PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ZYBACT 250 mg film-coated tablets

ZYBACT 500 mg film-coated tablets

Levofloxacin (as hemihydrate)

Sugar free

Read all of this leaflet carefully before you start taking ZYBACT.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ZYBACT 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 ZYBACT is and what it is used for
2. What you need to know before you take ZYBACT
3. How to take ZYBACT
4. Possible side effects
5. How to store ZYBACT
6. Contents of the pack and other information.

1. What ZYBACT is and what it is used for

ZYBACT is an antibiotic which is used to treat various bacterial infections such as sinus and lung infections, infection of the prostate gland in male patients (where you have a long-lasting infection), urinary tract infections and skin infections.

2. What you need to know before you take ZYBACT

Do not take ZYBACT:

- If you are allergic (hypersensitive) to levofloxacin, other quinolone antibiotics or any of the other ingredients of ZYBACT (listed in section 6).
- If you have epilepsy or a history of seizures.
- If you have a history of tendon disorders associated with previous fluoroquinolone antibiotic use.
- If you are under the age of 18 years.
- If you are pregnant or breastfeeding.
- If you are currently taking a medicine that contains tizanidine (used to treat muscle spasm).
- If your heart's mitral valve or aortic valve doesn't close tightly, causing blood to flow backwards in your heart.
- If you are on treatment for high blood pressure with medicines called angiotensin-converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs).

Warnings and precautions:

You should not take fluoroquinolone/quinolone antibacterial medicines, including ZYBACT, if you have experienced any serious adverse reaction in the past when taking a quinolone or fluoroquinolone. Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

You should not take ZYBACT if your heart's mitral valve or aortic valve doesn't close tightly. A thorough cardiovascular examination including electrocardiogram should be performed before you take ZYBACT.

Talk to your doctor before you take ZYBACT:

- If you have or ever have had heart problems. Caution should be taken when taking ZYBACT, if you were born with or have a family history of prolonged QT interval (seen on ECG, electrical

recording of the heart), have salt imbalance in your blood (especially low levels of potassium or magnesium in your blood), have a very slow heart rhythm (called bradycardia), have a history of heart disease, have a history of a heart attack (myocardial infarction) or if you are taking other medicines that result in abnormal ECG changes (see section Taking other medicines with ZYBACT).

- If you have diabetes (high blood sugar), ZYBACT may cause high or low blood sugar (especially if you are taking diabetic medicine or using insulin), and may even lead to a diabetic coma. Make sure you monitor your blood glucose levels carefully.
- If you have been diagnosed with an enlargement or bulge of a large blood vessel (aortic aneurysm or large vessel peripheral aneurysm).
- If you have experienced a previous episode of aortic dissection (a tear in the aorta wall).
- If you have a family history of aortic aneurysm or aortic dissection, or other risk factors or predisposing conditions (e.g. connective tissue disorders such as Marfan syndrome, or vascular Ehlers-Danlos syndrome, or vascular disorders such as Takayasu arteritis, giant cell arteritis, Behcet’s disease, high blood pressure, or known atherosclerosis).
- If you have ever had mental health problems.
- If you have kidney problems.
- If you are prone to convulsions.
- If you are taking theophylline used in asthma treatment.
- If you are taking other nonsteroidal anti-inflammatory pain medication.
- If you have porphyria, as ZYBACT may increase the chances of an acute attack.
- If you have glucose-6-phosphate dehydrogenase deficiency (a rare hereditary disease), inform your doctor, who will advise you whether ZYBACT is suitable for you.
- If you have a muscle disease called myasthenia gravis.
- If you had damage to your brain due to a stroke or other brain injury.

You should take caution while taking medicines from the group ACE inhibitors/ARBs (types of antihypertensive medicines) together with ZYBACT, as there is risk of acute kidney injury when

these medicines are taken together.

Take special care with ZYBACT:

- You may develop diarrhoea after receiving ZYBACT. If this becomes severe or persistent or you notice that your stools contain blood or mucus, you should stop taking ZYBACT immediately and consult your doctor.
- If you develop liver problems with symptoms such as yellowing of the skin and eyes, abdominal pain and swelling, dark coloured urine, pale stool, bloody or tarry stool, chronic tiredness, nausea (feeling sick) or vomiting (being sick) and loss of appetite.
- If you develop symptoms such as tingling in your hands or feet, sharp, stabbing pains, numbness in hands or feet, feeling of heaviness in the arms and legs (sometimes it may feel like your legs or arms are locked in place) while taking ZYBACT, stop taking ZYBACT immediately and consult your doctor.
- If you experience pain at the back of your lower leg or swelling of the ankle or foot while taking ZYBACT, stop taking ZYBACT immediately and consult your doctor. If you are an elderly person, using corticosteroids, also called steroids, or have received an organ transplant, you have a higher risk of experiencing pain at the back of your lower leg or swelling of the ankle or foot while taking ZYBACT.
- If you experience symptoms such as swelling of the face and tongue, skin sensitivity, hives, a red or purple skin rash that spreads within hours to days, blisters on your skin and the mucous membranes of your mouth, nose, eyes and genitals, or shedding of your skin while taking ZYBACT, stop taking ZYBACT immediately and consult your doctor.
- You may experience skin reactions when exposing yourself to excessive sunlight or sunbeds while taking ZYBACT. See section 4, Protect your skin from sunlight.
- If you experience any problems with your vision, like blurred vision, while taking ZYBACT, stop taking ZYBACT immediately and consult your eye specialist.
- Please inform your doctor that you are taking ZYBACT if you are undergoing tuberculosis (TB) testing, as ZYBACT may interfere with the results of these tests.

Serious skin reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported with the use of ZYBACT:

- SJS/TEN can appear initially as reddish target-like spots or circular patches often with central blisters on the trunk. Also, ulcers of your mouth, throat, nose, genitals and eyes (red and swollen eyes) can occur. These serious skin rashes are often preceded by fever and/or flu-like symptoms. The rashes may progress to widespread peeling of the skin and life-threatening complications or be fatal.
- DRESS appears initially as flu-like symptoms and a rash on the face, then an extended rash with a high body temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes.

If you develop a serious rash or another of these skin symptoms, stop taking ZYBACT and contact your doctor or seek medical attention immediately.

Children and adolescents:

ZYBACT is not indicated for use in children under the age of 18 years.

Other medicines and ZYBACT:

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

Do not take ZYBACT at the same time as the following medicines, this is because it can affect the way ZYBACT works:

- Iron salts, zinc supplements, antacids and sucralfate (used for heartburn or stomach ulcers).

It is recommended that preparations containing iron salts, sucralfate, magnesium- or aluminium-containing antacids should not be taken 2 hours before or after ZYBACT tablets are used.

ZYBACT may also interfere with certain medicines, such as:

- Corticosteroids, sometimes called steroids (used for inflammation).
- Theophylline (used to treat asthma).
- Nonsteroidal anti-inflammatory pain medicines (used to treat pain or inflammation).
- Warfarin (used to prevent blood from clotting).
- Glibenclamide (used to treat diabetes).
- Clozapine (used to treat severe schizophrenia, a mental disorder).
- Ropinirole (used to treat symptoms of Parkinson's disease such as stiffness, tremors, muscle spasms, and poor muscle control).
- Probenecid (used to treat gout).
- Cimetidine (used to treat ulcers and heartburn).
- Ciclosporin (used after organ transplants).
- Phenytoin (used to prevent and control seizures).

Please consult your doctor if you are taking any of the above-mentioned medicines.

Taking ZYBACT with heart medicines, such as quinidine, procainamide, amiodarone and sotalol, should be avoided as this may prolong the QT interval (seen on an ECG, electrical recording of your heart).

The following medicines should be taken with caution when used in combination with ZYBACT:

- Antimicrobial medicines (such as erythromycin or pentamidine, used to treat bacterial infections).
- Phenothiazines (used to treat serious mental and emotional disorders).
- Tricyclic antidepressants (used to treat depression).

Taking ZYBACT with food and drink:

ZYBACT can be taken on an empty stomach or with meals.

Pregnancy and breastfeeding:

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 health care provider for advice before taking ZYBACT. Do not take ZYBACT if you are pregnant.

If you are taking ZYBACT, you should not breastfeed your baby.

Driving and using machines:

ZYBACT may cause drowsiness or dizziness. Please take care before driving a vehicle or using machinery until you know how ZYBACT affects you.

3. How to take ZYBACT

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

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

You should swallow ZYBACT tablets whole, without crushing or chewing as ZYBACT has a bad taste when crushed or chewed.

ZYBACT is to be taken once or twice daily in a usual dose of 250 mg or 500 mg.

The dose of ZYBACT will be different for different patients.

The dose that is prescribed for you depends on a number of factors:

- What ZYBACT is used for.
- If you have any other diseases.
- Whether or not you are taking other medicines.

While you are being treated with ZYBACT, your doctor may want you to drink extra fluids so that you will pass more urine. This will help to prevent kidney problems.

Protect your skin from sunlight:

Keep out of direct sunlight while taking ZYBACT and for 2 days after you stop taking it. This is because your skin will become much more sensitive to the sun and may burn, tingle or severely blister if you do not take the following precautions:

- Make sure you use high factor sun cream.
- Always wear a hat and clothes which cover your arms and legs.
- Avoid sun beds.

Your doctor will tell you how long your treatment with ZYBACT will last.

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

If you take more ZYBACT than you should:

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

Take any remaining tablets and this leaflet with you so the doctor may know what you have taken.

If you forget to take ZYBACT:

Take the missed dose as soon as you remember. However, if it is almost time for your next dose, skip the dose you missed and take only the next regularly scheduled dose. Do not take a double dose of ZYBACT to make up for the forgotten individual doses.

If you stop taking ZYBACT:

Do not stop taking ZYBACT just because you feel better. It is important to finish your course of treatment prescribed by your doctor. If you stop taking the tablets too soon, the infection may return, your condition may get worse, or the bacteria may become resistant to the medicine.

4. Possible side effects

ZYBACT can have side effects. Not all side effects reported for ZYBACT are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ZYBACT, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop taking ZYBACT and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.
- Serious skin rashes including Stevens-Johnson syndrome and toxic epidermal necrolysis. These can appear as reddish target-like macules or circular patches often with central blisters on the trunk, skin peeling, ulcers of mouth, throat, nose, genitals and eyes and can be preceded by fever and flu-like symptoms.

These are all very serious side effects. If you have them, you may have had a serious reaction to ZYBACT. You may need urgent medical attention or hospitalisation.

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

- Diarrhoea with bloody stools.
- Restlessness, trembling or shaking, convulsions (fits), anxiety, changes in mood, hallucinations, seizures, feeling very suspicious.
- Loss of consciousness.
- Pain and inflammation in your tendons. In rare cases the tendon can rupture.
- Fever, low blood pressure (dizziness), cough or other lung symptoms, shock (cold, clammy skin, irregular breathing, weakness, anxiety).
- Inflammation of the pancreas (pancreatitis) causing severe abdominal pain, nausea and

vomiting.

- Damage to your liver. Loss of appetite, yellowing of skin and eyes, dark-coloured urine or a tender stomach may be signs of liver problems.
- Oedema (excessive build-up of fluid in your body's tissues, leading to swelling of your feet).
- Kidney problems, causing you to urinate either too much or too little.
- Shortness of breath, allergic lung reactions, difficulty breathing (wheezing).
- QT prolongation (characterised by an abnormal change in the electrical activity of your heart that can increase the risk of a fatal heart rhythm known as torsades de pointes).
- Unusual fast or slow beating of your heart.
- Having suicidal thoughts or actions.

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

Tell your doctor if you notice any of the following:

Frequent:

- Insomnia (inability to sleep).
- Nausea (feeling sick), vomiting (being sick), diarrhoea, loss of appetite, bloated feeling, constipation and stomach discomfort.
- Headaches, dizziness, sleep disturbances, taste disturbances.

Less frequent:

- Changes in the number of other bacteria or fungi, infection by fungi named Candida, which may need to be treated.
- Hot flushes.
- Anorexia (lack or loss of appetite for food).
- Abnormal enlargement of the breasts in male patients.
- Eye inflammation and increased tear production.
- Inflammation of the mouth.
- Loss of strength and energy.
- Feeling sleepy.

- Changes in the way things smell, loss of smell or taste.
- Vision, hearing or smell disturbances.
- Vertigo (feeling light-headed and off balance).
- Tinnitus (a ringing or buzzing in the ears).
- Skin reactions when exposed to sunlight or sunbeds.
- Muscle pain and weakness.
- Low or high blood sugar levels (especially if you have diabetes) or diabetic coma.
- Fever, low blood pressure (dizziness).
- Thrush.

Frequency unknown:

- Unsteady walking, numbness and tingling of the fingers and toes.
- Temporary loss of consciousness or posture (syncope).
- Impairment or loss of hearing.

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 or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ZYBACT.

5. How to store ZYBACT

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

6. Contents of the pack and other information

What ZYBACT contains:

The active substance is levofloxacin, as hemihydrate.

Each film-coated tablet contains levofloxacin hemihydrate equivalent to 250 mg or 500 mg levofloxacin, respectively.

The other ingredients are: crospovidone, hypromellose, Instacoat ICG-U-10236 Pink (containing hypromellose, macrogol, red iron oxide, talc, titanium dioxide, yellow iron oxide), microcrystalline cellulose, sodium stearyl fumarate.

What ZYBACT looks like and contents of the pack:

ZYBACT 250 mg: Pink coloured, capsule-shaped, biconvex, film-coated tablet with a break-line on both sides, with a thickness of approximately 4,30 mm.

ZYBACT 500 mg: Pink coloured, capsule-shaped, biconvex, film-coated tablet with a break-line on both sides, with a thickness of approximately 5,50 mm.

Transparent PVC/PVDC/aluminium blister strips, inside an outer cardboard box.

Pack sizes: 5 or 10 tablets.

Holder of certificate of registration and manufacturer:

Zydus Healthcare SA (Pty) Ltd

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Building B, Ground Floor

22 Karee Street

Centurion 0157

Tel. no.: 012 748 6400

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