEDD 500 - white capsule-shaped tablet marked "AT|500" and ">" on the reverse. Each blister pack contains 3 tablets.

##### *Ingredients*

The active ingredient in ZEDD is azithromycin (as monohydrate).

- each ZEDD 500 tablet contains 500 mg of azithromycin
- The tablets also contain:
- calcium phosphate
- pregelatinised maize starch
- croscarmellose sodium
- sodium lauryl sulfate
- magnesium stearate
- Opadry AMB white OY-B-28920.

The tablets are gluten free .

##### *Sponsor*

**Spirit Pharmaceuticals Pty Ltd**  
117 Harrington Street,  
The Rocks, Sydney NSW 2000  
Australia  
Phone: 1800 065 772

##### *Distributor*

**Sigma Pharmaceuticals (Australia) Pty Ltd**  
96 Merrindale Drive  
Croydon Vic 3136  
Australia

Australian registration number:  
ZEDD 500 - AUST R 107602

Date of preparation  
April 2009

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#### After using ZEDD

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##### *Storage*

**Keep ZEDD where children cannot reach it.**