PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

ZITHROMAX IV Powder for solution for infusion

Azithromycin

Read all of this leaflet carefully if you are given ZITHROMAX IV

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

1. WHAT ZITHROMAX IV CONTAINS:

Each ZITHROMAX IV vial contains 500 mg of the active ingredient azithromycin (as the dihydrate) providing 100 mg/ml solution following reconstitution.

ZITHROMAX IV contains citric acid and sodium hydroxide.

2. WHAT ZITHROMAX IV 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 IV is used to treat pneumonia, a lung infection caused by certain bacteria including *Legionella pneumophila.*

3. BEFORE YOU ARE GIVEN ZITHROMAX IV:

You should not be given ZITHROMAX IV:

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

Tell your doctor or healthcare professional before being given the injection 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 IV.
- Kidney problems
- Heart conditions

Tell your doctor immediately if you feel your heart beating in your chest or have an abnormal heartbeat when being given ZITHROMAX IV.

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.

Pregnancy and Breastfeeding:

The safety of ZITHROMAX IV in pregnancy and breastfeeding has not been established.

You will only be treated with ZITHROMAX IV when you are pregnant or breastfeeding if there are no adequate alternatives available.

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

Driving and using machinery:

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

Using other medicines with ZITHROMAX IV:

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

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

- Ergot or ergotamine (used to treat migraines) (see Take special care with Zithromax IV)
- 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 RECEIVE ZITHROMAX IV:

You will not be expected to give yourself ZITHROMAX IV. It will be given to you by a person who is qualified to do so.

Your doctor will decide how much ZITHROMAX IV you should receive and how long your treatment will last.

The usual dose of ZITHROMAX IV is 500 mg, as a single daily dose, given as an injection into a vein for at least 2 days. You may then be given 500 mg oral ZITHROMAX tablets once a day for another 5 – 7 days (to complete a 7 to 10 day course of antibiotics).

ZITHROMAX IV is a powder which is mixed with Water for Injections and then diluted by the pharmacist, doctor or nurse. It is then given via a drip into a vein, which takes approximately 1 to 3 hours.

If you have the impression that the effect of ZITHROMAX IV is too strong or too weak for you, tell your doctor or healthcare professional.

If you receive more ZITHROMAX IV than you should:

Since a healthcare professional will administer ZITHROMAX IV, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you missed a dose of ZITHROMAX IV:

If you miss a dose, your doctor or healthcare professional will immediately manage this.

You must not receive a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS:

ZITHROMAX IV can have side effects.

Not all side effects reported for ZITHROMAX IV 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 IV
- 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
- Pain or swelling at the site of injection and pain during the injection

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 IV:

Store all medicines out of reach of children.

ZITHROMAX IV is stored at or below 25 °C in its original packaging until use.

ZITHROMAX IV should not be given after the expiry date stated on the vial and carton.

Your doctor or the hospital staff will dispose of any leftover ZITHROMAX IV.

7. PRESENTATION OF ZITHROMAX IV:

ZITHROMAX IV is packaged in single use 10 ml clear and colourless glass vial and closed with a rubber stopper and aluminium over-seal.

8. IDENTIFICATION OF ZITHROMAX IV:

ZITHROMAX IV is a white to off-white cake powder. The reconstituted solution is clear and colourless, visually free of undissolved matter and essentially free from particles of foreign matter.

9. REGISTRATION NUMBER:

36/20.1.1/0190

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: 25 April 2003

Date of last Council approval: 16 October 2018