PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

PROPRIETARY NAME AND DOSAGE FORM:

Zithrogen 250 mg (tablet)

Zithrogen 500 mg (tablet)

COMPOSITION OF THE MEDICINE, THAT IS, WHAT THIS MEDICINE CONTAINS:

Each Zithrogen 250 mg tablet contains azithromycin monohydrate hemiethanolate 263.68 mg equivalent to 250 mg azithromycin.

Each Zithrogen 500 mg tablet contains azithromycin monohydrate hemiethanolate 527.36 mg equivalent to 500 mg azithromycin.

To make our tablets easy to identify, pick up and swallow, other ingredients have to be added. These other ingredients are pregelatinised maize starch, anhydrous dibasic calcium phosphate, croscarmellose sodium, magnesium stearate, sodium lauril sulfate, Opadry White OY-C-7000A, Hypromellose 5 cp, Ethylcellulose 10 cp, Diethyl phthalate and titanium dioxide (E171).

INDICATIONS AND USE, THAT IS, WHAT THIS MEDICINE IS USED FOR:

This medicine contains azithromycin which is an antibiotic used to treat a variety of different infections. These include infections of the skin and soft tissue, the upper respiratory system (nose, throat) , the lower respiratory system (chest, lungs) and uncomplicated sexually transmitted diseases in men and woman caused by *Chlamydia trichomatis*

BEFORE TAKING THIS MEDICINE:

Please read this leaflet before you take your Zithrogen. It gives you important information about your tablets. Please keep this leaflet safe. You may want to read it again. If you have any questions or if you are not sure about anything, ask your doctor or pharmacist.

Do not take this medicine if you:

- Have ever taken azithromycin or a similar medicine (eg. erythromycin) before and you suffered an unpleasant or allergic reaction
- are allergic to any of the other tablet ingredients

Zithrogen should not be in used in patients who are taking the following medicines:

- ergotamine, to treat migraine
- ergometrine, for uterine bleeding

You must tell your doctor before taking Zithrogen if:

- you have liver problems
- you are pregnant or plan to become pregnant
- you are breast feeding
- you have diarrhoea

Tell your doctor or pharmacist before taking this medicine if you are already taking any of the following medicines:

- Warfarin, an anticoagulant to thin the blood
- cyclosporin given after transplant surgery
- antacids containing aluminium of magnesium (indigestion remedies)
- digoxin, for heart problems

If you are taking medicines on a regular basis, concomitant use of the medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

If you are pregnant or breast feeding your baby while taking this medicine please consult your doctor, pharmacist or other health care professional for advice.

HOW TO TAKE THIS MEDICINE

- It is important that you complete the course of treatment as directed by your doctor
- Having completed your course of tablets, if you do not feel better go back to your doctor: You may need a different antibiotic.

Adults and children over 12 years old.

To treat a respiratory, skin or soft tissue infection:

The usual dose is 500 milligrams of Zithrogen per day for 3 days or alternatively your doctor may rather prescribe a starting dose of 500 milligrams, followed by 250 milligrams per day for 4 days.

To treat uncomplicated sexually transmitted disease caused by *Chlamydia trachomatis*.

1000 milligrams as a single dose

To treat uncomplicated gonorrhoea:

2000 milligrams as a single dose

Children between one year and 12 years.

The usual dose is 10 milligrams per kilogram of body weight for 3 days or alternatively a single dose of 10 milligrams per kilogram of body weight for the first day, then 5 milligrams per kilogram of body weight for the next four days.

The tablet is not recommended for children weighing less than 25 kilograms.

Your doctor has decided which dose is best for you. Follow your doctor's instructions and do not change the dose yourself.

If you forget to take a dose take it as soon as you remember. If it is almost time for your next dose though, do not double the dose just carry on as before.

In the event of an over-dosage, consult your doctor or pharmacist. If neither is available, rush the patient to the nearest hospital of poison control centre. Take any remaining tablets and the container with you and show the pack to the doctor.

Do not share medicines prescribed for you with others.

SIDE-EFFECTS

Like most medicines, Zithrogen tablets can sometimes cause side effects. Most people take these tablets without any problems.

The most common side effects include feeling or being sick, indigestion, diarrhoea (frequent or loose, watery stools), stomach pain and flatulence (excess air or gas in the stomach). Other side effects are ringing in the ears or hearing loss (usually reversible on stopping treatment), chest pain, palpitations (rapid irregular beat of the heart), tiredness, infection of the vagina or kidneys, headache and dizziness.

If any of the following happen, stop taking Zithrogen and tell your doctor immediately:

- itchy swollen skin, burning eyes, fever, tightness of the chest and difficulty breathing
- skin reactions which may be severe
- diarrhoea, blood in your stools
- itchy skin and jaundice, liver problems
- fainting or a racing heart
- unusual bruising or bleeding of the skin, look pale or feel feverish.

These side effects are rare but serious. You may need medical attention.

If you suffer from any of the side effects mentioned above or any other side effect, please tell your pharmacist or doctor.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

STORAGE AND DISPOSAL INFORMATION

- Do not store your tablets above 25ºC.
- Do not take the tablets after the expiry date printed on the packet.
- If you don’t need to take this medicine anymore take it to your doctor or nearest pharmacy who will correctly dispose of it.

Store all medicine out of reach of children

These tablets are for you. Please do not give them to anyone else, even they have the same symptoms as you.

PRESENTATION:

Zithogen 250 milligram tablets: PVC/PVdC/Aluminium foil blister packs of 5 tablets in a unit carton.

Zithogen 500 milligram tablets: PVC/PVdC/Aluminium foil blister packs of 2 or 3 tablets in a unit carton.

IDENTIFICATION OF THE MEDICINE:

Zithogen 250 milligram tablets: white, film-coated, capsule-shaped tablet with “AZ 250” printed on one side.

Zithogen 500 milligram tablets: white, film-coated, capsule-shaped tablet with “AZ 500” printed on one side.

REGISTRATION NUMBER / REFERENCE NUMBER:

To be allocated

THE NAME AND THE BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE:

Viatris South Africa (Pty) Ltd

4 Brewery Street,

Isando

Johannesburg,

1609

THE DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

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