DOXYLIN®

Consumer Medicine Information (CMI) summary

The full CMI 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 taking DOXYLIN?

DOXYLIN contains the active ingredient doxycycline hyclate (hydrochloride). DOXYLIN 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 using DOXYLIN? in the full CMI.

2. What should I know before I take DOXYLIN?

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 DOXYLIN? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DOXYLIN 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 DOXYLIN?

- 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 DOXYLIN? in the full CMI.

5. What should I know while taking DOXYLIN?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are taking DOXYLIN. • 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 DOXYLIN.
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 DOXYLIN 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 DOXYLIN affects you.
Drinking alcohol	• Tell your doctor if you drink alcohol.
Looking after your medicine	• Keep your tablets in the pack or bottle until it is time to take them. • Store in a cool dry place where the temperature stays below 30°C.

For more information, see Section 5. What should I know while taking DOXYLIN? in the full CMI.

6. Are there any side effects?

Some of the 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.
Some of the more serious side effects include depression, anxiety, joint pain, muscle tenderness/ weakness, 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.

DOXYLIN®

Active ingredient(s): doxycycline hyclate

Consumer Medicine Information (CMI)

This leaflet provides important information about using DOXYLIN. **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 DOXYLIN.**

Where to find information in this leaflet:

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

1. Why am I using DOXYLIN?

DOXYLIN contains the active ingredient doxycycline hyclate. This medicine belongs to a group of medicines called tetracyclines.

DOXYLIN is an antibiotic used to:

- treat certain infections caused by bacteria
- control acne
- prevent some forms of malaria

It works by killing or stopping the growth of bacteria which cause infections or make acne worse.

DOXYLIN also works against parasites that cause malaria. It is sometimes used in combination with other anti-malarial medicines.

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.

2. What should I know before I use DOXYLIN?

Warnings

Do not use DOXYLIN if:

- **You are allergic to doxycycline hyclate, any medicines containing other tetracyclines, or 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 give this medicine to children aged eight years or under (or to children under 50 kg) unless directed by the child's doctor. DOXYLIN 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 if the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes
- have any other medical conditions
- have liver problems
- take any medicines for any other condition
- work outdoors or if you are likely to be exposed to strong sunlight or ultra-violet light (e.g. on a sun bed).
- 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. High doses of tetracyclines may also cause liver problems in pregnant women.

Talk to your doctor if you are breastfeeding or intend to breastfeed. DOXYLIN, like other 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.

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 DOXYLIN and affect how it works. These include:

- preparations containing vitamin A, including vitamin supplements
- preparations containing calcium or iron, including vitamin supplements
- antacids, medicines used for indigestion
- some medicines used for skin problems such as isotretinoin or etretinate
- warfarin, a medicine used to prevent blood clots
- another group of antibiotics called penicillins
- phenytoin or carbamazepine, anticonvulsant medicines that are used to treat seizures
- barbiturates, such as phenobarbital

- methoxyflurane, an anaesthetic
- acetazolamide, a medicine used to help the body rid of salt and water
- the contraceptive pill (birth control pill)

  DOXYLIN may decrease the effectiveness of some birth control pills.

  Your doctor may advise you to use an additional method of contraception while you are taking DOXYLIN and for 7 days after taking DOXYLIN

These medicines may be affected by DOXYLIN 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 taking the following medicines, take them at least two hours before or two hours after taking DOXYLIN:

- antacids (containing aluminium, calcium, magnesium or bismuth) 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 DOXYLIN.

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

4. How do I use DOXYLIN?

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

How much to take / use

- For treating infections, the usual dose of doxycycline for adults is 200 mg on the first day, followed by 100 mg each day from then on.
- For controlling acne, the usual dose for adults is 50 mg a day.
- For the prevention of malaria, the usual dose for adults is 100 mg each day, starting two days before entering the malarious area, continuing during the visit, and for four weeks after leaving the area.

Follow the instructions provided when DOXYLIN was prescribed, including the number of days it should be taken. They may differ from the information contained in this leaflet.

Keep taking DOXYLIN for the full length of treatment. Continue taking your medicine even if you begin to feel better after a few days.

If you stop taking your medicine too soon, your infection may not clear completely, or your symptoms may return.

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

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

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

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

When to take / use DOXYLIN

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

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

Do not lie down immediately after swallowing DOXYLIN. 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.

If you forget to use DOXYLIN

DOXYLIN should be used regularly at the same time each day.

If you miss your dose at the usual time, 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 use too much DOXYLIN

If you think you or anyone else has used too much DOXYLIN, urgent medical attention may be required. .

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.

Symptoms of overdose may include an upset stomach, nausea and vomiting.

5. What should I know while using DOXYLIN?

Things you should do

Call your doctor straight away if you:

- you are taking DOXYLIN for an infection and your symptoms do not improve within a few days or they become worse
- you become pregnant while taking DOXYLIN
- you are about to have any blood tests
- you get severe diarrhoea. Do this even if it occurs several weeks after DOXYLIN 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.**

Remind any doctor, dentist or pharmacist you visit that you are using DOXYLIN.

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 DOXYLIN to make sure there is no problem with absorption.

Things you should not do

- **Do not stop taking DOXYLIN because you are feeling better, unless you are advised to by your doctor.** If you do not complete the full course, the bacteria causing your infection may not all be killed. 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 DOXYLIN to treat any other complaints unless your doctor tells you to.

Things to be careful of

DOXYLIN 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.

Protect your skin when you are in the sun, especially between 10 am and 3 pm. If outdoors, wear protective clothing and use a 30+ sunscreen.

If your skin does appear to be burning, see your doctor as soon as possible. You may need alternative treatment.

Sometimes the use of this medicine allows fungi to grow as they are not killed by DOXYLIN.

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 DOXYLIN, tell your doctor.

Driving or using machines

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

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may interfere with the absorption of DOXYLIN.

Looking after your medicine

- Keep your tablets in the original container until it is time to take them.
- Store below 30°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 your medicine where young children cannot reach it.

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.

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
• Stomach upset, feeling sick, vomiting, diarrhoea • mild irritation of the oesophagus (food-pipe) • taste loss • oral thrush (white, furry sore tongue and mouth) • vaginal thrush (sore and itchy vagina with or without discharge) • rash or itching • nail changes • persistent ringing or 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 • swollen painful joints, muscle tenderness or weakness (not related to exercise) • increased pressure in the brain (headache, blurred vision, vomiting) • severe blisters and bleeding in the lips, eyes, mouth, nose and genitals	**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 skin reactions starting as painful red areas then large blisters and ends with peeling of layers of skin • severe sunburn that occurs more quickly than normal • pain or difficulty in swallowing • flaking of the skin • dizziness • fast heart rate • bleeding or bruising more easily than normal • passing little or no urine • signs of liver disease such as feeling generally unwell, fever, itching, yellowing of the skin and/or eyes, and dark coloured urine • abnormal liver function tests • severe upper stomach pain often with nausea and vomiting (pancreatitis) • severe diarrhoea, usually with blood and mucus, stomach pain and fever • signs of an allergic reaction such as skin rash, itching or hives; shortness of breath, wheezing or trouble breathing; swelling of the face, lips, tongue or other parts of the body • 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 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 DOXYLIN

See your doctor immediately if you notice any of the following, particularly if they occur several weeks after stopping treatment with DOXYLIN:

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

DOXYLIN can cause some bacteria that are normally harmless and present in the bowel to multiply and cause the above symptoms.

You may have a serious condition affecting your bowels. Therefore, it is important to tell your doctor as 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 DOXYLIN contains

Active ingredient (main ingredient)	doxycycline hyclate
Other ingredients (inactive ingredients)	• microcrystalline cellulose • pregelatinised maize starch • colloidal anhydrous silica • magnesium stearate • Opadry Yellow OY□LS□32814 (ARTG PI No. 2734)
Potential allergens	lactose and trace amounts of sulfites.

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

What DOXYLIN looks like

DOXYLIN is available in two strengths:

- DOXYLIN 50 mg are normal convex, yellow film coated tablets debossed "DE" over "50" on one side and "G" on the reverse. They are available in blister packs of 25 tablets (AUST R 63511).
- DOXYLIN 100 mg are normal convex, yellow film coated tablets debossed "DE" over "100" on one side

and "G" on the reverse. They are available in blister packs of 7 and 21 tablets (AUST R 63509).

Who distributes DOXYLIN

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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DOXYLIN® is a Viatris company trade mark.

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