

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Doxycycline Sandoz.

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 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 need to read it again.

WHAT DOXYCYCLINE SANDOZ IS USED FOR

This medicine is used to:

- treat certain infections
- control acne
- prevent a form of malaria
- treat anthrax infection or for use after exposure to anthrax.

It contains the active ingredient doxycycline.

Doxycycline 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. They also work against parasites that cause malaria.

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 DOXYCYCLINE SANDOZ

When you must not take it

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

- doxycycline, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description
- any other similar medicines such as tetracyclines.

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 preparations containing isotretinoin, tretinoin or Vitamin A. Ask your doctor or pharmacist if you are not sure if you are taking one of these medicines.

Do not take this medicine if you are more than 18 weeks pregnant or are breast-feeding.

As with many medicines, 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. High doses of tetracyclines may also cause liver problems in pregnant women.

Do not give this medicine to children ages eight years or under unless directed by the child's doctor.

Doxycycline 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 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 ever had any other health problems
- you are scheduled to have surgery under general anaesthetic
- you work outdoors or you are exposed to direct sunlight or ultra-violet light.

Tell your doctor if you are pregnant or plan on getting pregnant.

Tell your doctor if you are breastfeeding or plan on breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking Doxycycline Sandoz.

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 Doxycycline Sandoz may interfere with each other. These include:

- preparations containing Vitamin A
- some medicines used for skin problems such as isotretinoin or tretinoin
- warfarin, a medicine used to prevent blood clots
- methoxyflurane, an inhaled anaesthetic
- the contraceptive (birth control) pill. Doxycycline Sandoz 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 this medicine.**
- penicillin antibiotics
- barbiturates such as phenobarbitone
- anticonvulsant medicines that are used to treat seizures, such as phenytoin and carbamazepine
- sodium bicarbonate
- acetazolamide, a medicine used to treat glaucoma.

These medicines may be affected by Doxycycline Sandoz or may affect how well it works. You may need different amounts of

your medicines, or you may need to take different medicines.

Alcohol and some medicines may interfere with the absorption of Doxycycline Sandoz. These include:

- iron preparations (including vitamin preparations containing iron)
- antacids and other medicines containing aluminium, calcium or magnesium.
- Bismuth salts, found in some medicines used to treat stomach ulcers

Do not drink alcohol or take any of these medicines if you are taking Doxycycline Sandoz.

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

HOW TO TAKE DOXYCYCLINE SANDOZ

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, ask your doctor or pharmacist for help.

How much to take

For treating infections, the usual dose of Doxycycline Sandoz 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:

- one 50 mg tablet each day.

For the prevention of malaria, the usual dose is:

- one 100 mg tablet each day, commencing two days before entering the malarious area, during the visit, and two weeks after leaving the area.

Doxycycline Sandoz is normally used in combination with other antimalarial medicine.

For the treatment of anthrax infection or after exposure, the usual dose is:

- one 100 mg tablet every 12 hours in adults and 2.2 mg/kg every 12 hours for children (8 years or younger and children weighing 45 kg and less).

Depending on your condition and how you react to the medicine, your doctor may ask you to take a different dose.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Doxycycline Sandoz may not work as well and your problem may not improve.

How to take it

If you need to break Doxycycline Sandoz 100 mg tablets, hold tablet with both hands and snap along break line.

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

Do not lie down immediately after swallowing your tablet(s).

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 (oesophagus).

When to take Doxycycline Sandoz

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

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

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

How long to take Doxycycline Sandoz

Continue taking your medicine for as long as your doctor tells 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 Sandoz is usually taken for one or two weeks.

For controlling acne, Doxycycline Sandoz is usually taken for a period up to 12 weeks.

For preventing malaria, Doxycycline Sandoz is normally recommended to be taken up to a maximum of 8 weeks.

For treating or after exposure to anthrax, Doxycycline Sandoz is usually taken for at least 60 days.

If you forget to take it

Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that 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 Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766) 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 Doxycycline Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include nausea and vomiting.

WHILE YOU ARE TAKING DOXYCYCLINE SANDOZ

Things you must do

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

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

If you are taking Doxycycline Sandoz 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 stopping this medicine.

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

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

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.

If you are taking iron preparations, including vitamins that contain iron, bismuth salts or antacids (containing aluminium, calcium or magnesium), you must take them at least two hours before or two hours after this medicine, to make sure there is no problem with absorption.

Things you must not do

Do not take Doxycycline Sandoz 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 10 am and 3 pm. Do not use a sunlamp while taking this medicine.

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

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.

SIDE EFFECTS

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

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.

While taking it

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

- oral thrush (white furry, sore tongue and mouth)
- vaginal thrush (sore and itchy vagina and/or discharge)
- rash or itching
- nail changes
- stomach upset or vomiting
- difficulty in swallowing
- mild irritation of the oesophagus (food pipe)
- taste loss
- ringing or other persistent noise in the ears.

These are the more common side effects of your medicine. These side effects are usually mild.

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

- depression
- feeling anxious or nervous
- muscle tenderness or weakness, not caused by exercise
- painful swollen joints

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

- increased pressure in the brain (headache, blurred vision, vomiting)
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
- severe skin reactions starting as painful red areas then larger blisters and ends with peeling layers of skin
- difficulty swallowing
- pain when swallowing
- flaking of the skin
- dizziness
- fast heart rate
- frequent bruising
- passing less urine
- yellowing of the eyes or skin (jaundice)
- severe upper stomach pain often with nausea and vomiting (pancreatitis)
- symptoms of an allergic reaction such as shortness of breath, wheezing or troubled breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin
- a rare, potentially life-threatening, drug-induced sensitivity reaction that includes skin rashes, blood changes, fever and dysfunction of internal organs (eg. Liver, kidney, lung)
- a reaction that can happen after starting doxycycline therapy for a particular bacterial infection (spirochete infections, eg. Lyme disease); symptoms include

fever, chills, muscle pain or worsening of skin rash.

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

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

Other side effects not listed above may also occur in some people.

After finishing it

Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after stopping Doxycycline Sandoz:

- severe abdominal cramps or stomach cramps
- watery and severe diarrhoea, which may 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 Sandoz can cause some bacteria that are normally harmless and present in the bowel to multiply and cause the above symptoms. Therefore you may need urgent medical attention.

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

AFTER TAKING DOXYCYCLINE SANDOZ

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

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

Keep your medicine where it is protected from light.

Do not store Doxycycline Sandoz 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

Doxycycline Sandoz comes in two types of tablets:

Doxycycline Sandoz 50 mg - dull yellow, round, biconvex tablet.

Available in blisters of 25 tablets.

Doxycycline Sandoz 100 mg - dull yellow, round, biplane tablet with a single sided score notch.

Available in blisters of 7 tablets.

Ingredients

Active ingredient:

- Doxycycline Sandoz 50 mg - 50 mg doxycycline (as monohydrate)
- Doxycycline Sandoz 100 mg - 100 mg doxycycline (as monohydrate).

Inactive ingredients:

- microcrystalline cellulose
- sodium starch glycolate type A
- hydrogenated castor oil
- povidone
- colloidal anhydrous silica
- magnesium stearate.

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

Supplier

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road
Macquarie Park, NSW 2113
Australia
Tel: 1800 726 369

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PO Box 99102
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Australian Register Numbers

Doxycycline Sandoz 50 mg tablets: AUST R 69049 (blisters)

Doxycycline Sandoz 100 mg tablets: AUST R 66302 (blisters)