Package leaflet: Information for the patient

ZITHROMAX® 600 mg TABLETS
azithromycin dihydrate

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 Zithromax is and what it is used for
2. What you need to know before you take Zithromax
3. How to take Zithromax
4. Possible side effects
5. How to store Zithromax
6. Contents of the pack and other information

1. What Zithromax is and what it is used for

This medicine contains azithromycin (as dihydrate), which is one of a group of antibiotics called macrolides. It is used to treat infections caused by bacteria and other micro-organisms. It can also be used to prevent bacterial infections.

Zithromax 600 mg tablets are prescribed to patients when their immune systems are not working properly. The tablets help to prevent infection by a bacterium called Mycobacterium avium - intracellulare complex (MAC), or to stop a MAC infection from coming back. Your doctor may prescribe Zithromax with another drug to make sure you do not get this infection.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Zithromax

Do not take Zithromax:

- if you are allergic to azithromycin or any other macrolide antibiotic such as erythromycin or clarithromycin or any of the ingredients (listed in section 6). An allergic reaction may cause skin rash or wheezing.

Warnings and precautions

Talk to your doctor or pharmacist before taking Zithromax if you/your child have or have had any of the following:

- kidney problems
- heart conditions
- diabetes

- liver problems: your doctor may need to monitor your liver function or stop the treatment
- myasthenia gravis (localised muscle weakness)
- or if you are taking any ergot derivatives such as ergotamine (used to treat migraine) as these medicines should not be taken together with Zithromax.

Tell your doctor immediately if you feel your heart beating in your chest or have an abnormal heartbeat, or get dizzy or faint or suffer from any muscle weakness when taking Zithromax.

If you develop diarrhoea or loose stools during or after treatment, tell your doctor at once. Do not take any medicine to treat your diarrhoea without first checking with your doctor. If your diarrhoea continues, please inform your doctor.

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

In particular, Zithromax may interact with the medicines listed below:
- ergot or ergotamine, see 'Warnings and precautions' section
- 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)
- digoxin (used to treat heart failure)
- terfenadine (for hay fever or a skin allergy)
- atorvastatin (for reducing blood cholesterol levels).

If you are taking antacids for indigestion, Zithromax should be taken one hour before or two hours after taking antacids.

Zithromax with food and drink
Please refer to section 3.

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.

Driving and using machines
Zithromax is not expected to affect your ability to drive or use machines.

Zithromax contains lactose
Zithromax contains lactose, a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicine.

3. How to take Zithromax

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The tablets should be swallowed whole.

Take your tablets with a glass of water. Try to take your tablets at the same time each week.

Zithromax tablets can be taken either with or without food.

The recommended dose for Zithromax to prevent MAC infections is 1200 mg (two tablets) taken together, once a week.

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

Doctors sometimes prescribe different doses to the recommended dose. The label on the pack will tell you which dose you should take. If you are still not sure, ask your doctor or pharmacist.

Always continue with your course even if you feel better. If your infection gets worse or you do not start to feel better within a few days or a new infection develops, go back and see your doctor.

If you take more Zithromax than you should
If you take too much Zithromax you may feel unwell. Tell your doctor or contact your nearest hospital casualty department immediately.

If you forget to take Zithromax
If you forget to take a dose, take it as soon as you can. Take your next dose at the right time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Zithromax
If you stop taking Zithromax too soon, the infection may return. Take the capsules for the full time of treatment, even when you begin to feel better.

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

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 taking this medicine. Although they are very rare, the symptoms can be severe.

- sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body)
- severe skin rash causing redness and flaking
- rapid or irregular heartbeat
- low blood pressure
- vomiting and diarrhoea can rarely cause dehydration. It is important to drink plenty of fluid if you experience sickness and / or diarrhoea
- diarrhoea may occur during, or after completing, treatment with antibiotics and could be a sign of serious bowel inflammation.

The most common side effects that occur when taking Zithromax 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
- diarrhoea

Common: may affect up to 1 in 10 people
- headache
- feeling sick, being sick, stomach pain
- low number of lymphocytes (a type of white blood cell), higher number of eosinophils (a type of white blood cell) and other blood changes
- low blood bicarbonate

Uncommon: may affect up to 1 in 100 people
- yeast infections of the mouth and vagina (thrush)
- fungal or bacterial infections such as severe sore throat, gastroenteritis
- breathing problems, runny nose, nose bleeds
- low number of leukocytes (a type of white blood cell),
- allergic reactions of various severity
- feeling nervous
- sleepiness or sleeplessness (insomnia)
- visual disturbances
- feeling dizzy, ear problems, vertigo
- heart palpitations, chest pain
- loss of appetite, taste disturbance
- constipation, wind, burping, indigestion
- stomach pain associated with diarrhoea and fever
- mouth ulcers, dry mouth, difficulty swallowing, excess saliva
- kidney pain, pain when urinating
- general loss of strength, tiredness or weakness, numbness or pins and needles
- swelling, swollen or painful muscles, back pain, neck pain
- general discomfort
- abnormal blood test values
- rash, red, dry or itchy skin, or excess sweating
- bleeding between periods in women
- testicular pain in men
- hot flushes.

Rare: may affect up to 1 in 1,000 people
- agitation
- skin more sensitive to sunlight than normal
- changes in liver function, yellowing of the skin and eyes

Very rare: may affect up to 1 in 10,000 people
- 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.

Not known: frequency cannot be estimated from the available data
- fits, fainting, twitching muscles
- aggression, anxiety delirium, hallucinations, sleep disturbances (e.g. nightmares, night terrors)
- feeling hyperactive
- localised muscle weakness
- painful joints
- deafness, hearing loss, ringing in the ears
- severe or prolonged diarrhoea, which may have blood or mucus in it, during or after treatment with Zithromax as this may be a sign of serious bowel inflammation

- 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
- bruising or prolonged bleeding after injury
- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness
- low blood pressure
- blistering of the skin, severe skin reaction
- abnormal electrocardiogram (ECG).

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

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

Do not store above 25 ºC.
Do not take this medicine after the expiry date which is stated on the blister and the carton after EXP. The expiry date refers to the last day of that month.
Do not throw away 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 Zithromax contains

The active substance is azithromycin as azithromycin dehydrate. Each white film-coated tablet contains 600mg of the active substance.

The other ingredients are: calcium phosphate dibasic anhydrous, croscarmellose sodium, magnesium stearate, pre-gelatinised starch and sodium lauryl sulfate. The film coat contains hypromellose, lactose monohydrate (see section 2 Zithromax contains lactose), titanium dioxide (E171) and triacetin.

What Zithromax looks like and contents of the pack

Zithromax 600mg Tablets are white, capsular shaped, film-coated tablets marked “Pfizer” on one side and “ZTM 600’’ on the other and come in packs of 2, 8 or 24 tablets or bottles containing 2, 30 or 100 tablets.

Not all pack sizes may be marketed.

Product Authorisation Holder
Pfizer Limited
Ramsgate Road

Sandwich
Kent
CT13 9NJ
United Kingdom.

Manufacturer

Haupt Pharma Latina S.r.l., Latina (LT)
Strada Statale 156 Km. 47, 600
04100 Borgo San Michele
Latina
Italy,

Company contact address:
For further information on your medicine contact Medical Information at Pfizer Healthcare Ireland, 9 Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24, Ireland. Telephone: 1800 633 363.

This leaflet was last revised in MM/YYYY

Ref ZX 8_1