

Clean Patient Information Leaflet for Medicines for Human Use:

AMOXY CO 1000/200 and 500/100 GDC

SCHEDULING STATUS: S4

AMOXY CO 1000/200 GDC sterile powder for injection

AMOXY CO 500/100 GDC sterile powder for injection

Amoxicillin and clavulanic acid

Sugar free.

Read all of this leaflet carefully before you are given AMOXY CO GDC

AMOXY CO GDC is not for self-medication, and must be administered by a healthcare professional.

- 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.

What is in this leaflet

1. What AMOXY CO GDC is and what it is used for
2. What you need to know before you receive AMOXY CO GDC
3. How to receive AMOXY CO GDC
4. Possible side effects
5. How to store AMOXY CO GDC
6. Contents of the pack and other information

1. What AMOXY CO GDC is and what it is used for



AMOXY CO GDC is an antibiotic and works by killing bacteria that cause infections. It contains two different medicines called amoxicillin and clavulanic acid. Amoxicillin belongs to a group of medicines called “penicillin” which is an antibiotic that can sometimes be stopped from working (made inactive). The other active component (clavulanic acid) stops this from happening.

AMOXY CO GDC is used in adults when oral antibiotic medicines cannot be used for the treatment of the following bacterial infections:

- Upper respiratory tract infections (sinusitis, recurring middle ear infection, infection of the tonsils)
- Lower respiratory tract infections (certain infections of the lungs)
- Genito-urinary tract infections (bladder infections, urethra infections, kidney infections)
- Skin and soft tissue infections.

2. What you need to know before you receive AMOXY CO GDC

Do not receive AMOXY CO GDC:

- if you are hypersensitive (allergic) to amoxicillin, clavulanic acid, penicillins, cephalosporins, carbapenems, monobactams, or to any of the other ingredients of AMOXY CO GDC (listed in section 6)
- if you have ever had a severe allergic reaction to any other antibiotic. This can include a skin rash or swelling of the face or throat
- if you have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.

Warnings and precautions

Take special care with AMOXY CO GDC:

- If you have glandular fever, a viral infection also known as infectious mononucleosis, which presents with symptoms such as high temperature, sore throat, joint pain, tiredness, swollen glands in the neck, armpit or groin and you must not receive AMOXY CO GDC as you may develop a measles like rash characterised by rose-red flat or slightly elevated rash over the trunk and your extremities.
- If you have a sexually transmitted infection called syphilis, you have a higher chance of experiencing the abrupt onset of fever, chills, shivers, feeling sick, headache, fast heartbeat, low blood pressure, breathing fast, flushing of skin, muscle aches and worsening of skin lesions (Jarisch-Herxheimer reaction) when you are receiving AMOXY CO GDC.
- If you have lymphatic leukaemia (a cancer that makes the bone marrow produce excess white blood cells), you have a higher chance of developing skin rashes when you are receiving AMOXY CO GDC.
- AMOXY CO GDC can make some existing conditions worse, or cause serious side effects (see section 4):
 - If have a history of allergic reactions to antibiotics or if you develop a skin rash while receiving AMOXY CO GDC, your treatment should be stopped
 - If you have a history of convulsions (fits), your fits can get worse, especially if you have kidney problems and/or are receiving high doses of AMOXY CO GDC
 - If you have a history of inflammation of the large intestine when taking/receiving antibiotics or if you develop severe diarrhoea, with a fever, painful stomach cramps, or blood, mucus or pus in your stool (antibiotic-associated colitis). Your treatment with AMOXY CO GDC must be stopped immediately
 - If you have liver problems, treatment with AMOXY CO GDC may cause very severe liver problems that can be fatal. If you have liver problems, you should not receive AMOXY CO GDC

- If you have kidney problems, treatment with AMOXY CO GDC may cause problems such as difficulty in passing water regularly and crystals in your urine which may cause symptoms like lower back pain and nausea. You should ensure that you drink enough water to reduce the possibility of crystals in your urine.
- If you are having blood tests (such as red blood cell status tests or liver function tests) or urine tests (for glucose), let the doctor or nurse know that you are using AMOXY CO GDC. This is because AMOXY CO GDC can affect the results of these types of tests.

Other medicines and AMOXY CO GDC

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

- AMOXY CO GDC can interact with the following medicines to make their effect and risk of adverse effects stronger. If you are taking any of the following, your doctor might monitor you more closely:
 - Methotrexate, used to treat cancer and severe psoriasis, where penicillins as in AMOXY CO GDC may reduce the excretion of methotrexate causing a potential increase in side effects of methotrexate
 - Medicines called oral anticoagulants (such as warfarin) used to help stop blood clots, when taken with AMOXY CO GDC, you may have an increased risk of bleeding as could be seen if you have small cuts that bleed more than normal, and for longer than normal, you may bruise easily, have frequent nosebleeds, or notice your gums bleeding. Extra blood tests may be needed, and your doctor may need to change your dose of the oral anticoagulant.
- AMOXY CO GDC can interact with the following medicines to make their effect weaker. If you are taking any of the following, your doctor might monitor you more closely:

- Oral contraceptives. AMOXY CO GDC may reduce the efficacy of oral contraceptives, you have a risk of falling pregnant. If you are taking a contraceptive pill you should talk to your doctor before receiving AMOXY CO GDC
- Mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs).
- Some medicines can interact with AMOXY CO GDC to make its effect and risk of adverse effects stronger. If you are taking the medicines below, your doctor might monitor you more closely.
 - Probenecid (used to treat gout), concomitant use of probenecid may reduce the excretion of amoxicillin and is not recommended. your doctor may decide to adjust your dose of AMOXY CO GDC
 - Allopurinol (used for gout) with AMOXY CO GDC, it may be more likely that you will have an allergic skin reaction.
- Some medicines can interact with AMOXY CO GDC to make its effect weaker. You should avoid taking AMOXY CO GDC together these medicines:
 - Other antibiotics used to treat bacterial infections, such as tetracyclines, may make AMOXY CO GDC less effective.

AMOXY CO GDC with food, drink and alcohol

You should avoid drinking alcohol during treatment with AMOXY CO GDC as you can have a disulfiram-like reaction that can vary from a mild reaction like facial flushing, nausea or vomiting, to a severe reaction including sudden swelling of the body with raised, itchy rash (hives), low blood pressure (hypotension), shock, or death.



Pregnancy and breastfeeding

You should not receive AMOXY CO GDC while you are pregnant or breastfeeding your baby as the safety of AMOXY CO GDC during pregnancy and whilst breastfeeding has not been established.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby while receiving AMOXY CO GDC, please consult your doctor, pharmacist or other healthcare provider for advice before receiving this medicine.

AMOXY CO GDC may reduce the efficacy of contraceptive pills. If you are taking a contraceptive pill you should talk to your doctor before receiving AMOXY CO GDC.

Driving and using machines

AMOXY CO GDC can have side effects and the symptoms such as allergic reactions, dizziness, convulsions (fits) that may make you unfit to drive (see section 4). Do not drive or operate machinery until you are aware of the measure to which AMOXY CO GDC affects you.

AMOXY CO GDC contains sodium and potassium

AMOXY CO 500/100 GDC contains 31,45 mg sodium (the main component of cooking/table salt) in each vial. This is equivalent to 1,57 % of the recommended maximum daily dietary intake of sodium for an adult.

AMOXY CO 500/100 GDC contains potassium, less than 1 mmol (39 mg) per vial, i.e. essentially 'potassium-free'.

AMOXY CO 1000/200 GDC contains 62,90 mg sodium (the main component of cooking/table salt) in each vial. This is equivalent to 3,15 % of the recommended maximum daily dietary intake of sodium for an adult.

AMOXY CO 1000/200 GDC contains 1mmol (or 39,25 mg) potassium per vial. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

3. How to receive AMOXY CO GDC

AMOXY CO GDC is a sterile powder for injection that can only be administered to you intravenously (through your vein) by injection or by intravenous infusion.

You will not be expected to give yourself AMOXY CO GDC. It will be administered to you by a person who is qualified to do so.

AMOXY CO GDC must not be injected into a muscle or under the skin.

Your doctor will decide how much AMOXY CO GDC you need to receive every day and how many days you should receive it for.

You will not normally be given AMOXY CO GDC for longer than 10 days without your doctor reviewing your treatment.

Make sure you drink plenty of fluids such as water or non-alcoholic drinks while receiving AMOXY CO GDC.

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

Patients with kidney and liver problems

- If you have kidney problems you may be given a different dose. A different strength or a different medicine may be chosen by your doctor.
- If you have liver problems your doctor will keep a close check on you, and you may have more regular liver function tests.

If you receive more AMOXY CO GDC than you should

Since a healthcare professional will administer AMOXY CO GDC to you, he/she will control the dosage and it is unlikely you will be given too much, but if you think you have been given too much AMOXY CO GDC, tell your doctor, pharmacist or nurse immediately. Signs may be an upset stomach (feeling sick, being sick or diarrhoea) or convulsion. In the event of overdosage your doctor will manage the overdosage.

If you missed a dose of AMOXY CO GDC

Do not receive a double dose to make up for forgotten individual doses. It is important for you to receive AMOXY CO GDC IV injections at regular intervals, and if a dose is missed a double dose should not be administered. Since a healthcare provider will administer AMOXY CO GDC, it is unlikely that the dose will be missed.

4. Possible side effects

AMOXY CO GDC can have side effects.

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

If any of the following happens, stop receiving AMOXY CO GDC and tell your doctor immediately:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing. This can be a serious allergic reaction to AMOXY CO GDC
- Severe and serious skin reactions which can include:
 - Toxic epidermal necrolysis (Lyell's syndrome) and Steven-Johnson syndrome (SJS) – life-threatening diseases that begin with a fever and flu-like symptoms and then within a few days the skin begins to blister and peel, forming very painful raw areas, called erosions that resemble severe hot-water burns, usually starting on the face and chest before spreading to other parts of the body
- Convulsions (fits)
- Chest pain (angina), heart attack (cardiac infarction) and sudden cardiac death associated with allergic reactions (Kounis syndrome)
- Severe diarrhoea, with a fever, painful stomach cramps, or blood, mucus or pus in your stool (antibiotic-associated colitis)
- Severe and on-going pain in the stomach area this could be a sign of acute pancreatitis
- Repetitive vomiting (1 – 4 hours after drug administration) which may be accompanied by other symptoms such as abdominal pain, diarrhoea, lethargy and low blood pressure
- Severe liver problems (hepatitis) which can cause symptoms such as fever, fatigue, loss of appetite, nausea, vomiting, abdominal pain, dark urine, light-coloured stools, joint pain, and jaundice (yellowing of the eyes and skin).

These are all very serious side effects. If you have them, you may have had a serious reaction to AMOXY CO GDC. 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:

- Additional bacterial or fungal infections such as bacterial or fungal infections of the lungs, organs of the genital (reproductive) and urinary systems, intestines or other parts of the body
- A severe reduction in the number of white blood cells (agranulocytosis) which can cause symptoms such as fever, chills, weakness, sore throat, sores in the mouth or throat, bleeding gums, bone pain, low blood pressure, fast heartbeat, and trouble breathing
- Your blood takes longer to clot as could be seen if you have small cuts that bleed more than normal, and for longer than normal, you bruise easily, have frequent nosebleeds, or notice your gums bleeding
- Skin rash, joint stiffness, joint pain, facial and extremity swelling, and fever which can lead to difficulty breathing (serum sickness-like syndrome)
- 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
- Inflammation of the protective membrane surrounding the brain and spinal cord (aseptic meningitis) which can cause symptoms such as headache, neck stiffness, sensitivity to light, increased sleepiness, unresponsiveness, fever, nausea and vomiting
- 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)
- 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))

- Inflammation (swelling) around parts of your kidneys' filters called the tubules that affects your kidneys' ability to filter waste and extra fluid and cause symptoms such as blood in your urine, feeling tired or confused, swelling in your hands, feet or other parts of your body, feeling sick to your stomach and throwing up, fever and rash
- The presence of crystals in urine which may cause kidney damage.

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

Tell your doctor if you notice any of the following:

Frequent side effects

- thrush (candida - a yeast infection of the vagina, mouth or skin folds)
- diarrhoea.

Less frequent side effects

- Low number of cells involved in blood clotting (thrombocytopenia) which will be shown in blood tests. This can cause easy bruising and abnormal bleeding (nosebleeds, bleeding gums)
- Low number of white blood cells (leukopenia). This will be shown in a blood test
- Dizziness, headache
- Swelling and redness along a vein where you have been injected which is extremely tender when touched (thrombophlebitis)
- Feeling sick (nausea), especially when taking high doses
- Vomiting
- Indigestion
- Pain in the upper abdomen just under the ribs (gastritis)



- Increase in some substances (enzymes) produced by the liver. This will show up in blood tests
- Skin rash, itching
- Raised red, itchy skin rash that can sting or burn (hives).

Side effects occurring with frequency unknown

- Low number of red blood cells (haemolytic anaemia) which will be shown in a blood test.
This can cause symptoms such as weakness, dizziness, confusion and abnormal paleness or lack of colour of the skin
- Rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease)
- Irritation, thickening and hardening of the skin and swelling at the site of injection.

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 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 AMOXY CO GDC.

Alternately you can contact Gulf Drug Company (Pty) Ltd at +27 31 538 8700 or per info@gulfdrug.co.za.

5. How to store AMOXY CO GDC



Store all medicines out of reach of children.

- Store at or below 25 °C.
- Protect from light and moisture.
- Do not freeze.
- Do not remove vials from unit carton until required for use.
- Do not use after the expiry date stated on the vial label/unit carton.

AMOXY CO GDC is for use in hospital only and the expiry date and storage instructions stated on the label are for the doctor, nurse or pharmacist's information. The doctor, pharmacist or nurse will make up your medicine. The reconstituted powder should be used within 4 hours if kept at 25 °C or 4 °C.

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 AMOXY CO GDC contains

- The active substances are amoxicillin and clavulanic acid.
 - AMOXY CO 1000/200 GDC:

Each vial contains amoxicillin sodium equivalent to 1000 mg amoxicillin and potassium clavulanate equivalent to 200 mg clavulanic acid.
 - AMOXY CO 500/100 GDC:

Each vial contains amoxicillin sodium equivalent to 500 mg amoxicillin and potassium clavulanate equivalent to 100 mg clavulanic acid.
- There are no other ingredients. However, please see section 2 for further important information about sodium and potassium in AMOXY CO GDC.

The doctor, nurse or pharmacist will make up the injection before use using an appropriate fluid (such as Water for Injections or an injection/infusion fluid).

What AMOXY CO GDC looks like and contents of the pack

AMOXY CO 500/100 GDC:

White or almost white powder in 10 ml clear EP type II glass vials.

AMOXY CO 500/100 GDC is presented in white printed unit carton containing 10 clear glass EP type II vials with a grey bromobutyl stopper EP Type I and a purple polypropylene and aluminium flip-off cap.

AMOXY CO 1000/200 GDC:

White or almost white powder in 20 ml clear EP type II glass vials.

AMOXY CO 1000/200 GDC is presented in white printed unit carton containing 10 clear glass EP type II vials with a red chlorobutyl stopper EP Type I and a purple polypropylene and aluminium flip-off cap.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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