

# APO-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

You can also download the most up to date leaflet from [www.apotex.com.au](http://www.apotex.com.au).

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 APO-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.

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.

#### 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.**

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 are taking oral retinoid medicines such as preparations containing vitamin A, isotretinoin or etretinate.**
- **You are hypersensitive to, or 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 hay fever-like symptoms.

**If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.**

- **The expiry date (EXP) printed on the pack has passed.**
- **The packaging is torn, shows signs of tampering or it does not look quite right.**

#### 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 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.
  4. You are currently pregnant or you plan to become pregnant, or you are currently breastfeeding or you plan to breastfeed.  
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.
  5. You are planning to have surgery or an anaesthetic.
  6. You are currently receiving or are planning to receive dental treatment.
  7. 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:

- 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.
- another group of antibiotics called penicillins

- barbiturates such as phenobarbitone
- anticonvulsant medicines that are used to treat seizures, 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.

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.

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## How to take this medicine

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Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

### *How much to take*

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

For treating infections, the usual dose of doxycycline is 100 mg twice a day for the first day, followed by 100 mg once a 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) 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.**

**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 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.

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

### *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, effectiveness after this period has not been established.

For preventing malaria, doxycycline 100 mg daily is normally taken for up to eight weeks, safety after this period has not been established.

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)*

**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.

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**While you are taking this medicine**

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*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.**

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 are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast-feed
- 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:**

- 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 tells you to.
  - Stop taking your medicine, or change the dosage, without first checking with 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.**

*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 does appear to be burning, tell your doctor as soon as possible.**

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

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## Possible side effects

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**Tell your doctor 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 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 Accident and Emergency department at your nearest hospital.**

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

- 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, and/or 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 (e.g. liver, kidney, lung).

**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 of the above.

These are serious side effects. You 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.

### *Allergic reactions*

**If you think you are having an allergic reaction to doxycycline, do not take any more of 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, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

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## Storage and disposal

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

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## Product description

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### *What APO-Doxycycline looks like*

APO-Doxycycline 50 mg Tablets:  
Dull yellow, round biconvex tablets.  
Blister packs of 25

APO-Doxycycline 100 mg Tablets:  
Dull yellow, round, biplane tablets with a single sided scored notch.  
Blister packs of 7 & 21

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

### *Ingredients*

Each tablet contains either 50 mg or 100 mg of doxycycline (as monohydrate) 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*

APO-Doxycycline 50 mg blister pack: AUST R 78597

APO-Doxycycline 100 mg blister pack: AUST R 78598

### *Sponsor*

Apotex Pty Ltd  
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