PATIENT INFORMATION LEAFLET FOR MYCLAV 375 / MYCLAV 625

SCHEDULING STATUS

Schedule 4

PROPRIETARY NAMES AND DOSAGE FORM

MYCLAV 375 (film coated tablet)

MYCLAV 625 (film coated tablet)

Please read this leaflet carefully before you start using / taking MYCLAV

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- **MYCLAV** 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.

1. WHAT MYCLAV CONTAINS

Active ingredients:

MYCLAV 375: Each film coated tablet contains amoxicillin trihydrate equivalent to amoxicillin 250,0 mg and clavulanate potassium Avicel (1:1) mixture equivalent to clavulanic acid 125,0 mg.

MYCLAV 625: Each film coated tablet contains amoxicillin trihydrate equivalent to amoxicillin 500,0 mg and clavulanate potassium Avicel (1:1) mixture equivalent to clavulanic acid 125,0 mg.

Inactive ingredients:

Both **MYCLAV 375** and **MYCLAV 625** contain the following inactive ingredients:

Magnesium stearate, sodium starch glycolate, colloidal anhydrous silica, microcrystalline cellulose, sodium lauryl sulphate, Opadry OY-C-7000A, methanol and dichloromethane.

2. WHAT MYCLAV IS USED FOR

MYCLAV is used for the treatment of sinusitis, middle-ear infections, bronchitis, lung infections, urinary tract infections, skin and soft tissue infections.

Your doctor or healthcare professional will tell you for what condition you are being treated for.

3. BEFORE YOU TAKE / USE MYCLAV

Do not take / use MYCLAV:

- if you are hypersensitive (allergic) to amoxicillin, clavulanic acid, penicillins, cephalosporins or any of the other ingredients of **MYCLAV** (see **WHAT MYCLAV CONTAINS**).
- if you have any liver problems or a history of jaundice.

Take special care with MYCLAV:

- **Tell your doctor if you have a history of allergies or are allergic to penicillin or cephalosporin type antibiotics before taking MYCLAV. If you experience any symptoms of an allergic reaction to MYCLAV, such as skin rash, itching, hives, difficulty breathing, swelling of the throat, tongue, mouth or lips, contact your doctor or nearest hospital immediately.**
- Do no use **MYCLAV** if you think you may have infectious mononucleosis (an infectious viral disease characterised by the swelling of the lymph glands and prolonged tiredness).
- If you are using anticoagulants (medicines used to make your blood thin) consult your doctor first before using **MYCLAV**.
- Use **MYCLAV** with caution if you have any liver or kidney disorders.
- Use **MYCLAV** with caution if you have syphilis (a sexually transmitted disease).
- Drink enough fluids if you have to take high doses of **MYCLAV**.
- Tell your doctor if you are on a salt-restricted diet.
- Use **MYCLAV** with caution if you have lymphatic leukaemia (a type of leukaemia affecting circulating lymphocyte cells).
- Your doctor may monitor your kidney, liver and blood functions on a regular basis.

Taking / Using MYCLAV with food or drink:

MYCLAV can be taken with or without food.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, please consult your doctor, pharmacist or other healthcare professional before taking this medicine.

You should not take **MYCLAV** if you are pregnant.

The use of **MYCLAV** is **not recommended** if you are breastfeeding.

Driving and using machinery:

MYCLAV may cause dizziness. Make sure you know how you react to **MYCLAV** before driving a vehicle, operating machinery or doing anything else requiring your attention.

Taking / Giving / Using other medicines with MYCLAV:

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

The following medicines could cause an interaction when used in combination with **MYCLAV**:

- Probenecid or allopurinol (used to treat gout).
- Oral contraceptives (used to prevent unplanned pregnancies).
- Other antibiotics (used to treat bacterial infections).
- Anticoagulants (used to prevent blood clots).
- Non-steroidal anti-inflammatory medicines (used to treat pain and inflammation/swelling).
- Methotrexate (used in rheumatoid arthritis – inflammation of the joints).

Not all medicines which may interact with **MYCLAV** are listed in this leaflet.

Discuss all your medication that you have taken recently and are presently taking with your doctor or healthcare professional.

4. HOW TO TAKE / USE MYCLAV

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

The usual duration of treatment is 5 to 7 days, depending on the type of infection. However, if you feel better after a day or two, do not stop taking your **MYCLAV** tablets. Complete the course even if you feel better. Consult your doctor if you are unsure.

Tablets should be taken immediately at the start of a meal.

During the use of **MYCLAV**, it is advisable to maintain adequate fluid intake and urinary output in order to prevent any possibility of amoxicillin crystalluria (the excretion of crystals when urinating).

Adults:

The adult dose for **MYCLAV** is one **MYCLAV 375** tablet every eight hours at the start of a meal.

For more severe infections and infections of the respiratory tract, the dose should be one **MYCLAV 625** tablet every eight hours at the start of a meal.

Impaired kidney function:

Your doctor may reduce your dosage depending on the severity of your kidney impairment.

If you have the impression that the effect of **MYCLAV** is too strong or too weak, talk to your doctor or pharmacist.

If you take / use more MYCLAV than you should:

In the event of an overdosage, contact your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre as soon as possible. Take this leaflet and any remaining **MYCLAV** tablets with you, so that the doctor knows what you have taken.

If you forget to take / use MYCLAV:

Take the missed dose as soon as possible. However, if it is almost time for you next dose, continue to take the next tablet at the usual time. Do not take a double dose.

If you have trouble remembering when to use your medicine, ask your pharmacist for advice.

5. POSSIBLE SIDE EFFECTS

MYCLAV may have side effects.

Not all side effects reported for MYCLAV are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking MYCLAV, please consult your doctor, pharmacist or other healthcare professional for advice.

Side effects that require urgent medical attention:

If any of the following symptoms of an allergic (hypersensitivity) reaction occur, contact your doctor or healthcare professional immediately:

- Severe skin rash, inflammation (redness and swelling) of the skin, swelling of the throat, tongue, mouth and lips.
- Difficulty breathing.
- Severe diarrhoea.

The following side effects may occur frequently:

- Headache, dizziness, tiredness.
- Diarrhoea, nausea, vomiting, heart burn, stomach pain, abnormal taste in the mouth.
- Blood in the faeces, inflammation in the stomach, mouth or colon, black ‘hairy’ tongue.
- Urticaria (hives).
- Vaginal infection.
- Hot flushes.

The following side effects may occur less frequently:

- Fungal infection in the mouth.
- Itching.

6. STORING AND DISPOSING OF MYCLAV

- Store at or below 25 °C, protected from light and moisture.

- Keep the blisters in the outer carton until required for use.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Do not use after the expiry date printed on the label or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

7. PRESENTATION OF MYCLAV

Tablets are packed in aluminium foil blisters, each blister strip containing five tablets. Three blister strips are packed in an outer carton.

8. IDENTIFICATION OF MYCLAV

MYCLAV 375: White, film coated, oval shaped, plain biconvex tablets.

Length of tablet 18,30 – 18,40 mm.

Width of tablet 8,30 – 8,40 mm.

MYCLAV 625: White, film coated, oval shaped, plain biconvex tablets.

Length of tablet 19,50 – 19,70 mm.

Width of tablet 9,50 – 9,70 mm.

9. REGISTRATION NUMBERS

MYCLAV 375: A39/20.1.2/0068

MYCLAV 625: A39/20.1.2/0069

10. NAME AND ADDRESS OF THE REGISTRATION HOLDER

Unichem SA (Pty) Ltd

San Domenico

Ground floor, Unit G4

10 Church Street

Durbanville

7551 Cape Town

021 531 0436

11. DATE OF PUBLICATION

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