

## PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

**MOCLAV 0,6 Powder for solution for injections**

**MOCLAV 1,2 Powder for solution for injections**

**Amoxicillin, Clavulanic acid**

**Sugar free**

**Read all of this leaflet carefully before you are given MOCLAV**

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

### **What is in this leaflet**

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

### **1. What MOCLAV is and what it is used for**

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

MOCLAV is used in adults to treat the following infections:

- Severe ear, nose and throat infections
- Lung infections
- Urinary tract infections
- Skin and soft tissue infections including dental infections

## **2. What you need to know before you use MOCLAV**

### **MOCLAV should not be administered to you:**

- if you are hypersensitivity (allergic) to penicillins, amoxicillin and cephalosporins or any other ingredient of MOCLAV (listed in section 6)
- if you have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic
- if you are a child under 12 years of age

### **Warnings and precautions**

Tell your doctor or health care provider before being given the injection:

- if you have several allergies or if you have developed a skin rash previously when receiving an antibiotic
- if you develop a skin rash during treatment, please notify your doctor or nurse. If you develop skin lesions, your doctor will discontinue your treatment
- if you experience chest pain in the context of allergic reactions, which may be a symptom of allergy triggered heart attack (Kounis syndrome) (see section 4 ‘Possible side effects’)
- if you develop convulsions during the treatment. In this case, you should inform your doctor or other healthcare professional immediately
- if you have glandular fever (if you are tired, have a fever and swollen glands)
- if you think you developed a new or worsening infection, inform your doctor or other healthcare professional immediately
- if you are being treated for liver problems
- if you have a history of developing severe diarrhoea after receiving an antibiotic, or if you

develop diarrhoea during or after your treatment. Do not take any medicine for the diarrhoea without first checking with your doctor

- if you have moderate or severe kidney problems
- if you are not passing water regularly
- if you have a condition named lymphocytic leukaemia (type of cancer of the blood or bone marrow)
- if you are going for blood tests (such as red blood cell status tests or a liver function tests) or urine tests (for glucose), because MOCLAV can influence the results of these tests

In some cases, your doctor may investigate the type of bacteria that is causing your infection. Depending on the results, you may be given a different strength of MOCLAV or a different type of medicine.

### **Other medicines and MOCLAV**

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

Before MOCLAV is being given, tell your doctor:

- If you are taking probenecid (used for the treatment gout).
- If you are taking anticoagulants (medication that prevents blood clotting), such as warfarin, together with MOCLAV extra blood tests for monitoring is required.
- MOCLAV can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works.
- MOCLAV can affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) works.
- If you are taking allopurinol (used for the treatment of gout), with MOCLAV it will be more likely to develop an allergic skin reaction.

- If you are using oral contraceptives, MOCLAV may reduce the efficacy of the oral contraceptives.

### **MOCLAV with food and alcohol**

If MOCLAV is taken with alcohol it may cause an adverse reaction to the alcohol, which includes nausea, vomiting, dizziness, headache.

### **Pregnancy, breastfeeding and fertility**

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 being administered this medicine.

Safety and efficacy during pregnancy has not been established.

You should not breastfeed your baby whilst using MOCLAV.

### **Driving and using machines**

It is not always possible to predict to what extent MOCLAV may interfere with your daily activities. MOCLAV can have side effects and symptoms that may make you unfit to drive or operate machinery.

Do not engage in the above activities until you are aware of the measure to which MOCLAV affects you.

### **MOCLAV contains sodium and potassium**

MOCLAV 0,6 contains 30 mg of sodium per vial, equivalent to 1.5 % of the WHO recommended maximum daily intake of 2 g sodium for an adult. This should be considered if you are on a controlled sodium diet.

MOCLAV 0,6 contains 19 mg of potassium which is less than 1 mmol (39 mg) per vial or bottle.

This is considered essentially as 'potassium-free'.

MOCLAV 1,2 contains 60 mg of sodium per vial or bottle, equivalent to 3 % of the WHO recommended maximum daily intake of 2 g sodium for an adult. This should be considered if you are on a controlled sodium diet.

MOCLAV 1,2 contains 38 mg of potassium which is less than 1 mmol (39 mg) per vial or bottle. This is considered to be 'potassium-free'. However, this can be taken in consideration by patients with reduced kidney function or patients on a controlled potassium diet.

### **3. How to use MOCLAV**

You will not be expected to give yourself MOCLAV. It will be given to you by a person who is qualified to do so.

#### **Adults**

For severe infections of the respiratory tract, urinary tract and skin and soft tissue one MOCLAV 1,2 vial will be administered intravenously (directly into the blood stream) every 6 to 8 hours.

You will not normally be given MOCLAV for longer than 10 days without the doctor reviewing your treatment.

#### **Children**

Not recommended.

#### **Patients with kidney 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 are given more MOCLAV than you should**

Since a healthcare provider will administer MOCLAV, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

**If a dose of MOCLAV is missed**

Since a healthcare provider will administer MOCLAV, it is unlikely that the dose will be missed.

**4. Possible side effects**

MOCLAV can have side effects.

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

If any of the following happens, after receiving MOCLAV tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- 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
- rash or itching,
- fainting (collapse),
- 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 reaction to MOCLAV. 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 skin rash with blisters that may cause the skin to peel, flake or bleed, particularly around the mouth, nose, eyes and genitals and a more severe form, causing extensive peeling of the skin (more than 30 % of the body surface)
- widespread red skin rash with small pus-containing blisters
- a red, scaly rash with bumps under the skin and blisters
- flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells and liver enzymes)
- bleeding or bruising more easily than normal
- blood takes longer to clot
- unusual tiredness, headaches, being short of breath when exercising, dizziness, looking pale
- convulsions
- inflammation of the large intestine, causing watery diarrhoea usually with blood and mucus, stomach cramps and/or fever
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems
- inflammation of tubes in the kidney
- crystals in urine leading to acute renal injury.

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:

- if you are more prone to flu or infections than usual (decrease in your immune systems activity because of less white blood cells)
- dizziness
- headache
- pain, redness and swelling at the injection site caused by blood clot in the vein
- feeling sick (nausea)
- vomiting
- pain or discomfort in the stomach associated with difficulty in digesting food
- inflammation of the lining of the stomach causing stomach pains
- increase in some substances (enzymes) produced by the liver
- hives (itchy lumps)

Frequency not known

- if you bleed more than usual (because of a decrease in cells that is responsible for blood clotting)
- inflammation of the protective membrane surrounding the brain
- rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease).

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](http://who-umc.org)) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of MOCLAV.

## **5. How to store MOCLAV**

Store all medicines out of reach of children

Store at or below 30 °C

Once the content of the vial has been mixed with an injection solution, it should be used within 20 minutes if stored below 25 °C

Do not use reconstituted MOCLAV if you notice any visible particles.

MOCLAV should not be administered after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering

Any MOCLAV which is left over, not used or has passed its expiry date will be disposed of by hospital staff

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

## **6. Contents of the pack and other information**

### **What MOCLAV contains**

MOCLAV 0,6 powder for solution for injections:

The active substances are amoxicillin and clavulanic acid. Each vial contains sodium amoxicillin equivalent to 500 mg amoxicillin and potassium clavulanate equivalent to 100 mg of clavulanic acid.

MOCLAV 1,2 powder for solution for injections:

The active substances are amoxicillin and clavulanic acid. Each vial or bottle contains sodium amoxicillin equivalent to 1000 mg amoxicillin and potassium clavulanate equivalent to 200 mg of clavulanic acid.

### **What MOCLAV looks like and contents of the pack**

The powder for solutions for injections is a white or almost white powder

MOCLAV 0,6: Clear 20 mL moulded glass vial (Type II) closed with halogenated butyl rubber stopper and flip-off caps (Aluminum-plastic combination caps)

Packs of 10 vials/tray/box, 12 boxes

MOCLAV 0,6: Clear 20 mL moulded glass vial (Type II) closed with halogenated butyl rubber stopper and flip-off caps (Aluminum-plastic combination caps).

Packs of 10 vials/tray/box, 12 boxes

**Holder of Certificate of Registration**

Ando Pharma (Pty) Ltd.

73 Keurboom Crescent

Platteklouf

+27 21 911 4003

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