

Ditropan

DIT-ro(h)-pan)

oxybutynin hydrochloride (oxy-BEAUT-in-in HIGH-dro(h)-CLOR-ride)

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Ditropan.

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 or pharmacist has weighed the risks of you taking Ditropan 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 Ditropan is used for

Ditropan is used to decrease the urgency and the frequency of urination. Ditropan works by relaxing the bladder smooth

muscle and helps to decrease muscle spasm. This delays the initial desire and the urge to urinate.

Your doctor may have prescribed Ditropan for another reason.

Ask your doctor or pharmacist if you have any questions about why Ditropan has been prescribed for you.

There is no evidence that Ditropan is addictive.

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

Ditropan is not recommended for use in children under the age of 5 years, as there have been no studies of its effects in children.

Before you take it

When you must not take it

Do not take Ditropan if you have an allergy to Ditropan or any of the ingredients listed at the end of this leaflet.

Do not take Ditropan if you have:

- angle closure glaucoma or shallow anterior chamber - disorders of the eye
- partial or complete intestinal blockage; stomach, intestinal or large bowel problems including colitis (inflammation of the colon)
- myasthenia gravis - a disease of the muscles

- urinary tract blockage
- severe bleeding

Do not take Ditropan if you are pregnant or intend to become pregnant.

The safety of the use of Ditropan in women who are pregnant or may become pregnant has not been established.

Like most medicines, Ditropan is not recommended for use during pregnancy, unless you and your doctor or pharmacist have discussed the risks and benefits involved.

Do not take Ditropan if you are breastfeeding or plan to breastfeed.

Like most medicines, Ditropan is not recommended while you are breastfeeding.

Do not give Ditropan to a child under 5 years, unless directed by the child's doctor or pharmacist.

The safety and effectiveness of Ditropan in children under 5 years have not been established.

Use caution when giving Ditropan to children age 5 years or older.

Children are more sensitive to the effects of Ditropan.

Do not take Ditropan after the expiry date (EXP) printed on the pack.

If you take this medicine after the expiry date has passed, it may not work as well.

Do not take Ditropan if the packaging is torn or shows signs of tampering or if the tablets don't quite look right.

If you are not sure whether you should start taking Ditropan, contact your doctor or pharmacist.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant.

Your doctor or pharmacist will discuss the possible risks and benefits of using Ditropan during pregnancy.

Tell your doctor or pharmacist if you are breastfeeding or plan to breastfeed.

Your doctor or pharmacist will discuss the possible risks and benefits of using Ditropan during breastfeeding or if planning to breastfeed.

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- liver, kidney or heart problems
- high blood pressure
- thyroid problems
- enlarged prostate gland
- autonomic neuropathy (a disorder of the nervous system)
- angle closure glaucoma or shallow anterior chamber - disorders of the eye
- partial or complete intestinal blockage; stomach, intestinal or large bowel problems including colitis (inflammation of the colon)
- myasthenia gravis - a disease of the muscles
- Parkinson's disease
- urinary tract blockage
- severe bleeding
- hiatus hernia (movement of the stomach up into the chest with heart burn)
- diarrhoea

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

Taking other medicines

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

Some medicines and Ditropan may interfere with each other. These include:

- digoxin - used to treat diseases of the heart (irregular heart rate, chronic heart failure)
- L-dopa - used to treat a disease of the brain affecting movement (Parkinson's disease)
- phenothiazines - a group of anti-psychotic drugs
- butyrophenones - a group of anti-psychotic drugs
- tricyclic antidepressants - used to treat depression
- amantidine - used to treat viral infection
- hyoscine - a muscle relaxant
- prokinetic drugs - medicines used to promote stomach emptying
- some antihistamines - used to treat the symptoms of hayfever

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

medicine, or you may need to take different medicines. Your doctor or pharmacist will advise you.

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

How to take it

How much to take

Your doctor or pharmacist will tell you how many tablets you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

The usual adult dose is one 5mg tablet two to three times per day. Your doctor may reduce this dosage depending on your general condition.

The usual dose for children over 5 years of age is one 5mg tablet twice a day.

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

These directions 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 to take it

Swallow Ditropan with a glass of water.

When to take it

Take Ditropan at about the same time each day.

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

How long to take it

Continue taking the tablets for as long as your doctor or pharmacist tells you.

Ditropan helps control your condition, but does not cure it. Therefore, you must take Ditropan every day.

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.

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 pharmacist or the Poisons

Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Ditropan. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much Ditropan, you may feel

- restless or excited
- flushing, light headedness or dizziness
- difficulty in breathing
- numbness in the hands or feet

While you are taking it

Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Ditropan.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking Ditropan.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking Ditropan.

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

Things you must not do

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

Do not take Ditropan to treat any other complaints unless your doctor or pharmacist tells you to.

Things to be careful of

Ditropan may make you sweat less, causing your body temperature to rise. Take extra care to avoid becoming overheated during exercise or hot weather, since overheating may result in heat stroke.

This is particularly relevant to children who often run around playing in the hot sun.

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

Ditropan may cause drowsiness or blurred vision in some people. Make sure you know how you react to Ditropan before

you drive a car, operate machinery, or do anything else that could be dangerous if you are drowsy or have blurred vision. If this occurs, do not drive.

Alcohol or other sedatives may increase the drowsiness that may be caused by Ditropan.

Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

You may not experience any of them.

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

Ditropan helps most people, but it may have unwanted side effects in a few people.

If you are elderly, you may be especially sensitive to the effects of Ditropan. This may increase the chance of side effects during treatment.

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

- nausea or vomiting
- headache

- dryness of the mouth, nose and throat
- drowsiness
- constipation
- decreased sweating
- diarrhoea
- stomach discomfort
- loss of appetite
- heartburn
- dry skin
- nosebleed
- muscle weakness, aches or spasms
- urinary tract infection

These side effects are usually mild.

Tell your doctor or pharmacist immediately if you notice any of the following:

- fast or irregular heartbeat
- flushing
- dizziness

- unusual tiredness or weakness
- restlessness or trouble sleeping
- hallucinations
- nightmares
- confusion, nervousness (feeling anxious) or severe suspiciousness (paranoia)
- agitation
- convulsions, fits or seizures
- eye problems, including dry eyes or blurred vision
- difficulty urinating
- skin rash
- decreased flow of breast milk
- impotence

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

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

- fever or heat stroke

- numbness in the hands or feet
- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- hives
- fainting
- yellowing of the skin and eyes also called jaundice

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

All of these side effects are very rare.

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

Other side effects not listed above may occur in some patients.

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

You may not experience any of them.

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

After taking 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 will not keep well.

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

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

Do not leave it in the car on hot days or on window sills.

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 or pharmacist tells you to stop taking Ditropan or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Return any unused medicine to your pharmacist.

Product description

What it looks like

Ditropan tablets are round, light blue in colour, single scored and blank on both sides. Ditropan is supplied in bottles containing 100 tablets.

Ingredients

Ditropan does not contain gluten, sucrose, tartrazine or any other azo dyes.

Active ingredient:

- oxybutynin hydrochloride 5mg

Inactive ingredients:

- lactose anhydrous
- cellulose - microcrystalline
- calcium stearate
- Brilliant Blue FCF (CI 42090)

Sponsor

Ditropan is supplied in Australia by:

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

Australian Registration Number: AUST R 48965

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