

PACKAGE LEAFLET: INFORMATION FOR THE USER

Fromilid

250mg Film-coated Tablets; 500mg Film-coated Tablets

CLARITHROMYCIN

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What Fromilid Tablets are and what they are used for
2. What you need to know before you take Fromilid Tablets
3. How to take Fromilid Tablets
4. Possible side effects
5. How to store Fromilid Tablets

1. WHAT FROMILID TABLETS ARE AND WHAT THEY ARE USED FOR

Clarithromycin belongs to a group of medicine called macrolide antibiotics. Antibiotics stop the growth of bacteria (bugs) which cause infections.

Fromilid Tablets are used to treat following infections:

- Chest infections such as bronchitis and pneumonia,
- Throat and sinus infections,
- Skin and soft tissue infections,
- Helicobacter pylori infections associated with duodenal ulcers.

Fromilid Tablets are indicated in adults and children 12 years and older.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FROMILID TABLETS

Do not take Fromilid Tablets if you:

- are allergic to clarithromycin or other macrolide antibiotics such as erythromycin or azithromycin, or any of the other ingredients of Fromilid Tablets.
- are taking medicines called ergotamine or dihydroergotamine tablets or use ergotamine inhalers for migraine.

- are taking medicines called terfenadine or astemizole (widely taken for hay fever or allergies) or cisapride (for stomach disorders) or pimozide (for mental health problems) as combining these drugs can sometimes cause serious disturbances in heart rhythm.
- are taking lovastatin or simvastatin (HMG-CoA reductase inhibitors, commonly known as statins, used to lower levels of cholesterol (a type of fat) in the blood).
- have low levels of potassium in the blood (a condition known as hypokalaemia)
- have an irregular heart rhythm
- have severe liver disease with kidney disease.

Fromilid Tablets are not suitable for use in children under 12 years of age.

Warnings and precautions:

- you are pregnant or breast-feeding
- you have, or are prone to, fungal infections (e.g. thrush)
- you are suffering from liver or kidney problems

If any of these apply to you, consult your doctor before taking Fromilid Tablets.

Other medicines and Fromilid Tablets:

You should not take Fromilid Tablets if you are taking any of the medicines listed in the section above “Do not take Fromilid Tablets if you;”

Tell your doctor if you are taking any of the following medicines as your dose may need to be changed or you may need to have regular tests performed.

Care is needed if you are taking

- Digoxin, disopyramide or quinidine (used to treat heart conditions)
- carbamazepine, valproate, phenobarbital or phenytoin (for epilepsy)
- atorvastatin, rosuvastatin (HMG-CoA reductase inhibitors, commonly known as statins, and used to lower levels of cholesterol (a type of fat) in the blood). Statins can cause rhabdomyolysis (a condition which cause the breakdown of muscle tissue which can result in kidney damage) and signs of myopathy (muscle pain or muscle weakness) should be monitored.
- theophylline (used in patients with breathing difficulties such as asthma)
- triazolam, alprazolam or midazolam (sedatives)
- Cilostazol (used to treat poor circulation)
- Methylprednisolone (a corticosteroid)
- Oral anticoagulants (e.g. warfarin, used to thin the blood)
- Nateglinide, pioglitazone, repaglinide, rosiglitazone or insulin (used to lower blood glucose levels)
- Sildenafil, vardenafil and tadalafil (used to treat impotence in adult males or to or for use in pulmonary arterial hypertension (high blood pressure in the blood vessels of the lungs)
- Vinblastine (used to treat cancer)
- Omeprazole (for treatment of indigestion and gastric ulcers) unless your doctor has prescribed it for you to treat Helicobacter pylori infection associated with duodenal ulcer
- Ciclosporin, sirolimus or tacrolimus (immune suppressants)
- etravirine, efavirenz, nevirapine, ritonavir, zidovudine, atazanavir, saquinavir (anti-viral drugs used in the treatment of HIV)
- Rifampicin, rifapentine, fluconazole, itraconazole or rifabutin (used for treatment of certain bacterial infections)
- Tolterodine (for overactive bladder)
- Verapamil, amlodipine, diltiazem (for high blood pressure)
- St John’s Wort (a herbal product used to treat depression)
- Colchicine (usually taken for gout).
- Aminoglycosides (a group of antibiotic to treat certain bacteria for example gentamicin, neomycin)

Clarithromycin does not interact with oral contraceptives.

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without a prescription.

Taking Fromilid Tablets with food and drink

Fromilid Tablets may be taken with or without food.

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, as the safety of Fromilid Tablets in pregnancy and breast-feeding is not known.

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

Driving and using machines

Fromilid Tablets may make you feel dizzy or drowsy. If they affect you in this way do not drive, operate machinery or do anything that requires you to be alert.

3. HOW TO TAKE FROMILID TABLETS

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

Do not give these tablets to children under 12 years. Your doctor will prescribe another suitable medicine for your child.

The dose of Clarithromycin varies with the condition being treated. The dose you should take will be on the pharmacist's label. Always take the tablets exactly as your doctor has told you to. You should check with your doctor or pharmacist if you are not sure.

Fromilid Tablets should be swallowed with at least half a glass of water.

- For treating chest infections, throat or sinus infections and skin and soft tissue infections:
Usual dose of Fromilid Tablets for adults and children over 12 years is 250mg twice daily for 6 to 14 days, e.g. one 250mg tablet in the morning and one in the early evening. Your doctor may increase the dose to 500mg twice daily in severe infections.
- For treating Helicobacter pylori infections associated with duodenal ulcers:
There are a number of effective treatment combinations available to treat Helicobacter pylori in which Fromilid Tablets are taken together with one or two other drugs. These combinations include the following and are usually taken for 6 to 14 days:
 - a) One clarithromycin 500 mg tablet taken twice a day together with amoxicillin, 1000 mg taken twice a day plus lansoprazole, 30 mg twice a day.
 - b) One clarithromycin 500 mg tablet taken twice a day together with metronidazole, 400 mg taken twice a day plus lansoprazole, 30 mg twice a day.
 - c) One clarithromycin 500 mg tablet taken twice a day together with amoxicillin, 1000 mg taken twice a day or metronidazole, 400 mg taken twice a day plus omeprazole, 40 mg a day.
 - d) One clarithromycin 500 mg tablet taken twice a day together with amoxicillin, 1000 mg taken twice a day plus omeprazole, 20 mg taken once a day.
 - e) One clarithromycin 500 mg tablet taken three times a day together with omeprazole 40 mg taken once a day.

The treatment combination that you receive may differ slightly from the above. Your doctor will decide which treatment combination is the most suitable for you. If you are unsure which tablets you should be taking or how long you should be taking them for, please consult your doctor for advice.

If you have any kidney problems your dose may be different from that given here, Do not change unless your doctor tells you to do so.

If you take more Fromilid Tablets than you should

If you or someone else swallows several of these tablets all together, or you think a child has swallowed any of these tablets, contact your doctor or pharmacist or hospital emergency department immediately. An overdose of Fromilid Tablets is likely to cause vomiting and stomach pains.

If you forget to take Fromilid Tablets

If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, do not take the missed dose and just carry on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Fromilid Tablets :

You must take your medicine for as long as your doctor has told you to. This will usually be for 6 to 14 days depending on the type and severity of infection. It is important not to stop taking the medicine just because you feel better as the infection could return.

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

4. POSSIBLE SIDE EFFECTS

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

If any of the following happen, stop taking Fromilid Tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:

- severe or prolonged diarrhoea, which may have blood or mucus in it. Diarrhoea may occur over two months after treatment with clarithromycin, in which case you should still contact your doctor.
- a rash, difficulty breathing, fainting or swelling of the face and throat. This is a sign that you may have developed an allergic reaction.
- severe skin reactions such as blistering of the skin, mouth, lips, eyes and genitals (symptoms of a rare allergic reaction called Stevens-Johnson syndrome/toxic epidermal necrolysis).
- yellowing of the skin (jaundice), skin irritation, pale stools, dark urine, tender abdomen or loss of appetite. These may be signs that your liver may not be working properly.
- Henoch-Schonlein purpura (a rash which appears as purple spots on the skin).
- Drug reaction with eosinophilia and systemic symptoms (DRESS). This can include symptoms such as rash, fever abnormal blood count and inflammation of internal organs.

Common side effects (may affect up to 1 in 10 people)

- headache
- difficulty sleeping
- changes in sense of taste
- stomach problems such as feeling sick, vomiting, stomach pain, indigestion, diarrhoea
- a change in the way the liver works
- skin rash
- increased sweating

Uncommon side effects (may affect up to 1 in 100 people)

- swelling, redness or itchiness of the skin. Sometimes brown scales may appear
- oral or vaginal 'thrush' (a fungal infection)

- reduction in the level of certain blood cells (which can make infections more likely or increase the risk of bruising or bleeding)
- loss of appetite, heartburn, bloating, constipation, wind
- anxiety, nervousness, drowsiness, tiredness, dizziness, tremor or shaking
- ringing in the ears, problems with hearing
- vertigo
- inflammation of the mouth or tongue
- dry mouth
- joint pain
- muscle pain or loss of muscle tissue. If you suffer from myasthenia gravis (a condition in which the muscles become weak and tire easily) clarithromycin may worsen these symptoms
- chest pain or changes in heart rhythm such as palpitations
- a change in the levels of products produced by the kidney,
- a change in the levels of certain cells or products found in the blood.

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

- acne
- Henoch-Schonlein purpura (a rash which appears as purple spots on the skin)
- inflammation of the pancreas
- confusion, loss of bearings, hallucinations (seeing things), change in sense of reality or panicking, depression, abnormal dreams or nightmares
- convulsion (fits)
- paraesthesia, more commonly known as ‘pins and needles’
- loss of taste or smell or inability to smell properly
- a change in the levels of products made by the liver, inflammation of the liver or an inability of the liver to function properly (you may notice yellowing of the skin, dark urine, pale stools or itchiness of the skin)
- inflammation of the kidney or an inability of the kidney to function properly (you may notice tiredness, swelling or puffiness in the face, abdomen, thighs or ankles or problems with urination).
- low blood sugar levels
- deafness
- discolouration of the tongue and/or teeth

Consult your doctor immediately if you develop any of these problems or have any other unexpected or unusual symptoms.

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

5. HOW TO STORE FROMILID TABLETS

Keep out of the reach and sight of children.

Do not store above 25°C. Keep in a dry place in the original package.

Do not use Fromilid Tablets after the expiry date stated on the carton or label.

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

This leaflet was last revised in 11/2014.