## **AXCEL CO-AMOXICLAV-625 TABLET**

Amoxycillin/Clavulanic Acid (500mg/125mg)

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## What Axcel Co-Amoxiclav-625 Tablet is used for

Axcel Co-Amoxiclay-625 Tablet is used for the treatment of:

- Upper and lower respiratory tract infections: sinusitis, otitis media, bronchitis.
- Skin and soft tissue infection: boils, abcesses, cellulitis, wound infections.
- Genitourinary tract infections: cystitis, urethritis, pyelonephritis.
- Bone and joint infections: osteomyelitis.

## How Axcel Co-Amoxiclav-625 Tablet works

Axcel Co-amoxiclav-625 Tablet is an antibiotic and works by killing bacteria that cause infections. It contains two active ingredients. One of these is a penicillin called amoxycilin and the other is clavulanic acid.

## Before you use Axcel Co-Amoxiclay-625 Tablet

- When you must not use it

Do not take Axcel Co-Amoxiclav-625 Tablet if:

• If you are having history of allergic reactions to any penicillin, beta-lactamase inhibitors or other beta-lactam antibiotics. Some of the symptoms of an allergic reaction may include skin rash, itching,

- difficulty in breathing and swelling of the face or tongue.
- If you are patients with previous history of amoxycillin with clavulanate or penicillin associated jaundice/liver dysfunction.
- Please consult your doctor before start to use Axcel Co-Amoxiclav-625 Tablet if you are pregnant, plan to become pregnant, breast-feeding or intend to breast-feed. Your doctor will have weighed the risks of you taking Axcel Co-Amoxiclav-625 Tablet against the benefits they expect it will have for you.

## - Before you start to use it

Tell your doctor if:

- If you have liver problem/ cholestatic jaundice.
- If you have moderate or severe kidney impairment.
- If you are hypersensitive to penicillin.
- If you are having medical problems such as stomach and intestinal disease such as pseudomembranous colitis.
- If you have glandular fever (mononucleosis)
- If you are not passing urine regularly (crystalluria).

### - Taking other medicines

You should tell your doctor if you are taking any medicine as it may interact with your Axcel Co-Amoxiclay-625 Tablet:

- Probenecid, as an adjunct therapy in antibiotics or for gout.
- Allupurinol for gout.
- Oral contraceptives.
- Concurrent use with amoxycillin/clavulanate.
- Anticoagulant agent, blood thinning agent.

## How to use Axcel Co-Amoxiclav-625 Tablet

- How much to use

Adult and children> 12 years: Mild to moderate infections: 1 tablet, 2 times daily. Your doctor might prescribe you a different dose if you have severe kidney impairment.

Treatment should not be extended beyond 14 days without review.

Not recommended for children of 12 years and below.

#### - When to use it

Your doctor will decide when it is appropriate for you to use Axcel Co-Amoxiclav-625 Tablet according to the type of condition you have.

## - How long to use it

Continue taking Axcel Co-Amoxiclav-625 Tablet for as long as doctor recommends.

Do not stop taking medication, even if you feel better after a few days, unless advised by your doctor. Your infection may not clear completely if you stop taking your medicine too soon.

#### - If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

## If you use too much (overdose)

- Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.
- Taking too many tablets may cause stomach and abdominal pain, vomiting and diarrhea, rash, hyperactivity or drowsiness.

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## While you are using it

## - Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Axcel Co-Amoxiclav-625 Tablet.
- Tell your doctor immediately if you become pregnant while talking this medication.
- If you get severe diarrhoea tell your doctor or pharmacist immediately.

#### - Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give Axcel Co-Amoxiclav-625 Tablet to anyone else, even if they have the same symptoms or condition as you.

#### - Things to be careful of

- Avoid prolonged use of this product.
- Adequate fluid intake and urinary output should be maintained during administration of high doses amoxycillin/clavulanate.
- Pregnancy and lactation.
- Be careful when driving or operating machinery until you know how Axcel Co-Amoxiclav-625 Tablet affects you.

#### **Side Effects**

Like all medicines, Axcel Co-Amoxiclav-625 Tablet can cause side effects although not everybody gets them. You are advised to consult doctor/ pharmacist for further information. The following common side effects have been reported:

- Diarrhoea
- Pseudomembranous colitis (inflammation of the colon)
- Indigestion.
- Nausea and vomiting.
- Candidiasis (fungal infection that can affect skin, genitals, throat and mouth).

- Hepatitis (inflammation of liver) and cholestatic jaundice (jaundice caused by thickened bile).
- Urticarial (hives) and erythematous rashes.
- Erythema multiform (hypersensitivity reaction triggered by infection, mostly herpes simplex virus (HSV).
- Steven-Johnson syndrome (serious disorder of skin and mucous membrane)
- Angioedema (rapid swelling of the deep layers of skin)
- Anaphylaxis (allergic reaction to an antigen that causes skin rash).
- Anaemia (deficiency of red blood cells in the blood, resulting in pallor or weariness).
- Agranulocytosis (deficiency of granulocytes in the blood, causing increased vulnerability to infection).
- Agitation
- Anxiety
- Convulsions
- Dizziness
- Insomnia
- Reversible hyperactivity
- Superficial tooth discoloration.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers -> Reporting).

## Storage and disposal of Axcel Co-Amoxiclay-625 Tablet

## **Storage**

Keep Axcel Co-Amoxiclav-625 Tablet out of reach of children. Store below 25°C. Protect from light and moisture.

## **Disposal**

Do not use Axcel Co-Amoxiclav-625 Tablet after the expiry date which is stated on the carton.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **Product description**

### What it looks like

Axcel Co-Amoxiclav-625 Tablet is white to off-white oblong shaped film coated tablet with dimension of 9.6mm x 20.2mm.

## **Ingredients**

Active Ingredient:

Amoxycillin, Potassium Clavulanate.

#### Inactive Ingredients:

Povidone K30, Opadry White, Microcrystalline Cellulose, Ethanol, Colloidal Silicon Dioxide, Croscarmellose Sodium, Magnesium Stearate.

#### MAL Number MAL10100171AC

# Manufacturer and product registration holder

KOTRA PHARMA (M) SDN BHD No. 1, 2 & 3, Jalan TTC 12, Cheng Industrial Estate, 75250 Melaka, Malaysia.

#### Date of revision

02/12/2015

## Serial number

BPFK(R4/1)121115/00417