PATIENT INFOMRATION LEAFLET: ZITHRACT

SCHEDULING STATUS: **S4**

ZITHRACT, 500 mg, film-coated tablet

Azithromycin

Read all of this leaflet carefully before you start taking ZITHRACT

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or your pharmacist.

ZITHRACT has been prescribed for you personally and you should not share your medicine with other people.

It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ZITHRACT is and what it is used for

2. What you need to know before you take ZITHRACT

3. How to take ZITHRACT

4. Possible side effects

5. How to store ZITHRACT

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1. What ZITHRACT is and what it is used for

ZITHRACT tablets is an antibiotic. It belongs to a group of antibiotics called macrolides. It is used to treat infections caused by bacteria.

This medicine is usually prescribed to treat:

• chest infections such as chronic bronchitis, pneumonia

• infections of the tonsils, throat (pharyngitis) and sinuses

• ear infections (acute otitis media)

• skin and soft tissue infections, with exception of infected burn wounds

• uncomplicated genital infections due to *Chlamydia trachomatis* and chancroid due to *Haemophilus ducreyi*

2. What you need to know before you take ZITHRACT

Do not take ZITHRACT

If you are allergic (hypersensitive) to:

- azithromycin
- erythromycin
- any other macrolide antibiotic
- any of the other ingredients of this medicine (listed in section 6)

If you have any liver problems or severe liver disease.

If you are taking medicines called ergot derivatives e.g. ergotamine used for the treatment of migraines.

Warnings and precautions

Talk to your pharmacist, doctor or other healthcare provider before taking this medicine:

• Liver problems: your doctor may need to monitor your liver function or stop the treatment.
• Kidney problems: if you have severe kidney problems, the dose may have to be adjusted.
• Heart problems such as a weak heart (heart failure), very slow heart rate, irregular heartbeat, or something called “long QT syndrome” (shown by an electro-cardiogram), since ZITHRACT may increase the risk of abnormal heart rhythm.
• Tell your doctor immediately if you feel your heart beating in your chest or have an abnormal heartbeat when taking ZITHRACT.
• 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, tell your doctor as soon as possible.
• If you develop skin reactions or new infections.
• If you have or develop a condition called myasthenia gravis (muscle weakness commonly affecting face and throat muscles causing drooping of eyelid/s; double vision; impaired speech; difficulty in swallowing and shortness of breath).

Use in children under 1 year of age:

The safety and efficacy of oral ZITHRACT preparations in children less than 1 year have not been established.

Other medicines and ZITHRACT

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

In particular, tell your doctor if you are taking any of the following:

- Warfarin or any similar medicine to prevent blood clots: concomitant use can increase the risk of bleeding.
- Ergotamine, dihydroergotamine (used to treat migraine): ergotism (i.e. itching in the limbs, muscle cramps and gangrene of hands and feet due to poor blood circulation) may occur. Concomitant use is therefore not recommended.
- Ciclosporin (used to suppress the immune system to prevent and treat rejection of an organ or bone marrow transplant): if concomitant use is required, your doctor will check your blood levels regularly and may adapt the dose.
- Digoxin (for heart failure): digoxin levels may increase. Your doctor will check your blood levels.
- Antacids (for indigestion): see section 3.
- Medicines for irregular heartbeat (called anti-arrhythmics).
- Nelfinavir (used to treat HIV infections): concomitant use can increase the side effects of ZITHRACT.
- Atorvastatin used in the treatment of high blood cholesterol.
- Rifabutin used in the treatment of tuberculosis (TB).

Taking ZITHRACT with food and drink:

ZITHRACT tablets may be taken with or without food. They must be taken whole with a drink of water.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Pregnancy and breastfeeding

You should not use this medicine during pregnancy and when you are breastfeeding unless your doctor has specifically recommended it.

The safety and efficacy of ZITHRACT in pregnancy and breastfeeding have not been established.

Driving and using machines

This medicine may cause side effects such as dizziness or fits. This may make you less able to do certain things, such as driving or using machines.

3. How to take ZITHRACT

Do not share medicines prescribed for you with any other person.

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

These doses are for adults and children weighing more than 45 kg. This formulation is not suitable for children under 45 kg. (An azithromycin suspension is recommended in children under 45 kg).

The usual dose for ZITHRACT is 500 mg once a day, for 3 days.

For sexually transmitted diseases, the dose is 1 g taken as a single dose, for one day only.

Swallow these tablets whole with a drink of water.

You can take these tablets with or without food.

Your doctor will tell you how long your treatment with ZITHRACT will last. Do not stop treatment early even if you feel better.

If you have the impression that the effect of ZITHRACT is too strong or too weak, tell your doctor or pharmacist.

Taking ZITHRACT with medicines for indigestion:

• If you need to take a medicine for indigestion, such as an antacid, take your tablets at least one hour before or two hours after the antacid.

If you take more ZITHRACT than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take ZITHRACT

If you forgot to take a dose, take it as soon as possible. Then go on as before.

Do not take more than one dose in a single day.

Do not take a double dose of ZITHRACT to make up for a forgotten individual dose.

If you stop taking ZITHRACT

Always keep taking the tablets until the course is finished, even if you feel better. If you stop taking the tablets too soon, the infection may come back. Also, the bacteria may become resistant to the medicine and will then be more difficult to treat. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

ZITHRACT can have side effects.

Not all side effects reported for ZITHRACT are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ZITHRACT, please consult your healthcare provider for advice.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Sudden signs of allergy such as rash, itching or hives on the skin
- Swelling of the face, lips, tongue or other parts of the body
- Sudden shortness of breath, wheezing or trouble breathing
- Hearing impairment, loss or ringing in the ears
- Diarrhoea, usually with blood and mucous, stomach pain and fever even if it occurs weeks after you have stopped taking ZITHRACT
- Stomach pain or cramps, loose bowel motions, nausea (feeling sick), vomiting, constipation, indigestion, wind, heartburn
- Yellowing of the eyes or skin, also called jaundice
- Chest pain
- Fainting
- Convulsions (fits)

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects reported include the following:

- Dark stools stained with blood

Other less frequent side effects reported include the following:

- Oral thrush - white, furry, sore tongue and mouth
- Vaginal thrush - sore and itchy vagina and/or white discharge
- Low white blood cell counts and low platelet count
- Loss of appetite
- Aggressive reaction, nervousness, agitation or anxiety
- Dizziness, headache, hyperactivity, sleepiness, spinning sensation, altered or loss of

taste or smell

- Abnormal vision
- Fast or irregular heartbeat
- Low blood pressure
- Inflammation of the pancreas, tongue discolouration
- Tingling, pricking, burning and decreased feeling or sensitivity, especially in the skin
- Redness, swelling or blistering of the skin
- Bleeding or bruising more easily than normal, reddish or purplish blotches under the skin
- Sensitivity to sunlight
- Muscle or joint pain
- Blood in the urine or bowel motions
- Tiredness, weakness or general feeling of being unwell

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of ZITHRACT.

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5. How to store ZITHRACT

Store all medicines out of reach of children.

Store at or below 30 °C in the original package.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ZITHRACT contains

The active substance is azithromycin.

The other ingredients are:

Core:

microcrystalline cellulose, sodium lauryl sulphate, sodium starch glycollate, povidone, isopropyl alcohol, croscarmellose sodium, purified talc, magnesium stearate.

Coating:

Lake ponceau 4R, titanium dioxide, purified talc, purified water, Hypromellose and macrogols 400.

What ZITHRACT looks like and contents of the pack

Pink coloured, capsule shaped film coated tablets, plain on both sides.

Each carton contains a blister pack of 3 film-coated tablets.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

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Access to the corresponding Professional Information:

Scan the QR Code below

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