Mayne Pharma Erythromycin Capsules

Consumer Medicine Information (CMI) summary

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

1. Why am I using Mayne Pharma Erythromycin capsules?

Mayne Pharma Erythromycin capsules contain the active ingredient erythromycin. They are used to treat infections in different parts of the body caused by bacteria and prevent infections in patients with a history of rheumatic disease who may be allergic to penicillin. For more information, see Section <u>1</u>. Why am I using Mayne Pharma Erythromycin capsules? in the full CMI.

2. What should I know before I use Mayne Pharma Erythromycin capsules?

Do not use if you have ever had an allergic reaction to erythromycin or any of the ingredients listed at the end of the CMI. Do not use if you have severe liver problems. Do not use if you have ever had changes in the rhythm or rate of the heartbeat, or disturbances in your 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 use Mayne Pharma Erythromycin capsules? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Mayne Pharma Erythromycin capsules and affect how they work. A list of these medicines is in Section <u>3. What if I am taking</u> <u>other medicines?</u> in the full CMI.

4. How do I use Mayne Pharma Erythromycin capsules?

- For treating most infections, the usual adult dose of Mayne Pharma Erythromycin capsules is one 250 mg capsule four times a day or two 250 mg capsules twice a day. For the long-term prevention of streptococcal infections in persons with a history of rheumatic heart disease and an allergy to penicillin, the usual dose is one 250 mg capsule twice a day.
- Swallow the capsules whole with a full glass of water. Do not chew or crush the capsule. Do not take with food.

More instructions can be found in Section <u>4. How do I</u> <u>use Mayne Pharma Erythromycin capsules?</u> in the full CMI.

5.	. What should I know while using May	
	Pharma Erythromycin capsules?	

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using erythromycin. Tell your doctor if your symptoms do not improve within a few days, or if you get severe diarrhoea, if you get a sore, white mouth or tongue while taking or soon after stopping Mayne Pharma Erythromycin capsules, if you get vaginal itching
	or discharge or if you become pregnant.
Things you should not do	 Do not take the capsules 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 because you are feeling better, unless advised by your doctor.
Driving or using machines	 Be careful driving or operating machinery until you know how Mayne Pharma Erythromycin capsules affect you.
Looking after your medicine	 Keep your capsules in the pack until it is time to take them. Keep your capsules in a cool, dry place where the temperature stays below 25°C.

For more information, see Section <u>5. What should I know</u> while using Mayne Pharma Erythromycin capsules? in the full CMI.

6. Are there any side effects?

Common side effects include mild stomach upsets such as feeling sick, diarrhoea, or mild stomach pains, vomiting and loss of appetite. Serious side effects include yellowing of the skin and eyes, difficulty hearing, hallucinations or confusion, increasingly poor appetite, signs of an allergic reaction (rash, itching or hives on the skin; swelling of the face, lips, tongue or other parts of the body; shortness of breath, wheezing or difficulty breathing), chest pain, changes in the rhythm or rate of the heartbeat, convulsions (fits), watery and severe diarrhoea, which may also be bloody, severe abdominal cramps, stomach cramps or stomach pain.

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.

Mayne Pharma Erythromycin Capsules

Active ingredient(s): *erythromycin* (s) (phonetic pronunciation – eh-RITH-roe-MYE-sin)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Mayne Pharma Erythromycin capsules. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Mayne Pharma Erythromycin capsules.

Where to find information in this leaflet:

<u>1. Why am I using Mayne Pharma Erythromycin</u> <u>capsules?</u>

2. What should I know before I use Mayne Pharma Erythromycin capsules?

3. What if I am taking other medicines?

<u>4. How do I use Mayne Pharma Erythromycin capsules?</u>

5. What should I know while using Mayne Pharma Erythromycin capsules?

6. Are there any side effects?

7. Product details

1. Why am I using Mayne Pharma Erythromycin capsules?

Mayne Pharma Erythromycin capsules contain the active ingredient erythromycin. Erythromycin is an antibiotic which belongs to a group of medicines called macrolides.

Mayne Pharma Erythromycin capsules are used to treat infections in different parts of the body caused by bacteria and to prevent infections in patients with a history of rheumatic disease who may be allergic to penicillin. This medicine works by killing or stopping the growth of bacteria which cause infections. It will not work against viral infections 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.

This medicine is not addictive.

2. What should I know before I use Mayne Pharma Erythromycin capsules?

Warnings

Do not use Mayne Pharma Erythromycin capsules if:

- you are allergic to erythromycin, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have ever had changes in the rhythm or rate of the heartbeat, or disturbances in your electrolyte levels.
- you have severe liver problems.
- you are taking any of the following medications:
 - cisapride, a medicine which helps move food through the digestive system
 - pimozide, a medicine used to treat some psychiatric (mental) conditions
 - ergotamine or dihydroergotamine, medicines used to treat migraine headache
 - astemizole or terfenadine, medicines used to treat allergy
 - some medicines used to treat irregular heartbeats
 - medicines used to lower high blood cholesterol, such as lovastatin, simvastatin and atorvastatin.

Check with your doctor if you:

- have any other medical conditions, especially:
 - liver problems
 - irregular or very slow heartbeat
 - myasthenia gravis, a condition in which the muscles become weak and tire easily.
- have allergies to any other medicines, foods, preservatives or dyes.
- take any medicines for any other condition.
- need any surgical procedures. This medicine is not suitable prior to surgery relating to the gastrointestinal tract or genital and urinary organs.

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 <u>6. Are there any side effects</u>?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

The active ingredient of Mayne Pharma Erythromycin may cross the placenta in pregnant women and is excreted in breast milk. **Information from studies** regarding the risk of birth defects is inconsistent, but some studies have reported heart defects following erythromycin use in early pregnancy.

Erythromycin should be used by women during pregnancy or while breast-feeding only if clearly needed.

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 and Mayne Pharma Erythromycin capsules may interfere with each other. These include:

- theophylline, a medicine used to treat asthma
- methylprednisolone or other corticosteroids given by mouth, by injection or inhaled (used to help suppress the body's immune system - this is useful in treating a wide range of conditions)
- some medicines used for epilepsy such as carbamazepine, phenytoin and valproate
- alfentanil, a medicine used to relieve pain and produce anaesthesia
- digoxin, a drug used to treat heart failure or heart disease
- some medicines used to treat irregular heartbeats, such as quinidine, disopyramide, procainamide, amiodarone and sotalol
- medicines used to treat conditions like rheumatoid arthritis

- medicines used to treat or prevent malaria such as hydroxychloroquine or chloroquine
- some medicines used to treat high blood pressure or angina such as verapamil, amlodipine and diltiazem
- alprazolam, triazolam or midazolam, medicines used to produce sleep or drowsiness and to relieve anxiety
- medicines used to prevent blood clots, such as warfarin and rivaroxaban
- medicines used to prevent organ transplant rejection or to treat certain problems with the immune system, such as cyclosporin and tacrolimus
- medicines used to lower high blood cholesterol, such as lovastatin, simvastatin and atorvastatin
- the antibiotics clindamycin, lincomycin, penicillin and rifabutin
- medicines used to treat fungal infections such as ketoconazole, itraconazole and fluconazole
- colchicine, a medicine used in the treatment of gout
- some medicines for migraine headache such as ergotamine or dihydroergotamine
- pimozide, a medicine used to treat some psychiatric (mental) conditions
- cisapride, a medicine which helps food move through the digestive system
- astemizole or terfenadine, medicines used to treat allergy
- bromocriptine, a medicine use to treat Parkinson's disease
- sildenafil, a medicine used to treat impotence

- vinblastine, a medicine used in the treatment of some types of cancer
- cimetidine, a medicine used to treat stomach problems, such as ulcers
- zopiclone, a medicine used for sleeping problems
- the contraceptive pill (birth control pill). Mayne Pharma Erythromycin capsules may decrease the effectiveness of some birth control pills. Your doctor may advise you to use an additional method of contraception such as a barrier method while taking Mayne Pharma Erythromycin capsules and for seven days after finishing the course of Mayne Pharma Erythromycin capsules. Consult your doctor or pharmacist for advice.

Some medicines may interfere with Mayne Pharma Erythromycin capsules and affect how they work.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Mayne Pharma Erythromycin capsules.

4. How do I use Mayne Pharma Erythromycin capsules?

How much to take

 Your doctor or pharmacist will tell you how many capsules you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

- For treating most infections, the usual adult dose of Mayne Pharma Erythromycin capsules is one 250 mg capsule four times a day (every 6 hours) or two 250 mg capsules twice a day (every 12 hours).
- For the long-term prevention of streptococcal infections in persons with a history of rheumatic heart disease and an allergy to penicillin, the usual dose is one 250 mg capsule twice a day.
- Swallow the capsules whole with a full glass of water.
- Do not chew or crush the capsule.
- Your doctor may ask you to take a different dose, depending on your condition and how you react to the medicine.
- For treating infections, this medicine is usually taken for one to two weeks. However, your doctor may prescribe it for longer periods.
- Keep taking this medicine for the full time of treatment, even if you begin to feel better after a few days.
- If you do not complete the full course prescribed by your doctor, the infection may not clear up completely or your symptoms may return.
- Follow the instructions provided when Mayne Pharma Erythromycin capsules were prescribed, including the number of days it should be taken.

When to take Mayne Pharma Erythromycin capsules

- Take your medicine on an empty stomach, for example one hour before food or two hours after food.
- Food can interfere with the absorption of this medicine.

If you forget to use Mayne Pharma Erythromycin capsules

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 it 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 are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too many Mayne Pharma Erythromycin capsules

If you think that you have taken too many Mayne Pharma Erythromycin capsules, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), 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.

You may need urgent medical attention.

If you take too many Mayne Pharma Erythromycin capsules you may feel sick (nauseous) or vomit, experience diarrhoea or hearing problems. Other effects may include those listed in the Serious Side Effects section.

5. What should I know while using Mayne Pharma Erythromycin capsules?

Things you should do

Call your doctor straight away if you:

- are taking Mayne Pharma Erythromycin capsules for an infection and your symptoms do not improve within a few days, or if they become worse.
- get severe diarrhoea. Do this even if it occurs several weeks after Mayne Pharma Erythromycin capsules have been stopped.

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. **Do not take any diarrhoea medicine without first checking with your doctor.**

- get a sore, white mouth or tongue while taking or soon after stopping Mayne Pharma Erythromycin capsules.
- get vaginal itching or discharge.

This may mean you have a fungal infection called thrush. Sometimes the use of Mayne Pharma Erythromycin capsules allows fungi to grow and the above symptoms to occur. Mayne Pharma Erythromycin capsules do not work against fungi.

Remind any doctor, dentist or pharmacist you visit that you are using Mayne Pharma Erythromycin capsules.

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

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

Things you should not do

- Do not take Mayne Pharma Erythromycin capsules 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 because you are feeling better, unless advised by your doctor.
- If you do not complete the full course prescribed by your doctor, all of the bacteria causing your infection may not be killed. These bacteria may continue to grow and multiply so that your infection may not clear completely, or it may return.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Mayne Pharma Erythromycin capsules affect you.

This medicine generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, it may cause dizziness in some people. If this occurs do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Follow the instructions in the carton on how to take care of your medicine properly.
- Keep your capsules in the pack until it is time to take them.
- If you take the capsules out of the pack, they may not keep well.
- Keep your capsules in a cool, dry place where the temperature stays below 25°C.

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 windowsills.

Keep it 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.

When to discard your medicine

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.

Getting rid of any unwanted medicine

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

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

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.

If you are over 65 years of age you may have an increased chance of getting side effects.

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

Less serious side effects

Less serious side effects	What to do
 mild stomach upsets	Speak to your doctor if
such as feeling sick,	you have any of these
diarrhoea, or mild	less serious side effects
stomach pains vomiting loss of appetite.	and they worry you.

Serious side effects

Serious side effects	What to do
 yellowing of the skin and eyes, also called jaundice difficulty hearing hallucinations or confusion increasingly poor appetite signs of an allergic reaction (for example, rash, itching or hives on the skin; swelling of the face, lips, tongue or other parts of the body; shortness of breath, wheezing or difficulty breathing) chest pain changes in the rhythm or rate of the heartbeat convulsions (fits) watery and severe diarrhoea, which may also be bloody 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Serious side effects	What to do
 severe abdominal cramps, stomach cramps or stomach pain. 	

Contact a doctor immediately if you experience a serious skin reaction: a red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis). The frequency of this side effect is not known (cannot be estimated from the available data).

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.

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 <u>www.tga.gov.au/reporting-problems</u>. 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 Mayne Pharma Erythromycin capsules contain

Active ingredient (main ingredient)	250 mg erythromycin
Other ingredients (inactive ingredients)	 lactose monohydrate povidone cellacefate diethyl phthalate gelatin shellac monobasic potassium phosphate erythrosine indigo carmine sunset yellow FCF carbon black purified water
Potential allergens	This medicine does not contain sucrose or gluten

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

What Mayne Pharma Erythromycin capsules look like

Mayne Pharma Erythromycin capsules are transparent red/yellow capsules, marked Eryc in black. The capsules are filled with white coated pellets. They are available in bottles of 25 capsules (Aust R 195842).

Who distributes Mayne Pharma Erythromycin capsules

Mayne Pharma International Pty Ltd

1538 Main North Road

Salisbury South, SA 5106

maynepharma.com

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