

# FUGENTIN FILM COATED TABLETS

Amoxicillin Trihydrate/ Potassium Clavulanate (500mg/ 125mg)

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## What Fugentin is used for

Fugentin is used for short term treatment of bacterial infections which do not respond to certain antibiotics suspected at the following conditions:

- Upper respiratory tract infections
- Lower respiratory tract infections
- Genito-urinary tract and abdominal infections
- Skin and soft tissue infections
- Bone and joint infections
- Dental infections
- Mixed infections.

## How Fugentin works

Fugentin is an antibiotic and works by killing bacteria that cause infections. It contains two medicines known as amoxicillin and clavulanic acid. Amoxicillin belongs to a group of medicines known as “penicillins” that can sometimes be inactivated. The other active ingredient (clavulanic acid) stops this from happening.

## Before you use Fugentin

### - When you must not use it

Do not take Fugentin:

- if you are allergic (hypersensitive) to amoxicillin, clavulanic acid, penicillin or any of the other ingredients of Fugentin.
- if you have ever had a severe allergic (hypersensitive) reaction to any other antibiotic such as cephalosporins. 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 penicillin (antibiotic).

Do not take Fugentin if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Fugentin.

### - Before you start to use it

Talk to your doctor or pharmacist before taking this medicine if you:

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

If you are not sure any of the above applies to you, talk to your doctor or pharmacist before taking Fugentin.

Sometimes, 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 amoxicillin + clavulanic acid tablet or a different medicine.

Fugentin should be avoided in pregnancy, especially during the first trimester, unless considered essential by the physician.

Fugentin may be taken during the period of lactation.

Ask your doctor or pharmacist for advice before taking any medicine.

### - Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

- if you are taking allopurinol (used for gout) with Fugentin, it may be more likely that you will have an allergic skin reaction.
- if you are taking oral contraceptives. Oral contraceptive pills may not work as well in preventing pregnancy when Fugentin is used. Talk to your doctor about the need for an additional method of contraception while taking Fugentin.
- if you are taking anticoagulants (used to prevent blood clot) with Fugentin, extra blood tests may be needed.

## How to use Fugentin

### - How much to use

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

Adults and children over 12 years old:

The usual dose is: 1 tablet two times a day.

For severe infections, it may be taken 1 tablet three times a day.

For dental infections, take 1 tablet two times a day for 5 days.

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 need more frequent blood tests to monitor your liver function.

### - When to use it

Swallow the tablet whole with a glass of water at the start of a meal. This makes it less likely to cause stomach upset or discomfort.

Space the doses evenly during the day.

### - How long to use it

Do not take Fugentin for more than 2 weeks. If you still feel unwell you should go back to see the doctor.

### - If you forget to use it

- If you forget to take a dose, take it 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.

### - If you use too much (overdose)

If you have too much Fugentin, 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 to show the doctor.

In some cases, Amoxicillin can cause crystals to be found in the urine leading to kidney failure.

**While you are using it**

- Things you must do

You must look out for certain symptoms while you are taking Fugentin, to reduce the risk of any problems.

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

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

**Inflammation of large intestine**

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

Drink plenty of water, juice or other fluids.

- 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 or pharmacist.

Do not give Fugentin to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy, or give you a headache, do not drive or use machines and contact your doctor immediately.

**Side effects**

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

The side effects are:

- diarrhoea
- thrush (candida - a yeast infection of the vagina, mouth or skin folds)
- feeling sick (nausea), especially when taking high doses
- vomiting
- skin rash, itching
- indigestion
- dizziness
- headache
- increase in liver enzymes
- changes in blood test and urine test.

If any of the side effects gets severe or troublesome, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Serious skin reactions may rarely occur:

- 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 (bullous exfoliative dermatitis);
- a red, scaly rash with bumps under the skin and blisters (exanthemous pustulosis).

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](http://portal.bpfk.gov.my) (Consumers → Reporting).

**Storage and disposal of Fugentin**

- Storage  
Keep out of reach of children.  
Store below 25°C, in a dry place.  
Do not use after the expiry date which is stated on the pack.

Keep the blister in the outer carton in order to protect from light and moisture.

- Disposal

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

Fugentin tablet is a white, oblong, biconvex, scored on one side film-coated tablets.

Fugentin tablets are packed into 3 blisters of aluminium foil and a product insert in a box. Each box contains 12 tablets.

- Ingredients

- Active ingredients:

The active ingredients are 500mg amoxicillin and 125mg clavulanic acid. The amoxicillin is present as amoxicillin trihydrate and the clavulanic acid is present as potassium clavulanate.

- Inactive ingredients

The other non active ingredients of Fugentin tablets are:  
Core tablet: Sodium starch glycolate, microcrystalline cellulose, colloidal anhydrous silica, magnesium stearate.  
Coating materials: Talc, hypromellose, diethyl phthalate, titanium dioxide (E171) and dimeticone.

- MAL number:

MAL09042393A

**Manufacturer**

Elpen Pharmaceutical Co. Ltd.,  
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**Product registration holder**

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