PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

ZITHROMAX 500 mg Tablets

Azithromycin

Read all of this leaflet carefully before you start taking ZITHROMAX

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- ZITHROMAX 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.

1. WHAT ZITHROMAX CONTAINS:

Each ZITHROMAX tablet contains the active ingredient azithromycin dihydrate equivalent to 500 mg azithromycin.

ZITHROMAX tablets contain the following inactive ingredients: calcium phosphate dibasic anhydrous, croscarmellose sodium, magnesium stearate, pregelatinised starch and sodium lauryl sulphate. The film coat contains hydroxypropyl methylcellulose, lactose, titanium dioxide (E171) and triacetin.

Contains sugar (lactose).

2. WHAT ZITHROMAX IS USED FOR:

ZITHROMAX is an antibiotic which belongs to a group of antibiotics called macrolides. It is used to treat infections caused by bacteria and other micro-organisms.

ZITHROMAX is usually prescribed to treat respiratory tract infections such as bronchitis, pneumonia, tonsillitis, pharyngitis, sinusitis and ear infections, skin and soft tissue infections (such as abscess), or sexually transmitted diseases such as chancroid, or those caused by an organism called *Chlamydia*.

3. BEFORE YOU TAKE ZITHROMAX:

Do not take ZITHROMAX:

- If you are hypersensitive (allergic) to azithromycin, erythromycin or any macrolide antibiotic or any of the other ingredients of ZITHROMAX.
- If you are taking any ergot derivatives as these medicines should not be taken together with ZITHROMAX.
- If you are suffering from or have ever suffered from liver disease.

Take special care with ZITHROMAX:

Your doctor needs to know before you take ZITHROMAX if you have had any of the following:

- Liver problems: your doctor may need to monitor your liver function or stop the treatment
- If you are taking any ergot derivatives such as ergotamine (used to treat migraine) as these medicines should not be taken together with ZITHROMAX
- Kidney problems
- Heart conditions

Tell your doctor immediately if you feel your heart beating in your chest or have an abnormal heartbeat 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, tell your doctor as soon as possible.

Taking ZITHROMAX with food and drink:

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

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

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

Driving and using machinery:

Feelings of unsteadiness or dizziness, fits, drowsiness and fainting have been reported whilst taking ULTREON. ULTREON may affect your ability to drive and operate machinery.

Important information about some of the ingredients of ZITHROMAX:

ZITHROMAX tablets contains lactose monohydrate and should not be given to patients with rare hereditary problems of galactose intolerance e.g. galactosaemia, the Lapp lactase deficiency or glucose-galactose malabsorption.

ZITHROMAX contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Using other medicines with ZITHROMAX:

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

Tell your doctor before taking ZITHROMAX if you are taking any of the medicines listed below:

- Ergot or ergotamine (used to treat migraines) (see Take special care with ZITHROMAX)
- Antacids (for indigestion)
- 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)
- Warfarin or any similar medicine to prevent blood clots

4. HOW TO TAKE ZITHROMAX:

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

Always take ZITHROMAX exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

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

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

ZITHROMAX tablets should not be taken by children weighing less than 45 kg. For children weighing more than 45 kg the doses mentioned above are usually prescribed.

Should you require to take an antacid for indigestion, take your tablet one hour before or two hours after the antacid.

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

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

If you take more ZITHROMAX than you should:

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

If you forget to take your ZITHROMAX:

If you miss a dose, take it as soon as you remember. Then take ZITHROMAX as normal.

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

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

5. POSSIBLE SIDE EFFECTS:

ZITHROMAX can have side effects.

Not all side effects reported for ZITHROMAX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional 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 ZITHROMAX
- 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 immediately 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 heart beat
- 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.

6. STORING AND DISPOSING OF ZITHROMAX:

Store at or below 30 °C.

Store all medicines out of reach of children.

Do not use after the expiry date stated on the blister pack and carton.

Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF ZITHROMAX:

PVC blister packs of 2 or 3 tablets in an outer cardboard carton.

8. IDENTIFICATION OF ZITHROMAX:

Oval, white scored film-coated tablets embossed with “ZTM 500” on one side and “PFIZER” on the other side.

9. REGISTRATION NUMBER:

31/20.1.1/0045

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Pfizer Laboratories (Pty) Ltd

85 Bute Lane

Sandton 2196

South Africa

11. DATE OF PUBLICATION:

Date of registration: 17 June 1997

Date of last Council approval: 16 October 2018