

Doxylin

doxycycline (hydrochloride)

CONSUMER MEDICINE INFORMATION

What is in this leaflet?

This leaflet answers some common questions about Doxylin. 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 Doxylin against the benefits they expect it will have 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 Doxylin is used for

Doxylin is used to:

- * treat certain infections caused by bacteria
- * control acne
- * prevent certain types of malaria.

Doxylin is an antibiotic that belongs to a group of medicines called tetracyclines. 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.

Doxylin will not work against infections caused by viruses, such as colds or flu.

Ask your doctor if you have any questions about why Doxylin has been prescribed for you.

Your doctor may have prescribed Doxylin for another reason.

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

Before you take Doxylin

When you must not take it

Do not take Doxylin if you are allergic to:

- * medicines containing doxycycline (e.g. Doryx, Vibramycin)
- * medicines containing other tetracyclines (e.g. Minomycin, Tetrex)
- * any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to a tetracycline antibiotic may include skin rash, itching or hives; swelling of the face, lips, tongue or other parts of the body or other parts of the body; asthma, shortness of breath, wheezing or troubled breathing and fainting.

If you are not sure if you are allergic to any of the above, ask your doctor.

Do not take Doxylin if you are taking preparations containing vitamin A, isotretinoin or etretinate.

Doxylin should not be taken during periods of tooth development (the last half of pregnancy or in children 8 years and under).

Doxylin, like other tetracyclines, may cause enamel loss and permanent discolouration (yellow-grey-brown) in developing teeth.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or show 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 start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, dyes or preservatives.

Tell your doctor if you have any other health problems.

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

Doxylin is not recommended during the last half of pregnancy (see 'When you must not take it' section).

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

Your doctor can discuss with you the risks and benefits of taking Doxylin during pregnancy.

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

Doxylin passes into breast milk. Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are scheduled to have surgery under general anaesthetic.

Tell your doctor if you work outdoors or if you are likely to be exposed to strong sunlight or ultra-violet light (e.g. on a sun bed).

You should avoid exposure to strong sunlight while taking this medicine as your skin may be more sensitive to sunburn than normal.

If you have not told your doctor about any of the above, tell him/her before you start taking Doxylin.

Taking other medicines

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

Some medicines and Doxylin may interfere with each other. These include:

- * preparations containing vitamin A, including vitamin supplements
- * preparations containing calcium or iron, including vitamin supplements
- * antacids, 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
- * anticonvulsant medicines that are used to treat seizures, such as phenytoin or carbamazepine
- * barbiturates, such as phenobarbitone
- * sodium bicarbonate

- * acetazolamide, a medicine used to treat glaucoma (raised eye pressure)
- * 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.

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

Alcohol may also interfere with the absorption of Doxylin.

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

How to take Doxylin

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

Ask your doctor or pharmacist for help, if you do not understand the instructions on the box.

How much to take

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.

For treating infections, the usual dose 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.

Children over 8 years of age may need smaller doses, depending on their weight.

How 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 not lie down for at least half an hour after swallowing your tablet, so that the tablet can move swiftly as possible into the stomach and prevent irritation of the throat or oesophagus (canal taking food from the mouth to the stomach).

When to take it

Take Doxylin during or immediately after a meal, preferably in the morning.

This will reduce the chances of stomach upset.

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it

Keep taking Doxylin for the full time of treatment, even if you begin to feel better after a few days, unless advised by your doctor.

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 or two weeks.

For controlling acne, Doxylin is normally taken for a few months.

For preventing malaria, Doxylin is normally recommended to be taken for up to 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.

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 tablets as you would normally.

Do not take a double dose to make up for the dose you missed.

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

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Doxylin. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention. Symptoms of overdose include nausea and vomiting.

While you are taking Doxylin

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Doxylin.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

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

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

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

If you are taking Doxylin for a long time, visit your doctor regularly so that they can check on your progress.

Your doctor may want you to have some blood tests from time to time. This helps to prevent unwanted side effects.

If you are taking iron or calcium preparations (including vitamin preparations that contain iron or calcium) or antacids, you must take them at least two hours before or two hours after Doxylin to make sure there is no problem with absorption.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

Doxylin may interfere with the results of some tests.

Things you must not do

Do not take Doxylin 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 without checking with your doctor.

If you do not complete the full course prescribed by your doctor, all the bacteria causing your infection may not be killed. These bacteria may continue to grow and multiply

so that your infection may not clean completely or may return.

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.

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 severe sunburn.

If your skin does appear to be burning, tell your doctor before you take your next dose of 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.

Sometimes use of this medicine allows fungi to grow. These fungi are not killed by Doxylin.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Doxylin.

Like other medicines, Doxylin may have unwanted 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.

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

You may not experience any of them.

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

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

- * feeling sick, vomiting, diarrhoea
- * taste loss
- * sore mouth or tongue
- * loss of appetite

- * stomach pain
- * oral thrush (white, furry sore tongue and mouth)
- * vaginal thrush (sore and itchy vagina, vaginal discharge)
- * tooth discolouration
- * nail changes from exposure to sunlight
- * persistent noise in the ears
- * difficulty or pain when swallowing.

The above side effects are usually mild.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at the nearest hospital:

- * heartburn or indigestion, which may be due to irritation of the oesophagus (food pipe)
- * severe diarrhoea, usually with blood and mucus, stomach pain and fever
- * bleeding or bruising more easily than normal
- * being short of breath when exercising, often with tiredness, headaches, dizziness, looking pale, and signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- * signs of liver disease such as feeling generally unwell, fever, itching, yellowing of the skin and/or eyes, and dark coloured urine
- * passing little or no urine
- * joint pain, muscle tenderness or weakness
- * severe sunburn that occurs more quickly than normal
- * rash or itching
- * flaking of the skin
- * 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.

The side effects listed above are serious and require medical attention.

However, these side effects are rare.

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

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

After finishing Doxylin

See your doctor immediately if you notice any of the following, even 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.

These are rare but serious side effects. You may need urgent medical attention or hospitalisation. Doxylin can cause some bacteria that are normally harmless and present in the bowel to multiply and cause the above symptoms.

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

After taking it

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30 degrees C.

Do not store Doxylin or any other medicine in the bathroom or near a sink. Do not leave it in the car or on a window sill.

Heat and dampness can destroy some medicines.

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.

Disposal

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.

Product description

What it looks like

Doxylin is available in two strengths:

- * Doxylin 50 mg - round, yellow tablet marked "DE" over "50" one side and "G" on the reverse.
- * Doxylin 100 mg - round, yellow tablet marked "DE" over "100" one side and "G" on the reverse.

Doxylin 50 is available in bottles of 25 tablets.

Doxylin 100 is available in packs of 7 tablets.

Ingredients

The active ingredient in Doxylin tablets is doxycycline (as hydrochloride).

Doxylin 50 tablets contain 50 mg of doxycycline and Doxylin 100 tablets contain 100 mg of doxycycline.

Doxylin tablets also contain the following inactive ingredients:

- * cellulose - microcrystalline
- * starch - pregelatinised maize
- * silica - colloidal anhydrous
- * magnesium stearate
- * lactose
- * hypromellose
- * macrogol 4000
- * titanium dioxide
- * quinoline yellow CI47005
- * sunset yellow FCF CI15985
- * indigo carmine CI73015.

This medicine does not contain gluten.

Manufacturer

Doxylin is made in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

Phone: (02) 9298 3999

www.alphapharm.com.au

Medical Information

Phone: 1800 028 365

Australian registration numbers:

Doxylin 50 - AUST R 63512

Doxylin 100 - AUST R 63509

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