

## **PATIENT INFORMATION LEAFLET**

### **KETACLAV 625 mg film coated Tablet**

Amoxicillin Trihydrate BP

Diluted Potassium Clavulanate BP

### **1. WHAT KETACLAV 625 IS AND WHAT IT IS USED FOR?**

KETACLAV 625 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 “penicillins” that can sometimes be stopped from working (made inactive). The other active component Clavulanic acid stops this from happening.

Co-amoxiclav is used in adults and children to treat the following infections:

- respiratory infections
- middle ear and sinus infections
- urinary tract and kidney infections
- skin and soft tissue infections including animal bites and dental infections
- bone and joint infections

You must talk to a physician if you do not feel better or if you feel worse after 14 days.

### **2. BEFORE YOU TAKE USE KETACLAV 625**

#### **Do not take use KETACLAV 625**

- If you are allergic to amoxicillin, clavulanic acid, penicillin or any of the other ingredients of this medicine.
- If you have ever had a severe allergic reaction to any other antibiotic. This can include a skin rash or swelling of the face, lips, tongue, throat or neck.
- If you have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic

#### **Take special care with KETACLAV 625**

Talk to your physician before taking KETACLAV 625 if you:

- have glandular fever
- have liver or kidney problems
- are not passing water regularly

#### **Taking Using other medicines**

##### Oral anticoagulants

Oral anticoagulants and penicillin antibiotics have been widely used in practice without reports of interaction. However, in the literature there are cases of increased international normalised ratio in patients maintained on acenocoumarol or warfarin and prescribed a course of amoxicillin. If co-administration is necessary, the prothrombin time or international normalised

ratio should be carefully monitored with the addition or withdrawal of amoxicillin. Moreover, adjustments in the dose of oral anticoagulants may be necessary

#### Methotrexate

Penicillins may reduce the excretion of methotrexate causing a potential increase in toxicity.

#### Probenecid

Concomitant use of probenecid is not recommended. Probenecid decreases the renal tubular secretion of amoxicillin. Concomitant use of probenecid may result in increased and prolonged blood levels of amoxicillin but not of clavulanic acid.

#### Mycophenolate mofetil

In patients receiving mycophenolate mofetil, reduction in pre-dose concentration of the active metabolite mycophenolic acid (MPA) of approximately 50% has been reported following commencement of oral amoxicillin plus clavulanic acid. The change in pre-dose level may not accurately represent changes in overall MPA exposure.

Therefore, a change in the dose of mycophenolate mofetil should not normally be necessary in the absence of clinical evidence of graft dysfunction. However, close clinical monitoring should be performed during the combination and shortly after antibiotic treatment

### **Taking Using KETACLAV 625 with food and drink**

Take KETACLAV 625 with a meal or snack. This will make you less likely to feel sick.

Swallow the tablets whole with a glass of water.

If you find tablets hard to swallow, you can break them in half. There is a line down the middle to make them easier to break. Take both pieces at the same time, swallowing one after the other.

### **Pregnancy and breast-feeding**

Amoxicillin is excreted into human milk in small amounts and is considered compatible with breast-feeding. Clavulanate has not been detected in human milk. Adverse effects in the nursing infant are unlikely. The manufacturer recommends caution when amoxicillin-clavulanate is administered to a nursing woman.

Amoxicillin and clavulanic acid is acceptable to use during breastfeeding. Limited information indicates that serious reactions in infants are very uncommon during the use of amoxicillin-clavulanic acid during nursing, with restlessness, diarrhea and rash occurring occasionally. If amoxicillin-clavulanic acid is required by the mother, it is not a reason to discontinue breastfeeding. Monitor the infant for these reactions during nursing.

### **Driving and using machines**

Co-amoxiclav can have side effects such as allergic reactions, dizziness or fits that may make you unfit to drive. Do not drive or use machinery unless you are feeling well

### **Important information about some of the ingredients of KETACLAV 625**

#### **Use in adults and children weighing 40 kg and over Page 3 of 6**

The recommended dose is 1 tablet three times a day.

### **Use in children weighing less than 40 kg**

Ask your doctor or pharmacist for advice when giving Ketaclav 625 tablets to children weighing less than 40 kg. The tablets are not suitable for children weighing less than 25 kg.

## **3. HOW TO TAKE USE KETACLAV 625**

Space the doses evenly during the day, at least 4 hours apart. Do not take 2 doses in 1 hour. Do not take KETACLAV 625 for more than 2 weeks. If you still feel unwell you should go back to see the physician.

### **If you take use more KETACLAV 625 than you should**

If you take too much Co-amoxiclav, signs might include an upset stomach (feeling sick, being sick or diarrhoea) or convulsions (fits). Talk to your doctor as soon as possible. Take the medicine carton to show the physician.

### **If you forget to take use KETACLAV 625**

If you forget to take a dose, take it as soon as you remember. You should then wait 4 hours before taking the next dose.

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

### **If you stop taking using KETACLAV 625**

Keep taking your medicine until the treatment is finished, even if you feel better. You need every dose to help fight the infection. If some bacteria survive they can cause the infection to come back.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

### **Serious side effects**

Stop taking Co-amoxiclav, contact a doctor immediately or go to your nearest hospital emergency department if you get any of the following:

#### **Allergic reactions:**

**Uncommon** (may affect up to 1 in 100 people)

- Skin rash

**Rare** (may affect up to 1 in 1000 people)

- Skin rash, which may, blister, and look like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge – erythema multiforme)

**Not known** (frequency cannot be estimated from available data)

- 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

- swelling, sometimes of the face or throat (*angioedema*), causing difficulty in breathing collapse.
- a widespread red 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).

## 5. HOW TO STORE KETACLAV 625

Keep this medicine out of the sight and reach of children.

Do not store tablets below 30°C. Store in the original package in order to protect from moisture.

Do not use if the tablets are chipped or damaged.

Do not use this medicine after the expiry date which is stated on the carton after “EXP”. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. FURTHER INFORMATION

### What KETACLAV 625 contains:

The active substances are amoxicillin trihydrate (corresponding to 500 mg amoxicillin) and potassium clavulanate (corresponding to 125 mg clavulanic acid). The other ingredients are Microcrystalline Cellulose, Croscarmellose Sodium, Colloidal anhydrous silica, Sodium Starch Glycolate, Magnesium Stearate, Silicon Dioxide, Sodium Lauryl Sulphate, Ethyl Cellulose, Diethyl Phthalate, Purified Talc, Isopropyl Alcohol, Dichloromethane, Hypromellose, Titanium Dioxide.

### What KETACLAV 625 looks like and contents of the pack:

KETACLAV 625 is looks like White coloured, capsule shaped, biconvex, film coated tablet with both side plain and contents of the pack is 1 x 10 Alu-Alu Blister pack in a printed carton along with package insert.

### Manufacturer



**saga** LABORATORIES

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