Mayne Pharma Doxycycline Capsules

Consumer Medicine Information (CMI) summary

The full CMI 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 Mayne Pharma Doxycycline Capsules?

Mayne Pharma Doxycycline Capsules contain the active ingredient doxycycline hyclate (hydrochloride). This medicine is an antibiotic used to treat certain types of infections, control acne and prevent some forms of malaria, sometimes in combination with another antimalarial medicine.

For more information, see Section 1. Why am I taking Mayne Pharma Doxycycline Capsules? in the full CMI.

2. What should I know before I take Mayne Pharma Doxycycline Capsules?

Do not use if you have ever had an allergic reaction to doxycycline hyclate (hydrochloride), other tetracyclines, or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have allergies to any**

medicines, have any other medical conditions, take any other medicines, work outdoors or are likely to be exposed to strong sunlight or ultra-violet light, are scheduled to have surgery under general anaesthetic, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I take Mayne Pharma Doxycycline Capsules? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Mayne Pharma Doxycycline Capsules and affect how they work.

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 Mayne Pharma Doxycycline Capsules?

- Your doctor or pharmacist will tell you how many capsules you will need to take each day.
- Swallow the capsules whole with a full glass of water or milk while sitting or standing upright.

More instructions can be found in Section 4. How do I take Mayne Pharma Doxycycline Capsules? in the full CMI.

5. What should I know while taking Mayne Pharma Doxycycline Capsules?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are taking this medicine. • Tell your doctor if your symptoms do not improve or worsen, you get severe diarrhoea, you become pregnant while taking this medicine, or you are about to have any blood tests. • If you are taking iron preparations you must take them at least two hours before or two hours after this medicine.
Things you should not do	• Do not stop taking your medicine because you are feeling better unless advised by your doctor. • Do not give your medicine to anyone else, even if they have

	the same condition as you. • Do not use this medicine to treat any other complaints unless your doctor tells you to.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how this medicine affects you.
Drinking alcohol	• Tell your doctor if you drink alcohol.
Looking after your medicine	• Keep your capsules in their pack until it is time to take them. • Store below 25°C. Protect from light.

For more information, see Section 5. What should I know while taking Mayne Pharma Doxycycline Capsules? in the full CMI.

6. Are there any side effects?

Less serious side effects include: oral/vaginal thrush, rash/itching, nail changes, stomach upset/vomiting, mild irritation of the oesophagus, taste loss, ringing in ears. Serious side effects include: depression, feeling anxious/ nervous, muscle tenderness/ weakness, painful swollen joints, increased pressure in brain, severe blisters

and bleeding in lips, eyes, mouth, nose and genitals, severe skin reactions, difficulty in/pain with swallowing, dizziness, fast heart rate, frequent bruising, passing less urine, yellowing of eyes/skin, severe upper stomach pain often with nausea and vomiting. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Mayne Pharma Doxycycline Capsules

Active ingredient(s): *doxycycline hyclate (hydrochloride)* (dox-I-SYE-kleen)

Consumer Medicine Information (CMI)

This leaflet provides important information about taking Mayne Pharma Doxycycline 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 taking this medicine.**

Where to find information in this leaflet:

1. Why am I taking Mayne Pharma Doxycycline Capsules?
2. What should I know before I take MaynePharma Doxycycline Capsules?
3. What if I am taking other medicines?
4. How do I take Mayne Pharma Doxycycline Capsules?
5. What should I know while taking Mayne Pharma Doxycycline Capsules?
6. Are there any side effects?
7. Product details

1. Why am I taking Mayne Pharma Doxycycline Capsules?

Mayne Pharma Doxycycline Capsules contain the active ingredient doxycycline hyclate (hydrochloride). This medicine belongs to a group of medicines called tetracyclines.

This medicine is an antibiotic used to:

- **treat certain types of infections**
- **control acne**
- **prevent some forms of malaria, sometimes in combination with another antimalarial medicine.**

It works by killing or stopping the growth of bacteria which cause infections or make acne worse. It also works against parasites that cause malaria.

Tetracyclines 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.

It is available only with a doctor's prescription.

2. What should I know before I take Mayne Pharma Doxycycline Capsules?

Warnings

Do not take this medicine if:

- **you are allergic to doxycycline hyclate (hydrochloride), other tetracyclines, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can take this medicine**
- **you are taking preparations containing vitamin A, isotretinoin or etretinate. Ask your doctor or pharmacist if you are not sure if you are taking one of these medicines.**
- **if you are more than 18 weeks pregnant or are breast-feeding.**

Do not give this medicine to children aged eight years or under (or to children under 50 kg) unless directed by the child's doctor. Mayne Pharma Doxycycline Capsules like other tetracyclines, may cause enamel loss and staining in developing teeth. It may also cause increased pressure on the brain if used in infants.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

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

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes,
- have any other medical conditions,
- take any medicines for any other condition,
- work outdoors or if you are likely to be exposed to strong sunlight or ultra-violet light. Doxycycline may cause your skin to become more sensitive to UV or sunlight, resulting in severe sunburn.
- are scheduled to have surgery under general anaesthetic.

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

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.

As with many medicines, tetracyclines may harm your developing or breast-feeding baby. Tetracyclines may cause enamel loss and staining of your child's teeth or increase the pressure on your child's brain. High

doses of tetracyclines may also cause liver problems in pregnant women.

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 doxycycline may interfere with each other and affect how they work.

These Include:

- preparations containing Vitamin A
- some medicines used for skin problems, such as isotretinoin or etretinate
- warfarin, a medicine used to prevent blood clotting
- another group of antibiotics called penicillins
- some medicines used in the treatment of epilepsy such as phenytoin, carbamazepine or phenobarbitone
- methoxyflurane, an anaesthetic
- acetazolamide, a medicine used to help the body get rid of salt and water
- the contraceptive pill (birth control pill). Doxycycline may decrease the effectiveness of some birth control pills. Your doctor may advise you to use an additional method of contraception while taking doxycycline and for 7 days after taking doxycycline. Refer to your doctor or pharmacist for advice.

These medicines may be affected by doxycycline or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines.

If you are taking the following medicines, take them at least two hours before or two hours after taking doxycycline:

- antacids (containing aluminium, calcium or magnesium) used for indigestion
- bismuth salts, found in some medicines used to treat stomach ulcers
- preparations that contain iron including vitamin preparations.

These medicines may interfere with the absorption of doxycycline.

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

4. How do I take Mayne Pharma Doxycycline Capsules?

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 pack, ask your doctor or pharmacist for help.

How much to take

Your doctor or pharmacist will tell you how many capsules you will need to take each day.

- For treating infections, the usual dose of doxycycline is two 100 mg capsules on the first day, followed by one 100 mg capsule each day from then on.
- For controlling acne, the usual dose is one 50 mg capsule each day.
- For the prevention of malaria, the usual dose is one 100 mg capsule each day, commencing two days before entering the malarious area, during the visit, and for four weeks after leaving the area.

Your doctor may ask you to take a different dose, depending on your condition and how you react to the medicine.

Follow the instructions provided when this medicine was prescribed, including the number of days it should be taken.

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 completely or your symptoms may return.

For treating infections, this medicine is usually taken for one to two weeks.

For controlling acne, this medicine is normally taken over a period of 12 weeks.

For preventing malaria, this medicine is recommended to be taken for up to a maximum of 8 weeks. However, your doctor may prescribe doxycycline for longer periods.

If you are not sure how long you should be taking this medicine, talk to your doctor.

How to take Mayne Pharma Doxycycline Capsules

Swallow the capsules whole with a full glass of water or milk while sitting or standing upright.

Do not lie down immediately after swallowing doxycycline. It is important to stay upright, for example sitting, standing or walking around for at least half an hour after swallowing your capsule. This is to help avoid irritation to your food pipe, also called the oesophagus.

Do not chew the capsules.

When to take Mayne Pharma Doxycycline Capsules

- **Take your medicine at about the same time each day (usually in the morning)**. Taking it at the same time each day will have the best effect. It will also help you to remember when to take it.

- **Take your medicine during or immediately after a meal**. If taken on an empty stomach, it may cause stomach upset.

If you forget to take Mayne Pharma Doxycycline Capsules

This medicine should be taken regularly at the same time each day.

If you miss a dose and 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 Doxycycline Capsules

If you think that you have taken too much of this medicine, 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.

Symptoms of an overdose may include an upset stomach or vomiting.

5. What should I know while taking Mayne Pharma Doxycycline Capsules?

Things you should do:

Call your doctor straight away if:

- **you are taking this medicine for an infection and your symptoms do not improve within a few days or they become worse**
- **you get severe diarrhoea. Do this even if it occurs several weeks after this medicine has been stopped.** Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. **Do not take diarrhoea medicine without first checking with your doctor**
- **you get a severe skin reaction (i.e. a well-defined, red or purple patch of skin which may also blister and reappear on the same area of the body each time you take the medicine).** This is a type of allergic

reaction and if this occurs you should stop taking Mayne Pharma Doxycycline Capsules immediately.

Remind any doctor, dentist or pharmacist you visit that you are taking this medicine.

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.

If you are taking iron preparations, including vitamin preparations containing iron, bismuth salts or antacids (containing aluminium, calcium or magnesium), you must take them at least two hours before or two hours after Mayne Pharma Doxycycline Capsules to make sure there is no problem with absorption.

Things you should not do:

- **Do not stop taking your medicine because you are feeling better unless advised by your doctor.** If you do not complete the full course, 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.
- **Do not give your medicine to anyone else, even if they have the same condition as you.**
- **Do not use this medicine to treat any other complaints unless your doctor tells you to.**

Things to be careful of:

- **Protect your skin when you are in the sun, especially between 10am and 3pm. If outdoors, wear protective clothing and use a 30+ sunscreen.** This medicine may cause your skin to be much more sensitive to sunlight than it is normally. Exposure to sunlight may cause a skin rash, itching, redness, or a severe sunburn. **If your skin does appear to be burning, see your doctor as soon as possible. You may need alternative treatment.**
- **If you get thrush (a fungal infection which can affect the mouth and/or vagina) or any other infection while taking, or soon after stopping this medicine, tell your doctor.** Sometimes the use of this medicine allows fungi to grow as they are not killed by Mayne Pharma Doxycycline Capsules.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how this medicine affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- **Keep your capsules in their pack until it is time to take them. Avoid exposure to light.** If you take the capsules out of the pack they may not keep as well.

- **Store 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 young children cannot reach it.

When to discard your medicine

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.

Less serious side effects

Less serious side effects	What to do
• oral thrush - white, furry, sore tongue and mouth • vaginal thrush - sore and itchy vagina with or without discharge • rash or itching • nail changes • stomach upset or vomiting • mild irritation of the oesophagus (food-pipe) • taste loss • ringing or other persistent noise in the ears.	**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
• depression • feeling anxious or nervous • muscle tenderness or weakness, not caused by exercise	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you**

Serious side effects	What to do
• painful swollen joints • increased pressure in the brain (headache, blurred vision, vomiting) • severe blisters and bleeding in the lips, eyes, mouth, nose and genitals • severe skin reactions starting as painful red areas then large blisters and ends with peeling layers of skin • difficulty in/pain with swallowing • flaking of the skin • dizziness • fast heart rate • frequent bruising • damage to the liver, which may result in yellowing of the eyes or skin (jaundice) and passing less or darker urine • severe upper stomach pain often with nausea and vomiting (pancreatitis)	**notice any of these serious side effects.**

Serious side effects	What to do
• symptoms of an allergic reaction such as shortness of breath, wheezing or troubled breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin • a rare, potentially life-threatening, drug-induced sensitivity reaction that includes skin rashes, blood changes, fever and dysfunction of internal organs (e.g. liver, kidney, lung) • a rare type of recurring skin reaction where red or dark patches appear on the same area of the body each time the medicine is taken. The reaction may worsen with repeated doses and can sometimes blister • a reaction that can happen after starting doxycycline therapy for	

Serious side effects	What to do
a particular bacterial infection (spirochete infections, e.g. Lyme disease); symptoms include fever, chills, muscle pain and worsening of skin rash.	

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 finishing it

Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after stopping treatment with this medicine.

Serious side effects	What to do
• 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.	**Call your doctor straight away if you notice any of these serious side effects.**

These are rare but serious side effects. You may have a serious condition affecting your bowel. This medicine may cause the bacteria which are normally harmless and present in the bowel to multiply, resulting in the above symptoms. Therefore you may need urgent medical attention.

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

Ask your doctor or pharmacist to answer any questions you may have about the side effects.

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 Mayne Pharma Doxycycline Capsules contain

Active ingredient **(main ingredient)**	doxycycline hyclate (hydrochloride)
Other ingredients **(inactive ingredients)**	• lactose monohydrate • microcrystalline cellulose • povidone • hypromellose phthalate • hypromellose • diethyl phthalate • wheat starch (contains gluten) • magnesium stearate • hyprolose • gelatin • Opacode Black A-10259
Potential allergens	This medicine does not contain sucrose, tartrazine or any other azo dyes

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

What Mayne Pharma Doxycycline Capsules look like

This medicine comes in two strengths:

Mayne Pharma Doxycycline Capsules 100 mg - clear capsules filled with yellow pellets, marked doxy 100 in black. It is available in HDPE bottles of 7 or 21* capsules (AUST R 107248).

Mayne Pharma Doxycycline Capsules 50 mg - clear capsules filled with yellow pellets, marked doxy 50 in black. It is available in HDPE bottles of 25 capsules (AUST R 107247).

*Not all pack sizes may be marketed.

Who distributes Mayne Pharma Doxycycline Capsules?

Mayne Pharma International Pty Ltd

1538 Main North Road

Salisbury South, SA 5106

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