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Package leaflet: Information for the user

**Co-Amoxiclav Aurobindo 500 mg/125 mg
film-coated tablets
(Amoxicillin/Clavulanic acid)**

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Co-Amoxiclav Aurobindo is and what it is used for

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

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

2. What you need to know before you take Co-Amoxiclav Aurobindo

Do not take Co-Amoxiclav Aurobindo

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

→ **Do not take Co-Amoxiclav Aurobindo if any of the above apply to you.** If you are not sure, talk to your doctor or pharmacist before taking Co-Amoxiclav Aurobindo.

Warnings and precautions

Talk to your doctor or pharmacist before taking Co-Amoxiclav Aurobindo if you:

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

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Co-Amoxiclav Aurobindo. 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 Co-Amoxiclav Aurobindo or a different medicine.

Conditions you need to look out for

Co-Amoxiclav Aurobindo can make some existing conditions worse, or cause serious side effects. These include allergic reactions, convulsions (fits) and inflammation of the large intestine. You must look out for certain symptoms while you are taking Co-Amoxiclav Aurobindo, to reduce the risk of any problems. See 'Conditions you need to look out for' in section 4.

Blood and urine tests

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 taking Co-Amoxiclav Aurobindo. This is because Co-Amoxiclav Aurobindo can affect the results of these types of tests.

Other medicines and Co-Amoxiclav Aurobindo

Tell your doctor if you are taking have recently taken or might take any other medicines.

If you are taking allopurinol (used for gout) with Co-Amoxiclav Aurobindo, it may be more likely that you will have an allergic skin reaction.

If you are taking probenecid (used for gout), your doctor may decide to adjust your dose of Co-Amoxiclav Aurobindo.

If medicines to help stop blood clots (such as warfarin) are taken with Co-Amoxiclav Aurobindo then extra blood tests may be needed.

Co-Amoxiclav Aurobindo can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works.

Co-Amoxiclav Aurobindo can affect how mycophenolate mofetil (a medicine used to prevent the rejection of new organs following a transplant operation) works.

Pregnancy, breast-feeding and fertility

If you are pregnant, or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Co-Amoxiclav Aurobindo can have side effects and the symptoms may make you unfit to drive.

Don't drive or operate machinery unless you are feeling well.

3. How to take Co-Amoxiclav Aurobindo

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Adults and children weighing 40 kg and over

- The recommended dose is:
- 1 tablet three times a day

Children weighing less than 40 kg

Children aged 6 years or less should preferably be treated with amoxicillin/clavulanic acid oral suspension or sachets.

Ask your doctor or pharmacist for advice when giving Co-Amoxiclav Aurobindo tablets to children weighing less than 40 kg. Children may be treated with Amoxicillin/Clavulanic acid tablets, suspensions or paediatric sachets.

Patients with kidney and liver problems

- If you have kidney problems the dose might be changed. A different strength or a different medicine may be chosen by your doctor.
- If you have liver problems you may have more frequent blood tests to check how your liver is working.

How to take Co-Amoxiclav Aurobindo

- Swallow the tablets whole with a glass of water at the start of a meal or slightly before
- Tablets can be broken along the score line to make them easier to swallow. You must take both pieces of the tablet at the same time
- Space the doses evenly during the day, at least 4 hours apart. Do not take 2 doses in 1 hour.
- Do not take Co-Amoxiclav Aurobindo for more than 2 weeks. If you still feel unwell you should go back to see the doctor.

If you take more Co-Amoxiclav Aurobindo than you should

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

If you forget to take Co-Amoxiclav Aurobindo

If you forget to take a dose, take it as soon as you remember. You should not take the next dose too soon, but wait about 4 hours before taking the next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Co-Amoxiclav Aurobindo

Keep taking Co-Amoxiclav Aurobindo 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.

Conditions you need to look out for

Allergic reactions:

- skin rash
- 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 mouth (angioedema), causing difficulty in breathing
- Collapse.
- allergic acute cardiac syndrome (Kounis syndrome)

→ **Contact a doctor immediately** if you get any of these symptoms. Stop taking **Co-Amoxiclav Aurobindo**.

Inflammation of large intestine

Inflammation of the large intestine, causing watery diarrhoea usually with blood and mucus, stomach pain and/or fever.

→ **Contact your doctor as soon as possible** for advice if you get these symptoms.

Very common side effects

These may affect more than 1 in 10 people

- diarrhoea (in adults).

Common side effects

These may affect up to 1 in 10 people

- thrush (candida – a yeast infection of the vagina, mouth or skin folds)
- feeling sick (nausea), especially when taking high doses
- if affected take Co-Amoxiclav Aurobindo before food
- vomiting
- diarrhoea (in children)

Uncommon side effects

These may affect up to 1 in 100 people

- skin rash, itching
- raised itchy rash (hives)
- indigestion
- dizziness
- headache

Uncommon side effects that may show up in your blood tests:

- increase in some substances (*enzymes*) produced by the liver.

Rare side effects

These may affect up to 1 in 1000 people

- 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*)

→ if you notice any of these symptoms contact a doctor urgently.

Rare side effects that may show up in your blood tests:

- low number of cells involved in blood clotting
- low number of white blood cells.

Not known side effects

Frequency cannot be estimated from the available data

- Allergic reactions (see above)
- Inflammation of the large intestine (see above)
- Inflammation of the layers lining the brain and spinal cord called meninges (*aseptic meningitis*)
- Inflammation of the bile tube (*cholangitis*)
- allergic acute cardiac syndrome (*kounis syndrome*)
- Serious skin reactions:
 - a widespread 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 (*bulbous exfoliative dermatitis*)
 - a red, scaly rash with bumps under the skin and blisters (*exanthematous pustulosis*).

→ **Contact a doctor immediately if you get any of these symptoms.**

- inflammation of the liver (hepatitis)
- jaundice, caused by increases in the blood of bilirubin (a substance produced in the liver) which may make your skin and whites of the eyes appear yellow
- inflammation of tubes in the kidney
- blood takes longer to clot
- hyperactivity
- convulsions (in people taking high doses of amoxicillin/clavulanic acid or who have kidney problems)
- black tongue which looks hairy
- stained teeth (in children), usually removed by brushing.

Not known side effects that may show up in your blood or urine tests:

- severe reduction in the number of white blood cells
- lower number of red blood cells (haemolytic anaemia)
- crystals in urine.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2.

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Co-Amoxiclav Aurobindo

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

Do not use this medicine after the expiry date which is stated on the label, carton and bottle after 'EXP'. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light and moisture.

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. Contents of the pack and other information

What Co-Amoxiclav Aurobindo contains

- The active substances are amoxicillin trihydrate and potassium clavulanate.

Each film-coated tablet contains amoxicillin trihydrate equivalent to 500mg amoxicillin with potassium clavulanate equivalent to 125mg clavulanic acid.

- The other ingredients are:

Core:

Microcrystalline cellulose (E460), colloidal anhydrous silica, magnesium stearate (E470b), sodium starch glycolate (Type A).

Film coating:

Hypromellose (E464), macrogol 400, titanium dioxide (E171).

What Co-Amoxiclav Aurobindo looks like and contents of the pack

Film-coated tablets.

Co-Amoxiclav Aurobindo 500/125 mg tablets are white, oval, film-coated tablets inscribed with 'A' on one side and '64' on the other side.

Co-Amoxiclav Aurobindo tablets are available in Alu/Alu (polyamide/aluminium/PVC - aluminium foil) blister packs with 4/5/6/7/8/10/12/14/15/16/20/21/24/25/30/35/40/50/100/500 film-coated tablets. Not all listed pack sizes will be marketed.

Marketing Authorisation Holder

Aurobindo Pharma Limited
Ares, Odyssey Business Park
West End Road
South Ruislip HA4 6QD
United Kingdom

Manufacturer

Milpharm Limited
Ares, Odyssey Business Park
West End Road
South Ruislip HA4 6QD
United Kingdom

or

APL Swift Services (Malta) Limited
HF 26, Hal Far Industrial Estate, Hal Far
Birzebbugia, BBG 3000
Malta

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Co-Amoxiclav Aurobindo 500 mg/125 mg Filmtabletten
Belgium	AmoxiclavApotex [®] 500 mg/125 mg comprimés pelliculés
Bulgaria	ALVOCLAV 500 mg/125 mg филмирани таблетки
Czech Republic	Amoxicillin/Clavulanic acid Dr.Max 500 mg/125 mg potahované tablety
Denmark	Amoxicillin/Clavulansyre Aurobindo
Estonia	Amoxicillin/Clavulanic acid Aurobindo
Finland	Amoxicillin/Clavulanic acid Aurobindo 500 mg/125 mg tabletti, kalvopäällysteinen
Germany	Amoxi-Clavulan Aurobindo 500 mg/125 mg Filmtabletten
Greece	ACCORDIA (500+125) mg επικαλυμμένο με λεπτό υμένιο δισκία
Hungary	Amoxicillin/Klavulánsav Aurobindo 500 mg/125 mg filmtabletta
Ireland	Co-Amoxiclav Aurobindo 500 mg/125 mg film-coated tablets
Latvia	Amoxicillin/Clavulanic acid Aurobindo 500 mg/125 mg apvalkotās tableti
Netherlands	Amoxicilline/Clavulaanzuur Aurobindo 500 mg/125 mg, filmomhulde tabletten
Poland	Auglavin
Portugal	Amoxicilina + Ácido Clavulánico Aurobindo
Romania	Amoxicilină / Acid clavulanic Aurobindo 500mg/125mg, comprimate filmate
Spain	AMOXICILINA/ACIDO CLAVULANICO AUROBINDO 500/125 mg comprimidos recubiertos con película
Sweden	Amoxicillin/Clavulanic acid Aurobindo 500 mg/125 mg filmdragerade tabletter
United Kingdom	Co-amoxiclav 500 mg/125 mg film-coated tablets

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