

AZITHROMYCIN-GA Tablets

contains the active ingredient azithromycin (as monohydrate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about AZITHROMYCIN-GA.

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 AZITHROMYCIN-GA 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 AZITHROMYCIN-GA is used for

AZITHROMYCIN-GA 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).

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

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

AZITHROMYCIN-GA does not work against viral infections such as colds or flu.

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

AZITHROMYCIN-GA is available only with a doctor's prescription.

Before you take AZITHROMYCIN-GA

When you must not take it

Do not take AZITHROMYCIN-GA 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 AZITHROMYCIN-GA 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 AZITHROMYCIN-GA 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 AZITHROMYCIN-GA during pregnancy.

Tell your doctor if you are breastfeeding.

Your doctor will discuss the risks and benefits of taking AZITHROMYCIN-GA 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 AZITHROMYCIN-GA.

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 AZITHROMYCIN-GA 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 AZITHROMYCIN-GA.

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

How to take AZITHROMYCIN-GA

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 AZITHROMYCIN-GA

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 AZITHROMYCIN-GA

Do not stop taking AZITHROMYCIN-GA 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 AZITHROMYCIN-GA (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 AZITHROMYCIN-GA. 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 AZITHROMYCIN-GA

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking AZITHROMYCIN-GA.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking AZITHROMYCIN-GA.

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 AZITHROMYCIN-GA, 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 AZITHROMYCIN-GA allows yeast to grow and the above symptoms to occur. AZITHROMYCIN-GA does not work against yeast.

Things you must not do

Do not use AZITHROMYCIN-GA to treat any other conditions unless your doctor tells you to.

Do not give AZITHROMYCIN-GA 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 AZITHROMYCIN-GA and tell your doctor immediately.

Talk to your doctor about the need for additional contraception while taking AZITHROMYCIN-GA.

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking AZITHROMYCIN-GA.

Like all other medicines, AZITHROMYCIN-GA 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 AZITHROMYCIN-GA 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 AZITHROMYCIN-GA:

- 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.

AZITHROMYCIN-GA 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.

After using AZITHROMYCIN-GA

Storage

Keep AZITHROMYCIN-GA where children cannot reach it.

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 AZITHROMYCIN-GA or any other medicine in the bathroom or near a sink.

Do not leave AZITHROMYCIN-GA in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

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

Product description

What it looks like

AZITHROMYCIN-GA is a white to off-white, film-coated, capsule-shaped biconvex tablet marked "ATI500" on one side and the arrow symbol ">" on the reverse. Each blister pack contains 1*2 or 3 tablets.

*currently not available in Australia

Ingredients

The active ingredient in AZITHROMYCIN-GA is azithromycin (as monohydrate).

Each AZITHROMYCIN-GA 500 tablet contains 500 mg of azithromycin.

The tablets also contain:

- calcium hydrogen phosphate anhydrous
- pregelatinised maize starch
- croscarmellose sodium
- sodium lauryl sulfate
- magnesium stearate
- Opadry AMB Complete film coating system OY-B-28920 White.

The tablets are gluten free.

Sponsor

Spirit Pharmaceuticals Pty Ltd

117 Harrington Street,
The Rocks, Sydney NSW 2000
Australia

Distributor

Ascent Pharma Pty Ltd
151-153 Clarendon Street
South Melbourne VIC 3205

Australian registration number:
AZITHROMYCIN-GA - AUST R 200051

Date of preparation:
13 December 2012