

DOXSIG® Tablets

doxycycline hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about DOXSIG Tablets. 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 DOXSIG Tablets against the benefits the medicine is expected to 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 DOXSIG® Tablets are used for

DOXSIG Tablets are an **antibiotic** used to:

- **treat bacterial 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. They also work against parasites which cause malaria.

Tetracyclines will not work against viral infections such as colds or the 'flu.

Your doctor may have prescribed this medicine for another purpose.

Ask your doctor if you have any questions about why DOXSIG Tablets have been prescribed for you.

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

There is no evidence that DOXSIG Tablets are addictive.

Before you take it

When you must not take it

Do not take DOXSIG Tablets 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 on 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 etretinate.**
Ask your doctor or pharmacist if you are not sure if you are taking one of these medicines.
3. **If you are pregnant 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.

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

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

Do not take DOXSIG Tablets if:

- **the expiry date on the pack has passed.**
If you take this medicine after the 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 Tablets to children of eight years and under unless directed by the child's doctor.

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

Before you start to take DOXSIG Tablets

You must tell your doctor if:

1. **You are allergic to any other medicines or other 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 to breastfeed.**
4. **You are scheduled to have surgery under general anaesthetic.**

If you have not told your doctor or pharmacist about any of the

above, tell them before you start taking DOXSIG Tablets.

Taking other medicines

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

There may be an interference between DOXSIG Tablets and some other medicines, including

- preparations containing **Vitamin A**
- some medicines used for skin problems such as **isotretinoin** or **etretinate**
- **warfarin**, a medicine used to stop blood clotting
- another group of antibiotics called **penicillins**
- the **contraceptive pill** (birth control pill). DOXSIG Tablets may decrease the effectiveness of some birth control pills.

Your doctor may advise you to use an alternative method of contraception while taking DOXSIG Tablets

- some **medicines for epilepsy** such as phenytoin, carbamazepine or phenobarbitone

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

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

- **iron preparations**, including vitamin preparations which contain iron.
- **antacids** used for indigestion

You can still take these medicines while you are taking DOXSIG Tablets. However, you must take 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 it

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 box/bottle, ask your doctor or pharmacist for help.

How much to take:

For treating infections, the usual dose of DOXSIG Tablets is:

- **2 tablets (200mg) on the first day of treatment** (usually given as one tablet every 12 hours), the dose is **then decreased to 100mg (one tablet) daily**. For more severe infections the (such as long term urinary tract infections) the dose may be 100mg (one tablet) every 12 hours.

For controlling acne, the usual dose is:

- 50mg (half a tablet) taken once a day, for several weeks.

For the prevention of malaria, the usual dose is:

- **one 100mg tablet each day**, commencing two days prior to entering an malarious area, during the visit, and for two weeks after leaving the area. DOXSIG Tablets are normally used in combination with another anti-malarial medicine.

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

How to take it

Swallow DOXSIG Tablets whole with a full glass of water or milk while standing upright. Do not lie down immediately after swallowing DOXSIG Tablets.

It is important 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 to your food pipe, also called oesophagus.

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 Tablets may cause a stomach upset.

How long to take it

For treating infections DOXSIG Tablets are usually taken for one to two weeks.

Do not stop taking DOXSIG Tablets 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 controlling acne, DOXSIG tablets are normally taken for a few months.

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 for.

Continue taking DOXSIG Tablets until you finish the bottle or until your doctor recommends.

If you forget to take it

If it is almost time to take your next dose, skip the dose that you have missed and take your next dose when you are meant to. Otherwise take it as soon as you remember, then go back to taking your tablets as usual.

Do not double a dose to make up for a dose that you have missed.

If you take too much (overdose):

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to the casualty

department at your nearest hospital, if you think that you or anyone else may have taken too many DOXSIG Tablets. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep telephone numbers of these places/services handy.

If you take too many DOXSIG Tablets, you may suffer nausea, vomiting and diarrhoea.

While you are using it

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 Tablets.

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 Tablets, 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 Tablets allows fungi to grow and the above symptoms to occur. DOXSIG Tablets do not work against fungi.

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

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

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 your medicine to anyone else even if they have the same condition as you.

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

Things to be careful of

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

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

Side effects

Check with your doctor or pharmacist as soon as possible if you have any problems while you are taking DOXSIG Tablets, 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 Tablets 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 you are taking DOXSIG Tablets

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

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

After finishing DOXSIG® Tablets

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

- 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 Tablets.

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 using it

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 as well.

Keep DOXSIG Tablets in a cool dry place where the temperature stays below 30°C.

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

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

Heat and dampness can destroy some medicines.

Keep your 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

Tell your doctor if you stop taking the tablets or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets which are left over.

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

Supplier

DOXSIG Tablets are supplied by:

Aspen Pharma Pty Ltd
34-36 Chandos Street
St Leonards NSW 2065
Australia

TGA registration No. AUST R
62056

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2004.

Product Description

What DOXSIG Tablets look like

DOXSIG Tablets are white, film-coated, biconvex tablets with a breakline on one face, the other face is plain. DOXSIG Tablets are available as bottles of 7 tablets.

Ingredients

Active ingredient:

DOXSIG Tablets contain, 100mg doxycycline as doxycycline hydrochloride.

Other ingredients (excipients):

Microcrystalline cellulose, maize starch, colloidal anhydrous silica, magnesium stearate and Opadry white Y-1-7000B.