

NEW ZEALAND CONSUMER MEDICINE INFORMATION

E-MYCIN

Erythromycin ethylsuccinate

Tablets, Film Coated 400 mg

Granules for Oral Suspension 200 mg per 5 mL and 400 mg per 5 mL



What is in this leaflet

Please read this leaflet carefully before you start taking E-Mycin. This leaflet answers some common questions about E-Mycin.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking E-Mycin against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What E-Mycin is used for

E-Mycin is used to:

- treat certain infections caused by bacteria
- prevent infections in patients with a history of rheumatic disease, who are allergic to penicillin antibiotics.

E-Mycin is an antibiotic that belongs to a group of medicines called macrolides. These medicines work by killing or stopping the growth of the bacteria which are causing the infection.

E-Mycin will not work against infections caused by viruses, such as colds or flu.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

There is no evidence that E-Mycin is addictive.

E-Mycin is available only with a doctor's prescription.

Before you take E-Mycin

When you must not take it:

Do not take E-Mycin if you have an allergy to:

- medicines containing erythromycin or any other antibiotic from the macrolide group
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take E-Mycin if you are taking:

- cisapride (a medicine that helps move food through the digestive system)
- pimozide (a medicine to treat certain mental and emotional conditions)
- ergotamine or ergotamine derivatives (medicines used for migraine).
- terfenadine or astemizole
- simvastatin, lovastatin or atorvastatin

Medicines which can cause heart muscle to take longer than normal to recharge between beats (prolongation of the QT interval) such as:

- some medicines used to manage psychosis mainly in schizophrenia and bipolar disorder
- some tri- and tetracyclic antidepressants
- some fluoroquinolones (a type of antibiotic)
- imidazole antifungal medicines
- some medicines used to prevent or treat malaria
- arsenic trioxide, methadone and budipine

Taking E-Mycin with any of the medicines above may cause serious side effects.

Do not take E-Mycin if you have:

- severe liver disease
- heart rhythm disorders from birth or have developed it
- irregular heartbeat or severe chronic heart failure
- deficiency of potassium and magnesium in blood

Do not take E-Mycin if the packaging shows signs of tampering.

Do not take E-Mycin if the expiry date printed on the label has passed.

If you take this medicine after the expiry date, it may not work as well.

Do not take any E-Mycin mixture left in the bottle after 10 days.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it:

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- liver problems
- heart problems
- salt imbalances
- myasthenia gravis, a condition where muscles become weak and tire easily
- eye disorder
- pneumonia

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking E-Mycin.

Taking other medicines

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

Some medicines and E-Mycin may interfere with each other. These include:

- theophylline (a medicine used to treat asthma)
- medicines used to treat heart failure and fast irregular heartbeats e.g. digoxin, disopyramide, quinidine, amiodarone
- medicines used to thin your blood such as warfarin
- medicines used to treat sleep problems or as a sedative (e.g. zopiclone, triazolam, alfantanil, hexobarbital)
- some medication used for epilepsy such as carbamazepine, phenytoin or sodium valproate

- cyclosporin, tacrolimus, (medicines used to prevent organ transplant rejection or to treat certain problems with the immune system)
- bromocriptine (a medicine used to treat Parkinson's Disease)
- risperidone and haloperidol (medicines used to treat some mental disorders such as schizophrenia and anxiety)
- citalopram (a medicine used to treat depression)
- methylprednisolone (a medicine used to suppress inflammation)
- ciprofloxacin (a medicine used to treat bacterial infections)
- cilostazol (a medicine used to help with blood circulation)
- vinblastine (a medicine used in the treatment of Hodgkin's Disease)
- sildenafil (Viagra) (a medicine used to treat erection problems in men)
- HMG-CoA Reductase Inhibitors (medicines used to lower high cholesterol and triglyceride levels in the body such as lovastatin and simvastatin (e.g. Lipex, Zocor))
- colchicine (a medicine used to treat gout)
- rifabutin (a medicine used in the treatment of tuberculosis).

These medicines may be affected by E-Mycin or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking E-Mycin.

How to take E-Mycin

Follow all directions given to you by your doctor or pharmacist

carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how much E-Mycin you need to take each day. It is important that you take E-Mycin as directed by your doctor.

Do not take more than the recommended dose.

The usual adult dose is one E-Mycin tablet (400 mg) every six hours. This will vary from person to person.

Your doctor may advise you to take a different dose. This depends on the infection being treated and how severe it is.

For children, their doctor will work out the dose according to their age, body weight and how severe the infection is.

How to take it

Tablets: Swallow whole with a glass of water.

Mixture: Always shake the bottle well before taking E-Mycin. Use a metric measure to ensure that you measure the correct dose.

When to take it

Space the doses of E-Mycin evenly apart and take them at about the same time(s) each day. This will allow E-Mycin to have its best effect and also help you remember when to take it.

E-Mycin can be taken with or without food. However, taking E-Mycin with food may help reduce the chance of a stomach upset occurring.

How long to take it

Keep taking E-Mycin until you finish the tablets or mixture, or for as long as your doctor recommends.

Do not stop taking E-Mycin, even if you feel better after a few days, unless advised by your doctor.

If you are being treated for an infection, E-Mycin is usually taken for one to two weeks. Your infection may not clear completely if you stop taking your medicine too soon.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take the missed dose as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose you missed.

This may increase the chance of you getting an unwanted side effect.

If you have any questions or are not sure what to do, ask your doctor or pharmacist.

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much E-Mycin. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Take the bottle of E-Mycin with you if you can.

Keep telephone numbers for these places handy.

While you are using E-Mycin

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking E-Mycin.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

Tell your doctor if you develop a skin rash or hives while taking E-Mycin.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take E-Mycin to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how E-Mycin affects you.

This medicine may cause dizziness in some people. If you have this symptom, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking E-Mycin. E-Mycin is effective in treating most

infections it is prescribed for, however it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- stomach cramps and pains
- feeling sick, vomiting, accumulation of gas and diarrhoea
- oral thrush (white, furry sore tongue and mouth)
- vaginal thrush (sore and itchy vagina, vaginal discharge).
- weight loss
- fever, headache

The above list includes the more common side effects of E-Mycin. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- yellowing of the eyes or skin (jaundice), feeling generally unwell and having poor appetite
- hearing loss / deafness
- ringing or buzzing in the ears
- dizziness, drowsiness
- confusion, hallucinations
- fits
- in infants, irritability with feeding or severe vomiting
- muscle pain, weakness and joint swelling
- any vision problem

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, stop taking E-Mycin and tell your doctor immediately or go to Accident and Emergency at the nearest hospital:

- signs of an allergic reaction such as any type of skin rash, itching, or hives
- swelling of the face, lips, tongue or other parts of the body
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
- shortness of breath, wheezing, troubled breathing
- fast, irregular or pounding heart beat
- chest pain
- watery and severe diarrhoea, which may also be bloody.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some of these side effects (for example, changes in liver function tests) can only be found when your doctor does tests from time to time to check your progress.

After you have finished taking E-Mycin

Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after stopping treatment with E-Mycin:

- severe abdominal cramps or stomach cramps
- watery and severe diarrhoea, which may also be bloody
- fever, in combination with one or both of the above.

You may have a serious condition affecting your bowel. These are rare but serious side effects. Therefore, you may need urgent medical attention.

Do not take any medicine for diarrhoea without first checking with your doctor.

After using E-Mycin

Storage

Keep your tablets/mixture in the bottle until it is time to take them. If you take the tablets/mixture out of the bottle they may not keep well.

Keep E-Mycin tablets in a cool dry place where the temperature stays below 30°C.

Keep E-Mycin mixture in the refrigerator but not in the freezer. Do not use any mixture left in the bottle after 10 days.

Do not store E-Mycin or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep E-Mycin where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

E-Mycin is available as tablets or mixtures.

E-Mycin tablets are flesh pink in colour, oval-shaped, film-coated and marked E-N on one side and "α" on the other.

E-Mycin mixtures come in 2 strengths - E-Mycin 200 and E-Mycin 400. Both mixtures are pink, cherry flavoured and sugar-free.

Ingredients

The active ingredient in E-Mycin tablets and mixtures is erythromycin (as erythromycin ethylsuccinate).

E-Mycin tablets

E-Mycin tablets contain 400 mg of erythromycin.

E-Mycin tablets also contain the following inactive ingredients:

- calcium hydrogen phosphate anhydrous
- maize starch
- sorbic acid
- povidone
- purified talc
- sodium starch glycollate
- magnesium stearate.

The film coating also contains:

- polyvinyl alcohol
- titanium dioxide
- lecithin
- iron oxide red
- xanthan gum.

E-Mycin tablets do not contain lactose or gluten.

E-Mycin mixtures

Each 5 mL of E-Mycin 200 mixture contains 200 mg of erythromycin.

Each 5 mL of E-Mycin 400 mixture contains 400 mg of erythromycin.

The mixtures also contain the following inactive ingredients:

- sorbitol
- sodium citrate dihydrate
- aspartame
- propylene glycol alginate
- silicon dioxide, colloidal
- sodium benzoate
- erythrosine CI45430
- cherry flavour (contains preservative 320).

E-Mycin mixtures do not contain lactose or gluten.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: (09) 579 2792

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18 June 2020

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