E-MYCIN

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking E-MYCIN?

E-MYCIN contains the active ingredient erythromycin. E-MYCIN is used to treat certain bacterial infections, control acne and prevent infections in people with a history of rheumatic, congenital or other acquired valvular heart disease who are allergic to penicillin antibiotics. For more information, see Section 1. Why am I taking E-MYCIN? in the full CMI.

2. What should I know before I take E-MYCIN?

Do not take if you have ever had an allergic reaction to erythromycin or any other antibiotic from the macrolide group (e.g. clarithromycin, roxithromycin), or any of the ingredients listed at the end of the CMI. Do not take if you have severe liver problems, an irregular heartbeat or heart rhythm disorder, or irregular electrolyte levels.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section 2.

What should I know before I take E-MYCIN? In the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with E-MYCIN and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? In the full CMI.

4. How do I take E-MYCIN?

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

More instructions can be found in Section 4. How do I take E-MYCIN? In the full CMI.

5. What should I know while taking E-MYCIN?

Things you should do

 Remind any doctor, dentist or pharmacist

- you visit that you are taking E-MYCIN.
- Tell your doctor if your symptoms do not improve within a few days or if they become worse.
- Tell your doctor if you develop severe diarrhoea, or get a sore, white furry mouth or tongue while taking or soon after stopping E-MYCIN.
- Tell your doctor if you develop vaginal itching or discharge or if you become pregnant while taking E-MYCIN.

Things you should not do

- Do not take 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.
Driving or using machines	 Be careful driving or operating machinery until you know how E- MYCIN affects you.
Looking after your medicine	 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.

For more information, see Section <u>5. What should I know while taking E-MYCIN?</u> in the full CMI.

6. Are there any side effects?

Less serious side effects: feeling sick (nausea), fever, headache, stomach cramps and pains, vomiting and oral or vaginal thrush. Serious side effects: yellowing of the eyes or skin (jaundice), poor appetite, hearing or visual disturbances, irregular heartbeat, muscle pain, dizziness, hallucinations, drowsiness and, in infants, irritability with feeding or severe vomiting. Very serious side effects: signs of an allergic reaction including skin rash, itching or hives; swelling of the face, lips, tongue or other parts of the body; shortness of breath, wheezing and troubled breathing, and watery, bloody or severe diarrhoea.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> <u>effects?</u> in the full CMI.

E-MYCIN

Active ingredient: erythromycin (as ethyl succinate)

Consumer Medicine Information (CMI)

This leaflet provides important information about taking E-MYCIN. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking E-MYCIN.

Where to find information in this leaflet:

- 1. Why am I taking E-MYCIN?
- 2. What should I know before I take E-MYCIN?
- 3. What if I am taking other medicines?
- 4. How do I take E-MYCIN?
- 5. What should I know while taking E-MYCIN?
- 6. Are there any side effects?
- 7. Product details

1. Why am I taking E-MYCIN?

E-MYCIN contains the active ingredient erythromycin. 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.

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.

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.

There is no evidence that E-MYCIN is addictive.

2. What should I know before I take E-MYCIN?

Warnings

Do not take E-MYCIN if:

- you are allergic to medicines containing erythromycin or any other antibiotic from the macrolide group (e.g. clarithromycin, roxithromycin), or 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.

Always check the ingredients to make sure you can take this medicine.

- you are taking any of the following medicines:
 - terfenadine or astemizole
 - o cisapride, pimozide 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 anti-mycotics and antimalarials e.g., petamidine I.V.
 - o 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.

- you have:
 - severe liver disease
 - heart rhythm disorders
 - o irregular heartbeat or severe chronic heart failure

- unbalanced electrolyte levels in the blood, particularly a deficiency of potassium and magnesium.
- the packaging shows signs of tampering or the tablets or mixtures do not look quite right.
- 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.
- it has been longer than 10 days since the date of preparation of the E-MYCIN mixture.

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

Check with your doctor if you:

- are allergic to any other medicines, foods, dyes or preservatives
- take any medicines for any other condition
- have any of the following medical conditions:
 - liver problems
 - heart problems
 - myasthenia gravis, a condition in which the muscles become weak and tire easily
 - o eye disorder
 - pneumonia.

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

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.

3. What if I am taking other medicines?

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

Some medicines may interfere with E-MYCIN. These include:

- medicines used to prevent blood clotting, such as warfarin, acenocoumarol
- some medicines used for epilepsy such as phenytoin, carbamazepine, hexobarbital, phenobarbital 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 the 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, and other corticosteroids
- vinblastine, a medicine used to treat Hodgkin's Disease
- sildenafil, used to treat erectile dysfunction in adult males
- fenofexadine, 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
- hydroxychloroquine and chloroquine.

Your doctor can tell you what to do if you are taking any of these medicines. You may need different amounts of your medicines, or you may need to take different medicines.

Check with your doctor or pharmacist if you are unsure about what medicines, vitamins or supplements you are taking and if these affect E-MYCIN.

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

4. How do I 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 are unsure, 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 E-MYCIN

- 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 E-MYCIN

 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 E-MYCIN 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 E-MYCIN

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 E-MYCIN

If you think that you or anyone else has taken too much E-MYCIN, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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

5. What should I know while taking E-MYCIN?

Things you should do

- If you are taking E-MYCIN for an infection and your symptoms do not improve within a few days or become worse, tell your doctor.
- 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 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 get a sore, white mouth or tongue while taking or soon after stopping E-MYCIN, tell your doctor.
 Also tell your doctor if you develop 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.

Call your doctor straight away:

- if your baby develops irritability with feeding or has severe vomiting during treatment with E-MYCIN. This may be a sign of a stomach disorder in the infant.
- if you get severe diarrhoea. 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 develop symptoms such as itching with swelling, skin rash or difficulty breathing while you are taking E-MYCIN and stop taking the medicine immediately.

Things you should not do

- Do not take 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how E-MYCIN affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Store E-MYCIN tablets below 30°C.
- Store E-MYCIN mixture in the refrigerator but not in the freezer.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

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

When to discard your medicine

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

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
 stomach cramps and pains feeling sick (nauseous), 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 	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
 yellowing of the eyes or skin (jaundice) severe stomach cramps feeling generally unwell and having poor appetite 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you

Serious side effects	What to do
 loss of hearing ringing or buzzing in the ears fast, irregular or pounding heartbeat, palpitations chest pain muscle pain, weakness and joint swelling dizziness, drowsiness, confusion, hallucinations, fits serious scaly red rash with bumps under skin and blisters vision problems in infants, irritability with feeding or severe 	notice any of these serious side effects.

Very serious side effects

Very serious side effects	What to do
 signs of an allergic reaction such as skin rash, itching or hives; swelling of the face, lips, tongue or other parts of 	Stop taking E-MYCIN and call your doctor straight away or go straight to the Emergency Department

Very serious side effects	What to do
the body; shortness of breath, wheezing and troubled breathing watery and severe diarrhoea, which may also be bloody	at your nearest hospital if you notice any of these very serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may 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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What E-MYCIN tablet contains

Active ingredient (main ingredient)	erythromycin (as erythromycin ethyl succinate) 400 mg per tablet
Other ingredients (inactive ingredients)	 calcium hydrogen phosphate anhydrous maize starch sorbic acid povidone purified talc

	 sodium starch glycollate magnesium stearate Opadry Pink OY- B-34901 (ID 2963)
Allergens	• contains sorbates.

What E-MYCIN mixture contains

Active ingredient (main ingredient)	 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)
Other ingredients (inactive ingredients)	 sorbitol propylene glycol alginate sodium citrate colloidal anhydrous silica aspartame sodium benzoate erythrosine Cl45430 Trusil Nature Identical Dark Cherry Flavour 163837 (ID 11977)

Allergens	contains benzoates, aspartame, phenylalanine (warning for patients
	with phenylketonuria)
	and sorbitol (which may
	have a laxative effect or
	cause diarrhoea).

Do not take this medicine if you are allergic to any of these ingredients.

What E-MYCIN looks like

E-MYCIN tablet is 19 mm X 8.7 mm oval, normal convex, flesh pink film coated tablet marked "E-N" on one side, "alpha symbol" on the reverse. Each pack contains 25 tablets. (AUST R 71310).

E-MYCIN 200 mixture is pink free flowing granules. When reconstituted, pink suspension with a cherry odour and flavour. Each bottle contains 100 mL of mixture. (AUST R 48286).

E-MYCIN 400 mixture is pink free flowing granules. When reconstituted, pink suspension with a cherry odour and flavour. Each bottle contains 100 mL of mixture. (AUST R 48287).

Who distributes E-MYCIN

Alphapharm Pty Ltd trading as Viatris Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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