

NEW ZEALAND CONSUMER MEDICINE INFORMATION

DOXINE

Doxycycline Film Coated Tablet 100 mg



What is in this leaflet

Please read this leaflet carefully before you start taking DOXINE.

This leaflet answers some common questions about DOXINE.

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 DOXINE 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 need to read it again.

What DOXINE is taken for

DOXINE is taken to treat infections of the chest, urethra, womb and rectum.

DOXINE may be used in combination with amoebicides, which are used to treat parasites.

DOXINE may also be used to treat severe acne.

DOXINE contains the active ingredient doxycycline. It is a broad spectrum antibiotic. This means it can be used to treat a wide range of organisms.

Doxycycline belongs to a class of medicines called tetracyclines. These medicines work by killing or stopping the growth of bacteria,

which cause infections or make acne worse.

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 available only with a doctor's prescription.

Before you take DOXINE

When you must not take it

Do not take DOXINE if you have an allergy to:

- doxycycline
- other tetracycline antibiotics (e.g. minocycline)
- 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 DOXINE if you are taking preparations containing vitamin A (e.g. Vesanoid), isotretinoin (e.g. Isotane, Oratane) or etretinate.

Do not give this medicine to children under the age of 12 years.

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

Do not take this medicine if you are pregnant or plan to become pregnant.

Doxine, like other tetracyclines, may

harm your developing baby if you take it during pregnancy.

Tetracyclines may cause enamel loss and staining of your baby's teeth or increase the pressure on your child's brain.

Do not breast-feed if you are taking this medicine.

The active ingredient in DOXINE passes into breast milk and there is a possibility that it may cause permanent staining (yellow-grey-brown) and enamel loss in developing teeth or affect your baby's bone growth.

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.

Tell your doctor if you plan to have surgery, including dental surgery, especially if it requires a general anaesthetic.

If you are given an anaesthetic containing methoxyflurane while taking Doxine, you may have a severe or life-threatening reaction.

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 medical conditions.

Tell your doctor if you work outdoors or 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 DOXINE.

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 DOXINE may interfere with each other. These include:

- another group of antibiotics called penicillins (e.g. Amoxil, Augmentin)
- phenytoin (e.g. Dilantin), carbamazepine or barbiturates (e.g. Phenobarbitone), which are anticonvulsant medicines used for epilepsy
- warfarin, a medicine used to prevent blood clots (e.g. Coumadin, Marevan)
- preparations containing vitamin A (e.g. Vesanoid), including vitamin supplements
- preparations containing calcium or iron, including vitamin supplements
- antacids, used for indigestion
- some medicines used for skin problems, such as isotretinoin (e.g. Isotane, Oratane) or etretinate
- sodium bicarbonate
- sodium lactate
- disodium hydrogen edetate
- acetazolamide (e.g. Diamox) or ethoxzolamide, medicines used to treat glaucoma (raised eye pressure). Acetazolamide may also be used as a diuretic (increasing urine output)
- methoxyflurane, an anaesthetic agent
- the contraceptive pill (birth control pill). DOXINE 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 DOXINE and for 7 days after taking DOXINE.

These medicines may be affected by DOXINE 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 DOXINE.

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

How to take DOXINE

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 bottle, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how much DOXINE you need to take each day and when to take it. This depends on your condition and other factors such as your weight, 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.

Children over 12 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 while sitting or standing upright. Stay upright for up to 2 hours. Do not lie

down immediately after taking DOXINE. This is so that the tablet can move swiftly as possible into the stomach and prevent irritation of your throat or oesophagus (food pipe), which you may feel as heartburn or indigestion.

Take DOXINE during or immediately after a meal, preferably in the morning. This will reduce the chances of a stomach upset.

When to take it

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.

If you need to take an antacid, take it at least 2 hours before or 2 hours after your dose of DOXINE.

How long to take it

Do not stop taking DOXINE, even if you feel better, unless advised by your doctor.

Your infection may not clear completely if you stop taking your medicine too soon.

For infections your doctor will tell you when to stop taking DOXINE as the length of treatment varies depending on the condition you have. It is usually stopped 24 to 48 hours after the fever and signs of the infection have gone.

For controlling acne, DOXINE is usually taken for a few months.

Keep taking DOXINE for as long as your doctor recommends. The duration of treatment your doctor has prescribed may be different from the above.

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 that you missed.

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.

While you are taking DOXINE

Things you must do

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

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

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 DOXINE to make sure there is no problem with absorption.

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

If you are going to have surgery, tell the surgeon or anaesthetist

that you are taking this medicine. It may affect other medicines used during surgery.

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 DOXINE 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 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. Do not use a sun lamp while taking DOXINE. DOXINE 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, stop taking DOXINE and tell your doctor.

If you get a sore, white mouth or tongue while taking or soon after stopping DOXINE, tell your doctor. Also tell your doctor if you get vaginal itching or discharge. **This may mean you have a fungal infection called thrush.**

Sometimes, the use of DOXINE allows fungi to grow and the above symptoms to occur. DOXINE does not work against fungi.

Be careful when drinking alcohol while you are taking this medicine. Levels of DOXINE in the body are reduced by the ingestion of alcohol.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much DOXINE. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Side effects

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

This medicine helps most people, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, 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.

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)
- nail changes
- joint pain, muscle tenderness or weakness
- persistent ringing in the ears
- heartburn or indigestion, which may be due to irritation of the oesophagus (food pipe)
- dizziness.

The above list includes the more common side effects of your medicine.

They are usually mild and short-lived.

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

- changes in mood.
- staining of the teeth, loss of tooth enamel.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

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

- headache with blurred visions and vomiting (signs of increased pressure in the brain)
- difficulty or pain when swallowing
- 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
- 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
- sharp chest pain, fast heart rate
- severe sunburn that occurs more quickly than normal
- severe skin rash, itching, or hives; blistering, flaking or peeling of the skin
- shortness of breath, wheezing or troubled breathing; swelling of the face, lips, tongue or other parts of the body.

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.

See your doctor immediately if you notice any of the following, even if they occur several weeks after stopping treatment with DOXINE:

- 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. DOXINE 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 checking with your doctor.

After taking DOXINE

Storage

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

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

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store DOXINE 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 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

DOXINE tablets are round, yellow film-coated tablets, debossed 'DE' over '100' on one side, 'G' on the reverse.

Ingredients

Active ingredient:

DOXINE contains 115 mg of doxycycline hyclate, which is equivalent to 100 mg of doxycycline as the active ingredient

Inactive ingredients:

DOXINE also contains:

- microcrystalline cellulose
- pregelatinised maize starch
- colloidal silicon dioxide
- magnesium stearate
- lactose monohydrate
- titanium dioxide (E171)
- hypromellose (E464)
- macrogol (E1521)
- quinoline yellow lake (E104)
- sunset yellow lake (E110)
- indigo carmine lake (E132)

Contains lactose and sulfites.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

DOXINE is supplied in New Zealand by:

Viatrix Ltd
PO Box 11-183
Ellerslie
AUCKLAND
www.viatrix.co.nz
Telephone 0800 168 169

Date of Preparation

06 November 2023 (Based on datasheet dated 06 November 2023)