

SCHEDULING STATUS

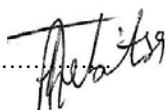
S4

ZOXIL S, 125 mg, powder for suspension**ZOXIL SF, 250 mg, powder for suspension****Amoxicillin****Contains sugar: Sucrose 3,002 g (125 mg)****Sucrose 2,819 g (250 mg)****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 healthxcare 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:**

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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 are 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:

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- asthma (a condition in which a person's airways become inflamed, narrow, 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;
- a history of seizures;
- 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.



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- 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. condoms (see 'Other medicines and CLAMENTIN 1000 mg').
- 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

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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'*).

Important information about the other ingredients of ZOXIL

Sucrose:

- ZOXIL suspension contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ZOXIL.

Sodium benzoate:

- ZOXIL suspension contains 9.45 mg sodium benzoate in each 5 ml. Benzoate salt may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

Sodium:

- ZOXIL suspension contains less than 1 mmol sodium (23 mg) per ml that is to say essentially 'sodium-free'. The sodium content in ZOXIL suspension must be taken into account in patients on a sodium-restricted diet if the administration of high doses is necessary.

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:

Adults:



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- 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.

Paediatric population:

- **Children 2 - 10 years:**
125 mg (5 ml of 125 mg/5 ml suspension) three times a day.
- **Children 6 months - 2 years:**
125 mg (5 ml of 125 mg/5 ml suspension) three times a day.
- **Infants 0 - 6 months:**
62,5 mg (2,5 ml of 125 mg/5 ml suspension) three times a day.
- **Premature infants 1,0 - 2,5 kg:**
30,0 - 62,5 mg (quarter to half medicine measure of 125 mg/5 ml suspension) once daily for the first 1 - 2 weeks depending on the size and maturity of the infant, thereafter the dose may be given 2 – 3 times daily.

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 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.

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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);
- chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome).

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

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extensive peeling of the skin (more than 30 % of the body surface - toxic epidermal necrolysis);

- a 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));
- a 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);
- rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease).

Drug-induced enterocolitis syndrome (DIES):

- DIES has been reported mainly in children receiving amoxicillin. It is a certain kind of allergic reaction with the leading symptom of repetitive vomiting (1-4 hours after medicine intake). Further symptoms could comprise abdominal pain, lethargy, diarrhoea, and low blood pressure.

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;

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- 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 leading to acute renal injury;
- 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.

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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.

You can also report side effects to SAHPRA on the SAHPRA website at:

<https://medsafety.sahpra.org.za/#download>, via email at: adr@sahpra.org.za or via

telephone at: 0125010311

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

5. How to store ZOXIL

- Dry powder ZOXIL S and ZOXIL SF must be store at or below 25 °C.
- Reconstituted suspension: Once reconstituted, ZOXIL S and ZOXIL SF must be used within 7 days kept at 25 °C or used within 14 days and kept in a refrigerator at 4 °C.
- Do not freeze.
- Store in the original container.
- Keep the container tightly closed.
- 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).
- Store all medicine out of reach of children.

6. Contents of the pack and other information

What ZOXIL contains:

- The active substance is:

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Amoxicillin

- The other ingredients are:

Sucrose

Sodium citrate

Citric acid anhydrous

Sodium benzoate

Disodium edetate

Capsaroma (peppermint)

Lemon flavour

Raspberry flavour

Peach apricot

Spectracol dual FD&C Red No.3 **or**

Idacol FD & C Red No.3 Powder

What ZOXIL looks like and contents of the pack:

What ZOXIL looks like:

ZOXIL S:

Free-flowing, pink powder. Pink suspension after being reconstituted.

ZOXIL SF:

Free-flowing, pink powder. Pink suspension after being reconstituted.

Contents of the pack:

ZOXIL S: Clear glass bottles containing powder for reconstitution to 100 ml of 125 mg/5 ml suspension.

ZOXIL SF: Clear glass bottles containing powder for reconstitution to 100 ml of 250 mg/5 ml suspension.

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Holder of Certificate of Registration and Manufacturer

Viatrix South Africa (Pty) Ltd

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1609

This leaflet was last revised in

Date of publication: 20 February 2024

Registration number

ZOXIL S: 28/20.1.2/0126

ZOXIL SF: 28/20.1.2/0127

Access to the corresponding Professional Information

Can be obtained on the SAHPRA website.

