

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I taking Ditropan?

Ditropan contains the active ingredient oxybutynin hydrochloride. Ditropan is used to decrease the urgency and the frequency of urination. For more information, see Section [1. Why am I taking Ditropan?](#) in the full CMI.

2. What should I know before I take Ditropan?

Do not take if you have ever had an allergic reaction to oxybutynin hydrochloride, oxybutynin or any of the ingredients listed at the end of the CMI.

Do not take if you have angle closure glaucoma or a shallow anterior chamber; partial or complete intestinal blockage; stomach, intestine or large bowel problems including colitis; myasthenia gravis; urinary tract blockage; or severe bleeding.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or breastfeeding. For more information, see Section [2. What should I know before I use Ditropan?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Ditropan and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take Ditropan?

- The usual adult dose is one 5 mg 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 5 mg tablet twice a day.
- Swallow Ditropan with a glass of water.
- More instructions can be found in Section [4. How do I take Ditropan?](#) in the full CMI.

5. What should I know while taking Ditropan?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking Ditropan.• If you become pregnant while taking Ditropan, tell your doctor immediately.
Things you should not do	<ul style="list-style-type: none">• 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 tells you to.
Things to be careful of	<ul style="list-style-type: none">• Take extra care to avoid becoming overheated during exercise or hot weather, since overheating may result in heat stroke.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how Ditropan affects you. Ditropan may cause drowsiness or blurred vision in some people.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.• Alcohol or other sedatives may increase the drowsiness that may be caused by Ditropan.
Looking after your medicine	<ul style="list-style-type: none">• Store in original bottle at below 25°C until it is time to take them. Protect from light.

For more information, see Section [5. What should I know while taking Ditropan?](#) in the full CMI.

6. Are there any side effects?

Serious side effects may include restlessness or trouble sleeping, nightmares, dizziness, unusual tiredness or weakness, hallucinations, confusion, nervousness or severe suspiciousness, convulsions, fits or seizures, agitation, fast or irregular heartbeat, eye problems, including dry eyes or blurred vision, flushing, skin rash, decreased flow of breast milk, difficulty urinating, impotence. Very serious side effects may include fever or heat stroke, numbness in the hands or feet, yellowing of the skin and eyes, swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing, hives, fainting.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Ditropan[®] (DIT-ro(h)-pan)

Active ingredient(s): *oxybutynin hydrochloride* (oxy-BEAUT-in-in HIGH-dro(h)-CLOR-ride)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Ditropan. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Ditropan.**

Where to find information in this leaflet:

- [1. Why am I taking Ditropan?](#)
- [2. What should I know before I take Ditropan?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take Ditropan?](#)
- [5. What should I know while taking Ditropan?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking Ditropan?

Ditropan contains the active ingredient *oxybutynin hydrochloride*.

Ditropan is an antispasmodic and anticholinergic 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 if you have any questions about why Ditropan has been prescribed for you.

2. What should I know before I take Ditropan?

Warnings

Do not take Ditropan if you:

- are allergic to *oxybutynin hydrochloride*, *oxybutynin*, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can take this medicine.

- have angle closure glaucoma or a 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 causing muscle weakness
- urinary tract blockage
- severe bleeding.

Check with your doctor if you have any other 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)
- Parkinson's disease
- hiatus hernia (movement of the stomach up into the chest with heart burn)
- diarrhoea.

Check with your doctor if you take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor 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.

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

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Ditropan is not recommended while you are breastfeeding.

Children under 5 years of age

Ditropan is not recommended for use in children under the age of 5 years, unless directed by the child's doctor.

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

Children over 5 years of age

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

Children are more sensitive to the effects of Ditropan.

3. What if I am taking other medicines?

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

Some medicines may interfere with Ditropan and affect how it works.

Medicines that may increase the effect of Ditropan 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
- amantadine - used in Parkinson's disease or to treat viral Type A influenza infection
- hyoscine - a muscle relaxant
- some antihistamines - used to relieve symptoms of allergy.

Ditropan may **reduce** the effect of some medicines, including:

- prokinetic drugs - medicines used to promote stomach emptying
- cholinesterase inhibitors - medicines used to treat myasthenia gravis and Alzheimer's disease.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Ditropan.

4. How do I take Ditropan?

How much to take

The usual adult dose is one 5 mg 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 5 mg tablet twice a day.

Follow the instructions provided by your doctor and take Ditropan until your doctor tells you to stop.

When to take Ditropan

- Ditropan should be taken 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 to take Ditropan

Swallow Ditropan with a glass of water.

If you forget to take Ditropan

Ditropan should be taken regularly at the same time each day.

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 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 doctor or pharmacist for some hints.

If you take too much Ditropan

If you think that you have taken too much Ditropan, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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.

5. What should I know while taking Ditropan?

Things you should do

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

Remind any doctor, dentist or pharmacist you visit that you are taking Ditropan.

Things you should 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 tells you to.

Things to be careful of

Take extra care to avoid becoming overheated during exercise or hot weather, since overheating may result in heat stroke.

Ditropan may make you sweat less, causing your body temperature to rise.

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

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Ditropan affects you.

Ditropan may cause drowsiness or blurred vision in some people. If you have any of these symptoms, do not drive, use any machines or tools or do anything else that could be dangerous if you are drowsy or have blurred vision.

Drinking alcohol

Tell your doctor if you drink alcohol.

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

Looking after your medicine

Store Ditropan tablets below 25°C. Protect from light.

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.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date printed on the bottle. Do not take this medicine if the packaging is torn or shows signs of tampering.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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

Less serious side effects

Less serious side effects	What to do
Alertness and sleep-related: <ul style="list-style-type: none"> • headache • drowsiness. 	Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you. These side effects are usually mild.
Infection-related: <ul style="list-style-type: none"> • urinary tract infection. 	
Bleeding-related: <ul style="list-style-type: none"> • nosebleed. 	
Stomach and gut-related: <ul style="list-style-type: none"> • nausea or vomiting • loss of appetite • heartburn • stomach discomfort • diarrhoea • constipation. 	
Skin and muscle-related: <ul style="list-style-type: none"> • dryness of the mouth, nose and throat • dry skin • decreased sweating 	

Less serious side effects	What to do
<ul style="list-style-type: none"> • muscle weakness, aches or spasms. 	

Serious side effects

Serious side effects	What to do
Alertness and sleep-related: <ul style="list-style-type: none"> • restlessness or trouble sleeping • nightmares • dizziness • unusual tiredness or weakness • hallucinations • confusion, nervousness (feeling anxious) or severe suspiciousness (paranoia) • convulsions, fits or seizures • agitation. 	Call your doctor or pharmacist straight away, if you notice any of these serious side effects.
Heart-related <ul style="list-style-type: none"> • fast or irregular heartbeat. 	
Sight, hearing, smell, taste or touch-related: <ul style="list-style-type: none"> • eye problems, including dry eyes or blurred vision. 	
Skin and muscle-related: <ul style="list-style-type: none"> • flushing • skin rash. 	
Other: <ul style="list-style-type: none"> • decreased flow of breast milk • difficulty urinating • impotence. 	

Very serious side effects

Very serious side effects	What to do
Alertness and sleep-related: <ul style="list-style-type: none"> • fainting. 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.
Allergy-related: <ul style="list-style-type: none"> • swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing • hives. 	
Sight, hearing, smell, taste or touch-related: <ul style="list-style-type: none"> • numbness in the hands or feet. 	
Skin and muscle-related: <ul style="list-style-type: none"> • yellowing of the skin and eyes (jaundice). 	
Other:	

Very serious side effects	What to do
<ul style="list-style-type: none"> fever or heat stroke. 	

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

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Ditropan contains

Active ingredient (main ingredient)	oxybutynin hydrochloride 5mg
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> lactose microcrystalline cellulose calcium stearate Brilliant Blue FCF aluminium lake
Potential allergens	lactose

Do not take this medicine if you are allergic to any of these ingredients.

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

What Ditropan 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 (AUST R 48965).

Who distributes Ditropan

Distributed by:

sanofi-aventis australia Pty Ltd

International Tower 3, Level 23

300 Barangaroo Avenue

Sydney NSW 2000

Freecall: 1800 818 806

Email: medinfo.australia@sanofi.com

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