

DOXYLIN

doxycycline hyclate (as 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 risks and benefits. 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 an antibiotic used to:

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

This medicine 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.

Tetracyclines will not work against infections caused by viruses, 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.

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 have an allergy to:

- any medicine containing doxycycline
- any medicines containing other tetracyclines
- 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 take this medicine if you are taking other medicines containing vitamin A, isotretinoin or etretinate.

DOXYLIN should not be taken if you are more than 18 weeks pregnant or are breastfeeding. 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.

Do not give this medicine to children aged eight years or under 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 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, preservatives or dyes.

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

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

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

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 them 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 your 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, 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 (phenobarbitone)
- 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.

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 this medicine.

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.

If you do not understand the instructions on the box/bottle, ask your doctor or pharmacist for help.

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 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.

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.

If you are taking iron or calcium medicines (including vitamins that contain iron or calcium) or antacids, you must take them at

least two hours before or two hours after taking DOXYLIN to make sure there are no problems with absorption.

Do not lie down immediately after taking DOXYLIN.

It is important to not lie down for at least half an hour after swallowing your medicine, so that the tablet can move swiftly 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 your medicine 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 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 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 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 much (overdose)

Immediately telephone your doctor or the 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 or pharmacist.

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.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

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 clear 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 SPF 30+ sunscreen.

DOXYLIN may cause your skin to be more sensitive to sunlight than normal. 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.

This medicine helps most people, but it may have unwanted side effects in a few people. 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 the following lists of 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
- stomach upset or vomiting
- oral thrush (white, furry sore tongue and mouth)
- vaginal thrush (sore and itchy vagina, vaginal discharge)
- rash or itching
- nail changes
- persistent ringing or noise in the ears

The above side effects are usually mild.

If any of the following happen, tell your doctor immediately or go to

Accident and Emergency at your nearest hospital:

- increased pressure in the brain (headache, blurred vision, vomiting)
- 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
- dizziness
- fast heart rate
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
- 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
- pain or difficulty in swallowing
- severe sunburn that occurs more quickly than normal
- severe skin reactions starting as painful red areas then large blisters and ends with peeling of layers of 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 above list includes serious side effects that may require medical attention. Serious 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, 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.

After taking DOXYLIN

Storage

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

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

Keep your tablets in a cool dry place where the temperature stays below 30°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:

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

DOXYLIN 50 mg is available in bottles of 25 tablets.

DOXYLIN 100 mg is available in blister packs of 7 and 21 tablets.

Ingredients

DOXYLIN contains either 50 mg or 100 mg of doxycycline (as hydrochloride) as the active ingredient.

The tablets also contain the following inactive ingredients:

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

DOXYLIN contains sulfites and lactose monohydrate. This medicine does not contain gluten.

Manufacturer

DOXYLIN is made in Australia by:

Alphapharm Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Australian registration numbers:

Doxylin 50 - AUST R 63512

Doxylin 100 - AUST R 63509

This leaflet was prepared in

May 2020.

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