APO-Doxycycline Tablets

Doxycycline monohydrate

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about doxycycline. 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 using this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may want to read it again.

What this medicine is used for

Doxycycline is used to:

- treat certain types of infections
- control acne
- · prevent some forms of malaria.

Doxycycline belongs to a group of medicines called tetracycline antibiotics.

How it works

Doxycycline works by killing or stopping the growth of bacteria which cause infections or make acne worse. It also works against parasites that cause malaria. It will not work against infections caused by viruses such as colds or the flu.

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

Your doctor may have prescribed this medicine for another reason.

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

This medicine is not addictive.

This medicine should not be given to children 8 years of age or under for infections, or to children 10 years of age or under for preventing malaria.

Doxycycline, like other tetracyclines, may cause enamel loss and staining in developing teeth or increase the pressure on your child's brain.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- doxycycline
- · 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, throat or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine if you are taking methoxyflurane or oral retinoid medicines such as vitamin A, isotretinoin or etretinate.

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 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 have or have had any of the following medical conditions:

- · liver disease
- systemic lupus erythematosus (a disease affecting the skin, joints and kidneys).

Tell your doctor if you work outdoors, or you are exposed to direct sunlight or ultra-violet light.

Doxycycline may cause your skin to become more sensitive to UV or sunlight, resulting in severe sunburn.

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

This medicine should not be taken during the last half of pregnancy.

Doxycycline, like other tetracyclines, may cause enamel loss and staining in developing teeth or increase the pressure on your child's brain. High doses of tetracyclines may also cause liver problems in pregnant women.

Doxycycline should not be used in breastfeeding women.

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you get from your pharmacy, supermarket or health food shop.

Some medicines may interact with doxycycline. These include:

 oral retinoid medicines such as preparations containing vitamin A, isotretinoin or etretinate.

You must not take doxycycline with these medicines.

- warfarin and other medicines used to prevent blood clots.
- penicillin antibiotics
- barbiturates (e.g. phenobarbitone)
- medicines used to treat seizures (e.g. phenytoin, carbamazepine)
- methoxyflurane, an anaesthetic
- acetazolamide and ethoxzolamide, used to help the body get rid of salt and water
- · disodium hydrogen edetate
- sodium bicarbonate, found in indigestion remedies
- · sodium lactate
- 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.

If you are taking any of these, you may need a different dose, or you may need to take different medicines.

Some medicines may interfere with the absorption of doxycycline into the body. Do not take any of the following medicines whilst taking doxycycline:

- medicines for indigestion (e.g. calcium, magnesium or aluminium salts found in antacids, or bismuth salts)
- preparations that contain iron including vitamin preparations.
- other preparations containing calcium, magnesium or aluminium

In addition, alcohol can reduce the blood levels of doxycycline and should be avoided.

Other medicines not listed above may also interact with doxycycline.

How to take this medicine

Follow carefully all directions given to you by your doctor.

They may differ to the information contained in this leaflet.

How much to take

Your doctor will tell you how much of this medicine you should take, depending on your condition, age, body weight and whether you are taking any other medicines.

For treating infections

The usual dose is 100 mg twice a day for the first day, followed by 100 mg once a day thereafter.

For acne:

The usual dose is 50 mg once a day.

For the prevention of malaria:

The usual dose is 100 mg once a day, commencing two days before entering the malarious area, during the visit, and for four weeks after

leaving the area. You should ensure that you take your medicine with unfailing regularity for the whole time you are there and after leaving the malarious area, as parasites may still emerge from the liver for up to four weeks after the last possible exposure to infection.

Travel medicine advice may change from time to time and it is best to ask your doctor or pharmacist for the most up to date information about which antimalarial medicines are suitable for certain areas, and for how long you need to take the medicine after leaving the malarious

How to take it

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

Do not crush or chew the tablets.

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 tablet. This is to help avoid irritation to your food pipe, also called the oesophagus.

When to take it

Take your medicine during or immediately after a meal, at about the same each day (preferably in the morning).

If you take it on an empty stomach, it may cause stomach upset.

Avoid taking doxycycline at bedtime.

How long to take it for

Keep taking this medicine for as long as your doctor has told you, 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, doxycycline is normally taken for one to two weeks.

For controlling acne, doxycycline 50 mg daily is normally taken over a period of twelve weeks.

For preventing malaria, doxycycline 100 mg daily is normally taken for up to eight weeks.

Your doctor may prescribe doxycycline for longer periods.

Make sure you have enough to last over weekends and holidays.

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 at the usual time.

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 missed doses.

This may increase the chance of you experiencing side effects.

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 the Emergency Department at your nearest hospital if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much doxycycline, you may feel sick or be sick.

While you are taking this medicine

Things you must do

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

If you get severe diarrhoea tell your doctor immediately. Do this even if it occurs several weeks after you have stopped taking this medicine.

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical attention.

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

If you are about to be started on any new medicine, tell your doctor that you are taking this medicine.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

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

Tell your doctor if you are about to have any blood tests.

Keep all your doctor's appointments.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

Things you must not do

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not take your medicine to treat any other complaint unless your doctor tells you to.

Do not stop taking your medicine, or change the dosage, without first checking with your doctor.

If you do not complete the full course, 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 it may return.

Things to be careful of

Protect your skin when you are in the sun, especially between 10am and 3pm. Do not use a sunlamp while taking doxycycline.

Doxycycline 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 outdoors, wear protective clothing and use a 30+ sunscreen.

If your skin appears to be burning, tell your doctor as soon as possible.

Be careful driving or operating machinery until you know how doxycycline affects you.

Side effects

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

All medicines can have side effects. Sometimes they are serious but most of the time they are not. You may need medical attention 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.

Tell your doctor if you notice any of the following:

- oral thrush white, furry, sore tongue and mouth
- vaginal thrush sore and itchy vagina and/or discharge
- nail changes (i.e. change in colour or loosening from the nail bed)
- stomach upsets, such as pain, indigestion, or feeling sick
- loss of appetite or taste sensation
- sore mouth or tongue
- mild irritation of the oesophagus (food pipe)

- difficulty or pain when swallowing
- tooth discolouration, changes in tooth enamel

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Emergency department at your nearest hospital:

- shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin (signs of an allergic reaction)
- increased pressure in the brain (headache, blurred vision, vomiting)
- severe diarrhoea, stomach cramps
- · severe sunburn
- flaking of the skin
- more frequent bruising than normal
- passing less urine than normal
- yellowing of the skin or eyes, pale stools, dark urine (jaundice)
- a rare, potentially life-threatening, drug-induced sensitivity reaction that includes skin rashes, blood changes, fever and dysfunction of internal organs

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after you have finished taking doxycycline:

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

These are serious side effects that may need urgent medical attention. Doxycycline can cause some bacteria that are normally harmless and present in the bowel to multiply and cause the above symptoms.

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

Other side effects not listed above may occur in some patients.

Storage and disposal

Storage

Keep your medicine in its pack until it is time to take it.

If you take your medicine out of its pack it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C. Protect it from light.

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

Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-anda-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 left over.

Product description

What it looks like

50 mg tablets: Dull yellow, round biconvex tablets.

Blister packs of 25. AUST R 78597

100 mg tablets: Dull yellow, round, biplane tablets with a single sided scored notch.

Blister packs of 7 & 21. AUST R 78598

*Not all strengths and/or pack sizes may be available.

Ingredients

Each tablet contains either 50 mg or 100 mg of doxycycline monohydrate as the active ingredient.

It also contains the following:

- microcrystalline cellulose
- sodium starch glycollate
- hydrogenated castor oil
- povidone
- colloidal anhydrous silica magnesium stearate.

This medicine does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Sponsor

Apotex Pty Ltd 16 Giffnock Avenue Macquarie Park NSW 2113

APO and APOTEX is a registered trade mark of Apotex Pty Ltd.

This leaflet was prepared in April 2019.