

E-Mycin

erythromycin (as ethyl succinate)

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about E-Mycin tablets and mixtures.

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

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

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

Keep this leaflet with your medicine.

You may need to read it again.

What E-Mycin is used for

E-Mycin is used to:

- treat certain bacterial infections
- control acne, in addition to other acne treatments
- prevent infections in people with a history of rheumatic disease, congenital heart disease or other acquired valvular heart disease and 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 bacteria, which cause infections or make acne worse.

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 E-Mycin has been prescribed for you.

Your doctor may have prescribed E-Mycin for another reason.

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

There is no evidence that E-Mycin is addictive.

Before you take E-Mycin

When you must not take it

Do not take E-Mycin if you are allergic to:

- medicines containing erythromycin (e.g. EES) or any other antibiotic from the macrolide group (e.g. clarithromycin, roxithromycin)
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- **Skin rash, itching or hives;**
- **Swelling of the face, lips, tongue or other parts of the body;**
- **Shortness of breath, wheezing or troubled breathing.**

Do not take E-Mycin if you are taking any of the following medicines:

- terfenadine or astemizole
- cisapride, pimozone or domperidone

- class IA and III antiarrhythmics e.g. quinidine, disopyramide, procainamide, amiodarone and sotalol
- certain neuroleptics and tri- and tetracyclic antidepressants
- arsenic trioxide, methadone, budipine, certain fluoroquinolones, imidazole antimycotics and anti-malarials e.g. petamidine i.v.
- simvastatin, lovastatin or atorvastatin
- ergotamine or dihydroergotamine

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

Ask your doctor or pharmacist if you are not sure if you are taking one of the above medicines.

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 or the tablets or mixtures do not look quite right.

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

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

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

If you are not sure whether you should start taking E-Mycin, talk to your doctor.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

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

Your doctor will discuss the risks and benefits of taking E-Mycin during pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed.

Your doctor will discuss the risks and benefits of taking E-Mycin when breastfeeding.

Tell your doctor if you have any medical conditions including:

- liver problems
- heart problems
- myasthenia gravis, a condition in which the muscles become weak and tire easily
- eye disorder
- pneumonia

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

Taking other medicines

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

Some medicines may interfere with EES. These include:

- medicines used to prevent blood clotting, such as warfarin, acenocoumarol
- some medicines used for epilepsy such as phenytoin, carbamazepine, hexobarbital, phenobarbital (phenobarbitone) and valproate
- theophylline, a medicine used to treat asthma
- diltiazem, verapamil, felodipine and mibefradil, medicines used to

treat high blood pressure and certain heart conditions

- digoxin, a medicine used to treat heart failure
- omeprazole and cimetidine, used to prevent ulcers by reducing amount of acid produced in stomach
- ciclosporin, used to prevent organ transplant rejection or to treat certain problems with the immune system
- tacrolimus, used as an adjunct to kidney transplantation
- triazolam, zopiclone and midazolam, used to treat sleeplessness
- nefazodone and St. John's wort, medicines used to treat depression
- alprazolam used to treat anxiety disorders
- methylprednisolone, a corticosteroid
- vinblastine, a medicine used to treat Hodgkin's Disease
- sildenafil, used to treat erectile dysfunction in adult males
- mizolastine and ebastine medicines used to treat allergies such as hay fever
- ritonavir, used to treat infections in patients with advanced HIV infection
- medicines used to treat fungal infections such as ketoconazole, itraconazole, fluconazole
- rifabutin, rifampicin, clindamycin, lincomycin, chloramphenicol, streptomycin, colistin and bactericidal betalactam antibiotics (e.g. penicillin, cephalosporin)
- bromocriptine, used to treat various conditions including Parkinson's Disease
- colchicine, used for pain relief in gout
- alfentanil, a medicine used for pain relief during anaesthesia

- cilostazol, a medicine used in the treatment of painful calves, due to poor blood flow to the muscles
- diphenoxylate with atropine used to treat diarrhoea
- opiates used as analgesics.

Your doctor can tell you what to do if you are taking any of these medicines. You may need different amounts of yours 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 and 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

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

Your doctor will tell you how many tablets you will need to take. 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.

Your doctor will adjust the amount or frequency of your doses according to the infection being treated and the severity of the condition.

How to take it

Tablets: Swallow whole with a glass of water.

Mixture: Always shake the bottle well before using a metric measure to measure the correct dose.

Shaking the bottle and using a medicine measure will make sure that you get the correct dose. You can buy a medicine measure from your pharmacist.

When to take it

Space the doses of E-Mycin evenly apart and take them at about the same time each day.

This will allow E-Mycin to have its best effect and also help you to 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 for

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

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.

For controlling acne, E-Mycin is normally taken for a few months.

Check with your doctor if you are not sure how long you should be taking E-Mycin.

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.

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 Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think 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.

If you take too much E-Mycin, you may have nausea, vomiting or problems with your hearing.

While you are taking E-Mycin

Things you must do

If you are taking E-Mycin for an infection and your symptoms do not improve within a few days, or if they become worse, tell your doctor.

If your baby develops irritability with feeding or has severe vomiting during treatment with E-Mycin, tell your doctor immediately. This may be a sign of a stomach disorder in the infant.

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.

If you are going to have surgery, tell the surgeon or anaesthetist that you are being given this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking E-Mycin, tell your doctor.

If you get severe diarrhoea, tell your doctor or pharmacist immediately. Do this even if it

occurs several weeks after you have stopped taking E-Mycin.

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

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care.

If you have to have any urine tests, tell your doctor you are taking E-Mycin.

E-Mycin may affect the results of some tests.

If you develop itching with swelling or skin rash or difficulty breathing while you are taking E-Mycin, do not take any more and contact your doctor immediately.

If you get a sore, white mouth or tongue while taking or soon after stopping E-Mycin, tell your doctor. Also tell your doctor if you get vaginal itching or discharge.

This may mean you have a fungal infection called thrush. Sometimes, the use of E-Mycin allows fungi to grow and the above symptoms to occur. E-Mycin does not work against fungi.

Things you must not do

Do not use E-Mycin to treat any other conditions unless your doctor tells you to.

Do not give E-Mycin to anyone else, even if they have the same condition as you.

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

If you stop taking E-Mycin too soon, the infection may not clear completely or your symptoms may return.

If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

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 treats infections and controls acne in most people, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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; shortness of breath, wheezing, troubled breathing
- 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.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- yellowing of the eyes or skin (jaundice)
- severe stomach cramps
- feeling generally unwell and having poor appetite
- loss of hearing
- ringing or buzzing in the ears
- fast, irregular or pounding heart beat, palpitations
- chest pain

- muscle pain, weakness and joint swelling
- dizziness, drowsiness, confusion, hallucinations, fits
- any type of skin rash, itching, hives, serious scaly red rash with bumps under skin and blisters
- severe diarrhoea especially if bloody
- any vision problems.
- in infants, irritability with feeding or severe vomiting.

The above list includes serious side effects which may require medical attention.

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

- stomach cramps and pains
- feeling sick, vomiting, accumulation of gas and severe 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 and mild side effects of E-Mycin.

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

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

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 taking E-Mycin

Storage

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.

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 E-Mycin in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

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

Product description

What it looks like

E-Mycin is available as a tablet and mixture.

- Tablets are flesh pink in colour, oval-shaped, film-coated and marked "E-N" on one side and a

Greek alpha symbol on the other.
Each pack contains 25 tablets.

- Mixtures are available as two strengths:
- E-Mycin 200
- E-Mycin 400.

Both mixtures are pink, cherry flavoured and sugar-free. Each bottle contains 100 mL of mixture.

Ingredients

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

E-Mycin tablets

E-Mycin tablets contain 400 mg of erythromycin (as erythromycin ethyl succinate).

The 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
- Opadry Pink OY-B-34901 (contains colours titanium dioxide CI 77891[171]), iron oxide red CI 77491 [172]).

E-Mycin tablets do not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

E-Mycin mixtures

- E-Mycin 200 - each 5 mL contains 200 mg of erythromycin (as erythromycin ethyl succinate).
- E-Mycin 400 - each 5 mL contains 400 mg of erythromycin (as erythromycin ethyl succinate).

The mixtures also contain the following inactive ingredients:

- sorbitol
- propylene glycol alginate
- sodium citrate
- colloidal anhydrous silica
- aspartame (951)
- sodium benzoate (211)
- erythrosine CI45430 (127)
- Trusil Nature Identical Cherry Flavour (contains preservative 320).

E-mycin mixtures contain benzoates, aspartame, phenylalanine and sorbitol.

Products containing sorbitol may have a laxative effect or cause diarrhoea.

Phenylketonurics are warned that this product contains phenylalanine.

E-Mycin mixtures do not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Manufacturer

E-Mycin is made in Australia by:

Alphapharm Pty Ltd
Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.mylan.com.au

Australian Registration Numbers:

Tablet:

E-Mycin - AUST R 71310

Mixtures:

E-Mycin 200 - AUST R 48286

E-Mycin 400 - AUST R 48287

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