

1.3.1 SPC, Labelling and Package Leaflet

PACKAGE LEAFLET

Package Leaflet: Information for the user

Co-amoxiclav Bluefish 500 mg /125 mg film-coated tablets
(Amoxicillin and 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 Bluefish is and what it is used for
2. What you need to know before you take Co-amoxiclav Bluefish
3. How to take Co-amoxiclav Bluefish
4. Possible side effects
5. How to store Co-amoxiclav Bluefish
6. Contents of the pack and other information

1. What Co-amoxiclav Bluefish is and what it is used for

Co-amoxiclav Bluefish 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 Bluefish 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 Bluefish

Do not take Co-amoxiclav Bluefish :

- if you are allergic (hypersensitive) to amoxicillin, clavulanic acid 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

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- if you have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.

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

Warnings and precautions :

Talk to your doctor or pharmacist before taking Co-amoxiclav Bluefish:

- if you are being treated for kidney or liver problems
- if you have glandular fever
- if you 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 Bluefish

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 Bluefish or a different medicine.

Conditions you need to look out for

Co-amoxiclav Bluefish 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 Bluefish, 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 Bluefish. This is because Co-amoxiclav Bluefish can affect the results of these types of tests.

Other medicines and Co-amoxiclav Bluefish

Please tell your doctor or pharmacist if you are taking, or have recently taken or might take, any other medicines.

If you are taking allopurinol (used for gout) with Co-amoxiclav Bluefish, it may be more likely that you'll have an allergic skin reaction.

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

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

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

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Co-amoxiclav Bluefish can affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) work.

Co-amoxiclav Bluefish with food and drink and alcohol

Co-amoxiclav Bluefish should be taken just before meals and swallowed whole with water. Do not chew them.

Pregnancy and 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 Bluefish Tablets can have side effects and the symptoms may make you unfit to drive.

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

Co-amoxiclav Bluefish contains potassium :

Each Co-amoxiclav Bluefish 500 mg/125 mg Film- coated Tablets contains 25 mg (i.e. 0.64 mmol) of potassium.

Co-amoxiclav Bluefish contains sodium:

This medicine contains less than 1 mmol sodium (23 mg) per 500 mg/125mg of amoxicillin and potassium clavulanate tablet, that is to say essentially 'sodium-free'.

3. How to take Co-amoxiclav Bluefish

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

Adults and children weighing 40 kg and over

The usual dose is:

- 1 tablet three times a day

Use in children and adolescents

Ask your doctor or pharmacist for advice when giving Co-amoxiclav Bluefish tablets to children weighing less than 40 kg.

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 see how your liver is working.

How to take Co-amoxiclav Bluefish

- Swallow the tablets whole with a glass of water at the start of a meal or slightly before
- 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 Bluefish for more than 2 weeks. If you still feel unwell you should go back to see the doctor.

If you take more Co-amoxiclav Bluefish than you should

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

If you forget to take Co-amoxiclav Bluefish

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 Bluefish:

Keep taking Co-amoxiclav Bluefish 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 :

- 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
- joint pain and fever, swollen glands in the neck, armpit or groin
- swelling, sometimes of the face or mouth (*angioedema*), causing difficulty in breathing
- chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome)

Contact a doctor immediately if you get any of these symptoms. **Stop taking Co-amoxiclav Bluefish.**

Inflammation of large intestine

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

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Drug-induced enterocolitis syndrome (DIES):

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DIES has been reported mainly in children receiving amoxicillin/clavulanate. It is a certain kind of allergic reaction with the leading symptom of repetitive vomiting (1-4 hours after drug intake). Further symptoms could comprise abdominal pain, lethargy, diarrhoea and low blood pressure.

Acute inflammation of the pancreas (acute pancreatitis)

If you have severe and on-going pain in the stomach area this could be a sign of acute pancreatitis.

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

Very common (may affect more than 1 in 10 people)

- diarrhoea (in adults).

Common (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 Bluefish before food

- vomiting
- diarrhoea (in children)

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

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

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

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

Rare side effects (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 (frequency cannot be estimated from the available data)

- Allergic reactions (see above)
- Inflammation of the large intestine (see above)
- 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 epiderm necrolysis)
- widespread red skin rash with small pus-containing blisters (bullous exfoliative)

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dermatitis)

- a red, scaly rash with bumps under the skin and blisters (bullous *exanthemous pustulosis*)
- flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS))
- a red rash commonly seen on both sides of buttocks, upper inner thighs, armpits, neck (*Symmetrical Drug-Related Intertriginous and Flexural Exanthema (SDRIFE)*).

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

- Rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease).
- 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 Co-amoxiclav Bluefish or who have kidney problems)
- black tongue which looks hairy
- stained teeth (in children), usually removed by brushing

Side effects that may show up in your blood or urine tests :

- severe reduction in the number of white blood cells
- low number of red blood cells (haemolytic anaemia)
- crystals in urine leading to acute kidney injury.
- Rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease).
- Inflammation of the membranes that surround the brain and spinal cord (aseptic meningitis).

Reporting of side effects

If you get any side effects talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: + 35316764971; Fax : + 35316762517. 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 Bluefish

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

Do not store above 25°C.

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Do not use this medicine after the expiry date which is stated on the label, carton or bottle. 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. Contents of the pack and other information

What Co-amoxiclav Bluefish tablets contains

The active substances are amoxicillin and clavulanic acid.

Each tablet contains 500mg amoxicillin as amoxicillin trihydrate and 125mg clavulanic acid as potassium clavulanate.

The other ingredients are microcrystalline cellulose (E460) (AVICEL Ph 102), croscarmellose sodium, purified talc, magnesium stearate, hypromellose(E-15), titanium dioxide, Hydroxypropyl cellulose, ethyl cellulose and propylene glycol.

What Co-amoxiclav Bluefish looks like and contents of the pack

Co-amoxiclav Bluefish 500 mg/125 mg Tablets are white to off-white, film-coated, oval- shaped tablets which are supplied in PVC/Al blisters and are sealed in aluminium pouches and blister packs of 7,10,12, 14, 20, 21,24 and 30 tablets. Not all pack sizes may be marketed

Marketing Authorisation Holder

Bluefish Pharmaceuticals AB
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100 28 Stockholm,
Sweden.

Manufacturer

Bluefish Pharmaceuticals AB
Gävlegatan 22
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Sweden

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

Ireland	: _Co-amoxiclav Bluefish 500 mg /125 mg film-coated tablets
Poland	: Co-amoxiclav Bluefish 500 mg+125 mg tabletki powlekane

This leaflet was last revised in