

DOXSIG tablets

doxycycline hyclate (hydrochloride) 50 mg & 100 mg tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DOXSIG.

It does not contain all of 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 taking DOXSIG against the benefits they expect it will have for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What DOXSIG is used for

DOXSIG is an antibiotic used to

- Treat certain infections
- Control acne
- Prevent malaria

DOXSIG tablets belong 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. They also work against parasites which cause malaria. Tetracyclines will not work against viral infections such as colds or the 'flu'.

Your doctor, however, may prescribe DOXSIG for another purpose. Ask your doctor if you have any questions about why DOXSIG has been prescribed for you.

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

There is no evidence that DOXSIG is addictive.

Before You Take DOXSIG

When you must not take DOXSIG

Do not take DOXSIG if:

1. You have ever had an **allergic reaction** to
 - Medicines containing doxycycline, or doxycycline hydrochloride
 - Medicines containing other tetracyclines
 - Any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction to tetracyclines may include: rash, itching or hives of the skin, swelling of the face, lips and tongue or other parts of the body, shortness of breath, wheezing or troubled breathing

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

3. You are **in the second or third trimester of pregnancy or breastfeeding**

As with many medicines, tetracyclines can harm the developing or breastfeeding baby. This may include enamel loss and staining of the child's teeth and increase the pressure on your child's brain.

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

If you are not sure whether you should be taking DOXSIG, talk to your doctor.

Do not take DOXSIG if:

- **The expiry date on the pack has passed**
If you take this medicine after the expiry date has passed it may have no effect at all, or worse, an entirely unexpected effect.
- The packaging is torn or shows signs of tampering.

Do not give DOXSIG to children of eight years and under unless directed by the child's doctor.

DOXSIG like all other tetracyclines may cause enamel loss and staining in developing teeth.

Before you start to take DOXSIG

You must tell your doctor if:

1. **You are allergic to any other medicines or substances such as foods, dyes or preservatives**
2. **You have or have ever had any other health problems**
3. **You plan to become pregnant or breastfeed**
4. **You are scheduled to have surgery under general anaesthetic**
5. **You are exposed to direct sunlight or ultra violet light**

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking DOXSIG.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and DOXSIG may interfere with each other, including:

- preparations containing Vitamin A
 - some medicines used for skin problems such as isotretinoin or tretinate
 - warfarin, a medicine used to stop blood clotting
 - another group of antibiotics called penicillins
 - Methoxyflurane, an inhaled anaesthetic
 - Barbiturates such as phenobarbitone
 - Medicines containing sodium bicarbonate
 - Acetazolamide and ethoxzolamide, a medicine used to treat glaucoma
 - The contraceptive pill (birth control pill). DOXSIG may decrease the effectiveness of some birth control pills.
- Your doctor may advise you to use an alternative method of contraception while taking DOXSIG**
- some medicines for epilepsy such as phenytoin, carbamazepine or phenobarbitone

These medicines may be affected by DOXSIG or may affect how well it works. You may need different amounts of your medicine.

Some medicines may interfere with the absorption of DOXSIG tablets. These include:

- **iron preparations**, including vitamin preparations which contain iron
- **antacids** used for indigestion containing aluminium, calcium or magnesium
- do not drink alcohol or take any of these medicines if you are taking DOXSIG tablets.

You can still take these medicines while you are taking DOXSIG. However, you must take your DOXSIG Tablets at least two hours before or two hours after taking any of these medicines to make sure that there is no problem with absorption.

How to take DOXSIG

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help

How much to take

Depending on your condition, your doctor will tell you how much DOXSIG to take. Follow all instructions carefully.

How to take it

Swallow the prescribed dose of DOXSIG whole with a full glass of water or milk while standing upright. Do not lie down immediately after swallowing DOXSIG. It is important to drink adequate amounts of fluid and to stay upright, for example sitting, standing or walking for at least half an hour after swallowing your tablet. This is to help avoid irritation and ulceration oesophagus (foodpipe).

When to take it

Take DOXSIG tablets during or immediately after a meal, at about the same time each day (usually in the morning). If taken on an empty stomach, DOXSIG may cause a stomach upset.

Late evening ingestion of the tablet should be avoided.

How long to take it

For controlling acne, DOXSIG tablets should be taken as prescribed by your doctor. For severe acne the tablets may be taken up to a maximum of 12 weeks.

For treating infections DOXSIG tablets are usually taken for one to two weeks. Do not stop taking DOXSIG because you are feeling better. If you do not complete the full course prescribed by your doctor, the infection may not clear completely or your symptoms may return.

For preventing malaria, DOXSIG tablets are normally recommended to be taken for up to a maximum of eight weeks.

However, your doctor may prescribe DOXSIG tablets for longer periods. Check with your doctor if you are not sure how long you should be taking it.

Continue taking DOXSIG tablets until you finish the pack or until your doctor recommends.

Follow all directions given to you by your doctor and pharmacist carefully.

If you forget to take DOXSIG

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 the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much DOXSIG. 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, vomiting and diarrhoea.

While you are taking DOXSIG

Things you must do

If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.

If you get severe diarrhoea tell your doctor, pharmacist or nurse immediately.

Do this even if this occurs several weeks after you have stopped taking DOXSIG. 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.

If you get a sore white mouth or tongue while taking or soon after stopping DOXSIG 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 DOXSIG allows fungi to grow and the above symptoms to occur. DOXSIG do not work against fungi.

If you become pregnant while you are taking DOXSIG, tell your doctor.

If you are about to start taking a new medicine tell your doctor and pharmacist that you are taking DOXSIG.

Things you must not do

Do not stop taking your tablets because you are feeling better, unless advised to do so by your doctor.

If you do not complete the full course prescribed by your doctor, the infection may not clear completely or your symptoms may return.

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

Do not use DOXSIG to treat any other complaints unless your doctor tells you to.

Things to be careful of

Protect your skin when you are in the sun, especially between 10am and 3pm. 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, stop taking DOXSIG and tell your doctor.

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

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

Side Effects

Tell your doctor or pharmacist as soon as possible if you have any problems while you are taking DOXSIG, even if you do not think that the problems are connected with the medicine or are not listed in this leaflet.

Like all medicines, DOXSIG can cause side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

Ask your doctor or pharmacist to answer any questions you may have.

While taking DOXSIG

Tell your doctor 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
- nausea
- vomiting
- loss of appetite
- stomach pain
- darkened tongue
- taste loss
- tooth discolouration

Tell your doctor immediately, or go to the nearest casualty at your local hospital if you notice any of the following:

- skin rash/hives/itchy skin
- joint pain
- difficulty breathing
- fever
- sore throat
- more frequent bruising than normal
- severe sunburn
- yellowing of the eyes or skin (jaundice).

After finishing DOXSIG

Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after stopping treatment with DOXSIG

- **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.

Therefore you may need urgent medical attention.

However, this side effect is very rare.

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

Some people may experience other side effects while taking DOXSIG.

Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects you may not experience any of them.

After taking DOXSIG

Storage

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

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

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store DOXSIG or any other medicine in the bathroom or near a sink.

Do not leave DOXSIG in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep DOXSIG 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 DOXSIG, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

DOXSIG 50 mg and 100 mg tablets contain 50 or 100 mg of doxycycline respectively as doxycycline hyclate (hydrochloride).

DOXSIG 50 mg tablets
White film-coated, circular, biconvex tablet having a diameter of approximately 6.3mm. Presented in PVC/PVDC/Al blister packs of 25 tablets (AUST R 148807)

DOXSIG 100 mg tablets
White, film-coated, biconvex tablets with a breakline on one face, for oral use, diameter 9.1mm. Presented in PVC/PVDC/Al blister packs of 7 or 21 tablets (AUST R 148808),

Ingredients

Active Ingredient:

Doxycycline (as doxycycline hydrochloride)

Other Ingredients:

- microcrystalline cellulose
- magnesium stearate
- colloidal anhydrous silica
- maize starch
- Opadry White Y-7000B

DOXSIG tablets do not contain any gluten, lactose, sucrose, tartrazine or any other azo food dyes.

Name and Address of the Sponsor

Arrow Pharma Pty Ltd
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