SCHEDULING STATUS

S4

ZOXIL 250, capsules; ZOXIL 500, capsules

Amoxicillin

Sugar free

Read all of this leaflet carefully before you start taking ZOXIL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- ZOXIL 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 ZOXIL is and what it is used for.

2. What you need to know before you take ZOXIL**.**

3. How to take ZOXIL**.**

4. Possible side effects.

5. How to store ZOXIL**.**

6. Contents of the pack and other information.

1. What ZOXIL is and what it is used for

What ZOXIL is:

ZOXIL belongs to a group of antibiotics called ‘penicillins’.

These antibiotics work by killing the bacteria that are causing your infection.

What it is used for:

ZOXIL is used to treat infections caused by bacteria in different parts of the body.

2. What you need to know before you take ZOXIL

Do not take ZOXIL:

- if you are hypersensitive (allergic) to amoxicillin, any other penicillins or any of the other ingredients of ZOXIL (listed in section 6).
- if you have had a serious allergic reaction to any antibiotics.

  Some of the symptoms of an allergic reaction may include asthma, wheezing, shortness of breath, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, skin rash, itching or hives.

Warnings and precautions

Take special care with ZOXIL:

- if you have kidney problems;
- if you have glandular fever (fever, sore throat, swollen glands and extreme tiredness);
- if you are not urinating regularly;
- if you you are breastfeeding or intend to breastfeed;
- ZOXIL passes into breast milk and can be used only with caution during breastfeeding. However, breastfeeding must be stopped if gastrointestinal disorders (diarrhoea, candidosis or skin rash) occur in the newborn.

if you have or have had any medical conditions, including:

- asthma (a condition in which a person's airways become inflamed, narrow and swell and produce extra mucus, which makes it difficult to breathe);

- kidney problems;
- liver problems;
- lymphatic leukaemia (a type of cancer of the blood and bone marrow);
- glandular fever which can cause symptoms such as fatigue, swollen glands, a sore throat;
- diabetes;
- seizures history;
- stomach or bowel problems;
- a history of allergic problems, including hay fever.

Having urine or blood tests

If you are having:

- Urine tests (glucose) or blood tests for liver function.
- Oestriol tests (used during pregnancy to check that the baby is developing normally).This is because ZOXIL can affect the results of these tests.

Other medicines and ZOXIL

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

Tell your doctor if you are taking any of the following medicines:

- Medicines used to treat gout (e.g. probenecid or allopurinol). It may be more likely that you will have an allergic skin reaction or your doctor may decide to adjust the dose of ZOXIL.
- Digoxin, a medicine used to treat heart failure.
- Medicines used to prevent blood clots from the coumarin class (e.g. warfarin) as you may need extra blood tests.
- Methotrexate, a medicine used to treat arthritis and some types of cancers. ZOXIL may cause an increase in side effects.

- Oral contraceptives (birth control pills). You are advised to take supplementary non-hormonal contraceptive measures e.g. condom (see 'Other medicines and ZOXIL').
- Other antibiotics (e.g. tetracycline), ZOXIL may be less effective.

ZOXIL with food and drink and alcohol

ZOXIL may be taken with meals.

Pregnancy and breastfeeding and fertility

The safety of ZOXIL during pregnancy as not been established.

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking ZOXIL.

ZOXIL is excreted in breast milk, and should be used with caution when taken by breastfeeding women.

ZOXIL may reduce the effectiveness of some birth control pills and patients should use an additional method of contraception e.g. condoms (see section 'Other medicines and ZOXIL').

Driving and using machinery

It is not always possible to predict to what extent ZOXIL may interfere with the daily activities of a patient. ZOXIL may cause allergic reactions, dizziness or convulsions. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ZOXIL affects them (*see section 4 'Possible side effects'*).

ZOXIL is sugar free.

3. How to take ZOXIL

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

Always take ZOXIL exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

- The average adult dose for ZOXIL is 750 mg - 1,5 g/day, but in serious infections up to 6 g daily has been administered.
- Your doctor will tell you how long your treatment with ZOXIL will last.
- If you have the impression that the effect of ZOXIL is too strong or too weak, tell your doctor or pharmacist.

If you take more ZOXIL than you should

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

If you forget to take a dose of ZOXIL

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

If you stop taking ZOXIL

• Do not stop treatment early because the infection can come back. Take ZOXIL until the treatment is finished, even if you feel better.

4. Possible side effects

ZOXIL can have side effects.

Not all side effects reported for ZOXIL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ZOXIL, please consult your healthcare provider for advice.

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

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting;
- inflammation of the protective membrane surrounding the brain (aseptic meningitis).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ZOXIL. 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:

- a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome), and a more severe form, causing extensive peeling of the skin (more than 30 % of the body surface - toxic epidermal necrolysis);
- widespread red skin rash with small pus-containing blisters (bullous exfoliative dermatitis);
- a red, scaly rash with bumps under the skin and blisters (exanthemous pustulosis);
- flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS));
- skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge – erythema multiforme).

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

Tell your doctor if you notice any of the following:

The following side effects have been reported less frequently:

- Inflammation of blood vessels (vasculitis) which may be visible as red or purple raised spots on the skin, but can affect other parts of the body;
- fever, joint pain, swollen glands in the neck, armpit or groin;
- inflammation of the large intestine, causing watery diarrhoea usually with blood and mucus, stomach pain and/or fever;
- jaundice, caused by increases in the blood of bilirubin (a substance produced in the liver) which may make your skin and whites of the eyes appear yellow;
- inflammation of the liver (hepatitis);
- convulsions (in people taking high doses of ZOXIL or who have kidney problems);
- black tongue which looks hairy.
- nausea;
- vomiting;
- diarrhoea;
- thrush (*Candida* - a yeast infection of the vagina, mouth or skin folds);
- indigestion;
- dizziness;
- headache;
- low number of cells involved in blood clotting;
- a state of excessive restlessness;
- tooth discolouration;
- low number of red blood cells (haemolytic anaemia);
- crystals in urine;
- inflammation of tubes in the kidney;

The following side effects have been reported but the frequency is unknown:

- increase in some substances (enzymes) produced by the liver;
- severe reduction in the number of white blood cells;
- low number of red blood cells (haemolytic anaemia);
- low number of cells involved in blood clotting.

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, pharmacist or nurse.

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8

By reporting side effects, you can help provide more information on the safety of ZOXIL.

5. How to store ZOXIL

Store at or below 25 °C.

Store in the original package / container.

Keep the container tightly closed.

Protect from moisture.

Do not store in a bathroom.

Do not use after the expiry date stated on the label / carton / bottle.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What ZOXIL contains:

The active substance is:

- Amoxicillin

The other ingredients are*:*

- Magnesium stearate

What ZOXIL looks like and contents of the pack:

What ZOXIL looks like:

ZOXIL 250:

Dark grey/pink opaque capsules overprinted “ZOXIL 250” in white.

ZOXIL 500:

Dark grey/pink opaque capsules overprinted “ZOXIL 500” in white.

Contents of the pack:

ZOXIL 250: White HDPE Securitainers with snap-on LDPE cap and foam wad containing 15, 100 or 500 x 250 mg amoxycillin capsules.

ZOXIL 500: White HDPE Securitainers with snap-on LDPE cap and foam wad containing 15 or 100 x 500 mg amoxycillin capsules.

Holder of Certificate of Registration and Manufacturer

Viatris South Africa (Pty) Ltd

4 Brewery Street, Isando

Johannesburg,

1609

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Access to the corresponding Professional Information

Can be obtained on the SAHPRA website