PATIENT INFORMATION LEAFLET FOR AZERO

Please read this leaflet carefully before taking AZERO.

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

SCHEDULING STATUS

Schedule 4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

AZERO 500 mg azithromycin film coated tablets

1. WHAT AZERO CONTAINS

Active ingredient: **AZERO** contains azithromycin dihydrate equivalent to 500 mg azithromycin base.

Inactive ingredients: Pregelatinised starch, anhydrous dibasic calcium phosphate, croscarmellose sodium, magnesium stearate, Opadry clear (containing hypromellose and macrogol).

Sugar free.

2. WHAT AZERO IS USED FOR

AZERO is used to treat lower respiratory tract infection including bronchitis, pneumonia (infection in the lungs); skin infections and infections in the genital area in adults.

3. BEFORE YOU TAKE AZERO

Do not take AZERO:

- If you are hypersensitive (allergic) to azithromycin, erythromycin (or any of the members of the macrolide antibiotics group), or other inactive ingredients (see **WHAT AZERO CONTAINS**).
- If you are taking medication containing ergotamine (usually in migraine medication).
- If you suffer from any liver disease.
- If you are pregnant or breastfeeding your baby (see **Pregnancy and breastfeeding**).

Take special care with AZERO:

- If you develop a severe allergic reaction (hives, difficulty breathing, swelling of your face, lips, tongue, or throat) to **AZERO**, please inform you doctor immediately. This reaction can reoccur even after you have stopped the treatment.
- If you develop diarrhoea during the treatment with **AZERO**, please inform your doctor immediately.
- If you have a kidney disorder.

AZERO should not be given to children weighing less than 40 kg.

Pregnancy and breastfeeding:

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

Safety in pregnancy and breastfeeding has not been established.

Driving and using machinery:

AZERO may make you feel dizzy, tired or drowsy, therefore be careful when driving or using machinery.

Taking AZERO with food or drink:

AZERO can be taken with or without food.

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Using other medicines with AZERO:

Always tell your healthcare professional if you are taking any other medicine.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **AZERO** with these medicines may cause undesirable interactions.

Tell your doctor or pharmacist if you are currently using the following medicines:

- Hay fever tablets (astemizole and cisapride).
- Ciclosporin (immunosuppressant medication).
- Digoxin (heart medication).
- Hexobarbital (sleeping tablets).
- Phenytoin (used for the treatment of epilepsy/fits).
- Aluminium or magnesium containing antacids (used for heartburn).
- Migraine medication containing ergotamine (see **Do not take AZERO**).
- Blood thinning tablets (e.g. warfarin).
- Oral contraceptive tablets (used to prevent unwanted pregnancies).
- Methotrexate (used in the treatment of rheumatoid arthritis).

4. HOW TO TAKE AZERO

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

Always take **AZERO** exactly as your doctor has instructed you. You should check with your doctor if you are unsure. If you have the impression that the effect of **AZERO** is too strong or too weak, talk to your doctor or pharmacist.

Do not stop taking **AZERO** before you have consulted with your doctor. This is an antibiotic and you should complete the course.

AZERO is usually administered as a single dose daily for 3 days.

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The dosage remains the same for elderly people as well as children with a body weight over 45 kg.

If you take more AZERO than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

If you forget to take your AZERO:

If you forget to take a dose, take it as soon as you remember. Do not take a double or larger dose to make up for the forgotten individual doses. Continue to take the next tablet at the usual time.

5. POSSIBLE SIDE EFFECTS

AZERO can have side effects. Not all side effects reported for **AZERO** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking **AZERO**, please consult your doctor, pharmacist or other healthcare professional for advice.

Stop taking **AZERO** and seek medical help immediately if you have any of these signs of an allergic reaction:

Hives, difficulty breathing, swelling of your face, lips, tongue or throat.

Consult your doctor if any of the following side effects continue which may occur less frequent:

- Blood disorder (characterising by a low number of white blood cells).
- Dizziness, headache, unusual weakness or tiredness, sensation of tingling, numbness or burning, sleepiness, epileptic seizure (fit).

Signed: _____

- Whirling or spinning movement, ringing sound in the ears, hearing loss.
- Abnormal or fast and irregular heartbeat, chest pain.
- Stomach pain, diarrhoea, nausea, vomiting, weight loss, bloating, constipation, loose stools, heart burn, black (tarry) stools.
- Yellowing of the skin and eyes (hepatitis).
- Skin rash, redness and itchiness of skin, sensitivity of the skin to sunlight.
- Joint pain.
- Kidney disorders.
- Inflammation of the vagina (resulting in discharge, itching and pain).

6. STORING AND DISPOSING OF AZERO

- Store at or below 25 °C.
- Keep blisters in outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the label or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

7. PRESENTATION OF AZERO

Aluminium/ PVC/PVdC blisters strips containing 3 or 10 tablets per blister strip. 1 blister strip is placed in an outer carton.

8. IDENTIFICATION OF AZERO

White to off-white capsule shaped, biconvex film coated tablets with a break line on one side.

9. REGISTRATION NUMBER

44/20.1.1/0492

Signed: _____

10. NAME AND BUSINESS ADDRESS OF THE REGISTRATION HOLDER

Zydus Healthcare SA (Pty) Ltd.

Southdowns Office Park

Building B, Ground Floor

22 Karee Street

Centurion 0157

Tel. no.: 012 748 6400

11. DATE OF PUBLICATION

Date of registration: 1 March 2013

Date of this revision: September 2015

Signed: _____