

DORYX®

(dor-IX)

doxycycline hyclate (hydrochloride) (dox-I-SYE-kleen)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DORYX. 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 DORYX against the benefits this 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 DORYX is used for

DORYX is an antibiotic used to:

- treat certain types of infections
- control acne
- prevent some forms of malaria, sometimes in combination with another antimalarial medicine.

This medicine 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. It also works against parasites that cause malaria.

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

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 not addictive.

It is available only with a doctor's prescription.

Before you take DORYX

When you must not take it

Do not take DORYX if you have an allergy to:

- any medicine containing doxycycline
- other tetracyclines
- 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 troubled 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 vitamin A, isotretinoin or etretinate. 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 aged eight years or under unless directed by the child's doctor.

DORYX 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 be taking DORYX, 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 any other health problems.

Tell your doctor if you work outdoors or if you are likely to be exposed to strong sunlight or ultra-violet light.

Doxycycline may cause your skin to become more sensitive to UV or sunlight, resulting in severe sunburn.

Tell your doctor if you are scheduled to have surgery under general anaesthetic.

Taking other medicines

Tell your doctor 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 DORYX may interfere with each other. These include:

- preparations containing Vitamin A
 - some medicines used for skin problems, such as isotretinoin or etretinate
 - warfarin, a medicine used to prevent blood clotting
 - another group of antibiotics called penicillins
 - some medicines used in the treatment of epilepsy such as phenytoin, carbamazepine or phenobarbitone
 - methoxyflurane, an anaesthetic
 - acetazolamide, a medicine used to help the body get rid of salt and water
 - the contraceptive pill (birth control pill). DORYX may decrease the effectiveness of some birth control pills.
- Your doctor may advise you to use an additional method of contraception while taking DORYX and for 7 days after taking DORYX. Refer to your doctor or pharmacist for advice.**

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

If you are taking the following medicines, take them at least two hours before or two hours after taking DORYX:

- antacids (containing aluminium, calcium or magnesium) used for indigestion
- bismuth salts, found in some medicines used to treat stomach ulcers

- preparations that contain iron including vitamin preparations.

These medicines may interfere with the absorption of DORYX.

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

How to take DORYX

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

Your doctor or pharmacist will tell you how many capsules you will need to take each day.

For treating infections, the usual dose of doxycycline is two 100 mg capsules on the first day, followed by one 100 mg capsule each day from then on.

For controlling acne, the usual dose is one 50 mg capsule each day.

For the prevention of malaria, the usual dose is one 100 mg capsule each day, commencing two days before entering the malarious area, during the visit, and for four weeks after leaving the area.

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

How to take it

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

Do not lie down immediately after swallowing DORYX.

It is important to stay upright, for example sitting, standing or walking around for at least half an hour after swallowing your capsule. This is to help avoid irritation to your food pipe, also called the oesophagus.

Do not chew the capsules.

When to take it

Take your medicine at about the same time each day (usually in the morning).

Taking it at the same time each day will have the best effect. It will also help you to remember when to take it.

Take your medicine during or immediately after a meal.

If taken on an empty stomach, it may cause stomach upset.

How long to take it

Continue taking your medicine until you finish the pack or for as long as your doctor recommends.

Keep taking this medicine for the full time of treatment 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, DORYX is usually taken for one to two weeks.

For controlling acne, DORYX is normally taken over a period of 12 weeks.

For preventing malaria, DORYX is recommended to be taken for up to a maximum of 8 weeks. However, your doctor may prescribe DORYX for longer periods.

If you are not sure how long you should be taking this medicine, talk to your doctor.

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 double a dose to make up for the dose you have 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 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much DORYX. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include an upset stomach or vomiting.

While you are taking DORYX

Things you must do

If you are taking DORYX 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 or pharmacist immediately. Do this even if it occurs several weeks after DORYX has been stopped.

Diarrhoea may mean that 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.

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

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

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 vitamin preparations containing iron, bismuth salts or antacids (containing aluminium, calcium or magnesium), you must take them at least two hours before or two hours after DORYX to make sure there is no problem with absorption.

Things you must not do

Do not stop taking your medicine because you are feeling better unless advised by 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.

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

Do not use DORYX 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. If outdoors, wear protective clothing and use a 30+ sunscreen.

DORYX 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 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 DORYX, tell your doctor.

Sometimes the use of this medicine allows fungi to grow as they are not killed by DORYX.

Side effects

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

This medicine is effective against infections/acne and helps prevent malaria for most people, but it may have unwanted side effects in some people. 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:

- oral thrush - white, furry, sore tongue and mouth
- vaginal thrush - sore and itchy vagina with or without discharge
- rash or itching
- nail changes
- stomach upset or vomiting
- mild irritation of the oesophagus (food-pipe)
- taste loss
- ringing or other persistent noise in the ears.

The above list includes the more common side effects.

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.

The above list includes serious side effects which may require medical attention.

If any of the following happen, 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 large blisters and ends with peeling layers of skin
- difficulty in 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 (e.g. liver, kidney, lung).
- a reaction that can happen after starting doxycycline therapy for a particular bacterial infection (spirochete infections, e.g. Lyme disease); symptoms include fever, chills, muscle pain and worsening of skin rash.

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

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

Other side effects not listed above may 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 treatment with DORYX:

- 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. DORYX may cause the bacteria which are normally harmless and present in the bowel to multiply, resulting in the above symptoms. Therefore you may need urgent medical attention.

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

Ask your doctor or pharmacist to answer any questions you may have about the side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using DORYX

Storage

Keep your capsules in their pack until it is time to take them. Avoid exposure to light.

If you take the capsules out of the pack they may not keep as well.

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

Do not store DORYX 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

DORYX capsules come in two strengths:

DORYX 100 mg - clear capsules filled with yellow pellets, marked DORYX 100 in black. It is available in HDPE bottles of 7 or 21 capsules.

DORYX 50 mg - clear capsules filled with yellow pellets, marked DORYX 50 in black. It is available in HDPE bottles of 25 capsules.

Ingredients**Active ingredients:**

DORYX 100 mg - contains 100 mg of doxycycline as doxycycline hyclate (hydrochloride) in each capsule.

DORYX 50 mg - contains 50 mg of doxycycline as doxycycline hyclate (hydrochloride) in each capsule.

Other ingredients:

- lactose monohydrate
- cellulose (460)
- povidone
- hypromellose phthalate
- hypromellose
- diethyl phthalate
- wheat starch (contains gluten)
- magnesium stearate
- hyprolose
- gelatin
- Opacode Black A-10259 (contains shellac, carbon black, pharmaceutical glaze and ethanol)

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

Manufacturer/Distributor

Mayne Pharma International Pty Ltd
 ABN 88 007 870 984
 1538 Main North Road
 Salisbury South SA 5106

Doryx® is a registered trademark of Mayne Pharma International Pty Ltd.

AUST R numbers

- DORYX 100 mg - AUST R 30100
- DORYX 50 mg - AUST R 29728

This leaflet was prepared in May 2019.