

GenRx Doxycycline Tablets

Contains the active ingredient, doxycycline (as monohydrate)

Consumer Medicine Information

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

What is in this leaflet

Read this leaflet carefully before taking your medicine.

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.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information

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.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is GenRx Doxycycline. It contains the active ingredient, doxycycline (as the monohydrate).

It is an antibiotic which belongs to a group called tetracyclines.

It is used to:

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

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.

How it works

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.

It will not work against infections caused by viruses such as colds or the flu.

There is no evidence that this medicine is addictive.

This medicine is not expected to affect your ability to drive a car or operate machinery, but make sure

you know how it affects you before driving.

As with many other medicines, doxycycline may cause dizziness or tiredness in some people.

Use in children

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.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **you are more than 16 weeks pregnant, or you are breast-feeding**

Doxycycline, like other tetracyclines, may harm your developing or breast-feeding baby by causing enamel loss and staining of your child's teeth, affecting bone growth or increasing the pressure on your child's brain.

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

- **it has passed the expiry date (EXP) printed on the pack.**
- **the packaging is torn, shows signs of tampering or it does not look quite right.**
- **you have had an allergic reaction to doxycycline, other**

tetracyclines or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include cough, 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, fainting or hayfever-like symptoms.

If you think you are having an allergic reaction, contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

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

Do not give this medicine to children aged eight years or under for infections, or to children aged 10 years or under for preventing malaria, unless directed by the child's doctor.

Doxycycline, like other tetracyclines, may cause enamel loss and staining in developing teeth and affect bone growth. It may also cause increased pressure on the brain if used in infants.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

2. You have or have had any medical conditions, especially the following:

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

3. You are pregnant or planning to become pregnant

This medicine must not be used in pregnant women 16 weeks post-conception.

4. You are breast-feeding or planning to breast-feed

This medicine passes into breast milk and may harm your baby. Your doctor will discuss with you other options such as a different antibiotic or stopping breast-feeding.

5. You are planning to have surgery

Some anaesthetics and other drugs used during operations may be affected by or interfere with doxycycline.

6. You are about to have any blood or urine tests

Some tests are affected by doxycycline in the body.

7. You are likely to be exposed to UV light or direct sunlight

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

8. You are currently receiving or are planning to receive dental treatment.

9. You are taking or are planning to take any other medicines.

This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with doxycycline. These include:

- preparations containing Vitamin A
- some medicines used for skin problems, such as isotretinoin or etretinate
- warfarin, and other medicines used to prevent blood clots.
- another group of antibiotics called penicillins
- barbiturates such as phenobarbitone
- some medicines used in the treatment of epilepsy (and certain other conditions) such as phenytoin and carbamazepine
- methoxyflurane, an anaesthetic
- acetazolamide and ethoxzolamide, medicines used to

help the body get rid of salt and water

- disodium hydrogen edetate
- sodium bicarbonate, found in indigestion remedies and also given by injection
- 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 and for 7 days after taking doxycycline. Refer to your doctor or pharmacist for advice.

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:

- calcium, magnesium or aluminium salts found in antacids, medicines for indigestion
- bismuth salts, found in some medicines used to treat stomach ulcers or indigestion
- 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 or pharmacist.

Their instructions may be different to the information in this leaflet.

How much to take

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

For children over 8 years old who weigh less than 50 kg:

Your doctor will work out the right dose, depending on the weight of the child.

For adults and children over 8 years old (who weigh more than 50 kg):

For treating infections, the usual dose of doxycycline is two 100 mg tablets on the first day, followed by one 100 mg tablet each day from then on.

For controlling acne, the usual dose is 50 mg (taken as one 50 mg tablet or half a 100 mg tablet) each day.

For the prevention of malaria in adults, and children older than 10 years:

The usual dose is one 100 mg tablet each day, commencing two days before entering the malarious area, during the visit, and for two 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.

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

How to take it

Doxycycline tablets are taken by mouth.

Swallow the tablets whole with a full glass of water or milk while sitting or standing upright. Do not crush or chew doxycycline 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 this medicine at the same time each day. Taking it at the same time each day will have the best effect and it will also help you remember when to take it.

Take your medicine during or immediately after a meal.

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, 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, doxycycline is usually taken for one to two weeks.

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

For preventing malaria, doxycycline is recommended to be taken for up to 8 weeks.

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 unwanted side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

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, pharmacist or nurse 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 care.

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

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you plan to have any vaccinations or immunisations
- you become pregnant or plan to breastfeed

- you are about to have any blood tests
- you are going to have surgery.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

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

Things you must 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.

- **give this medicine to anyone else, even if their symptoms seem similar to yours.**
- **take your medicine to treat any other condition unless your doctor or pharmacist tells you to**
- **stop taking your medicine, or change the dosage, without first checking with your doctor.**

Things to be careful of

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

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 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 doxycycline, tell your doctor.

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

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

Doxycycline generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, doxycycline may cause dizziness or tiredness in some people.

Possible side effects

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

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

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

This list includes the more common side effects. Mostly, these are mild:

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

- tooth discolouration, changes in tooth enamel
- headache
- flushing
- itchy or swollen eyes
- strange touch sensations
- sleepiness, apathy
- ringing or other persistent noise in the ears.

Tell your doctor as soon as possible if you notice any of the following.

These may be serious side effects. You may need medical attention. Most of these side effects are rare.

- vomiting
- depression
- fever, joint pain and swollen glands
- feeling confused, anxious or nervous
- hallucinations (seeing, hearing or feeling things that are not there)
- muscle tenderness or weakness, not caused by exercise
- painful swollen joints
- painful or ulcerated oesophagus (food pipe)
- yellowing of the skin or eyes, and/or pale stools, dark urine (jaundice)
- dizziness
- bleeding or bruising more easily than normal
- severe sunburn
- flaking of the skin
- hypotension /low blood pressure (feeling faint or dizzy)

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

These are very serious side effects and are usually very rare. You may need urgent medical attention or hospitalisation.

- fast heart rate

- severe diarrhoea, stomach cramps,
- 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
- increased pressure in the brain (headache, blurred vision, vomiting)
- passing less urine than normal
- if you suffer from Systemic Lupus Erythematosus, and your symptoms become worse.

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

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

Allergic reactions

If you think you are having an allergic reaction to doxycycline, stop taking this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, 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
- fainting
- hayfever-like symptoms

After finishing it

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 abdominal cramps or stomach cramps
- watery and severe diarrhoea, which may also be bloody

- fever, in combination with one or both of the above.

These are rare but serious side effects. You may have a serious condition affecting your bowel.

Doxycycline can change bacteria (which are normally present in the bowel and normally harmless), so that they multiply and cause the above symptoms. You may need urgent medical attention. However, this side effect is rare.

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

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it. If you take your medicine out of its original packaging 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-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What GenRx Doxycycline Tablets look like

GenRx Doxycycline 50 mg Tablets:

Dull yellow, round tablets.

Blister packs of 25.

GenRx Doxycycline 100 mg Tablets:

Dull yellow, round tablets with a single sided score notch.

Blister packs of 7 and 21.

Ingredients

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

It also contains the following inactive ingredients:

- microcrystalline cellulose
- sodium starch glycollate
- hydrogenated castor oil
- povidone
- colloidal silicon dioxide
- magnesium stearate.

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

GenRx Doxycycline 50 mg Tablets

Blister packs

AUST R Number 78597

GenRx Doxycycline 100 mg Tablets

Blister packs

AUST R Number 78598

Sponsor

Apotex Pty Ltd

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North Ryde NSW 2113

Australia

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