

PACKAGE LEAFLET: INFORMATION FOR THE USER

Ditropan® 2.5mg and 5mg Tablets

Oxybutynin hydrochloride

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. Section 4.

What is in this leaflet:

1. What Ditropan Tablets is and what it is used for
2. What you need to know before you take Ditropan Tablets
3. How to take Ditropan Tablets
4. Possible side effects
5. How to store Ditropan Tablets
6. Contents of the pack and other information

1. What Ditropan Tablets are and what they are used for

What Ditropan Tablets are

Ditropan Tablets contains a medicine called oxybutynin hydrochloride. This belongs to two groups of medicines called 'anticholinergics' and 'antispasmodics'.

How Ditropan Tablets work

It works by relaxing the muscles of the bladder and stops sudden muscle contractions (spasms). This helps control the release of water (urine).

What Ditropan Tablets are used for

Ditropan Tablets can be used in adults and children 5 years or older to treat:

- Loss of control in passing water (urinary incontinence)
- Increased need or urgency to pass water (urine)
- Night time bedwetting, when other treatments have not worked

2. What you need to know before you take Ditropan Tablets

Do not take Ditropan tablets:

- X You are allergic (hypersensitive) to oxybutynin hydrochloride or any of the other ingredients of Ditropan Tablets (listed in Section 6: Contents of the pack and other information)
Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue

- X You have a rare muscle illness called 'Myasthenia gravis'
- X You have glaucoma (increased pressure in the eye, sometimes sudden and painful with blurred vision or loss of vision)
- X Your gut (stomach or intestine) is blocked, perforated or not working properly
- X You have a severe form of a condition known as 'ulcerative colitis'
- X You have a blockage that makes it difficult for you to pass water (urine)

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Ditropan Tablets.

Warnings and precautions

Talk to your doctor or pharmacist before taking Ditropan Tablets

- You have kidney or liver problems
- You are 65 years of age or older
- The person taking the medicine is a child (use is not recommended under 5 years of age)
- You have an illness affecting the nerves called 'autonomic neuropathy'
- You have an overactive thyroid gland (Hyperthyroidism)
- You have heart disease or high blood pressure
- You have an irregular heart beat (palpitations) and/or increased or rapid heart beat
- You have an enlarged prostate gland
- You have indigestion or heart burn caused by a 'hiatus hernia' (where part of your stomach pushes through the diaphragm)
- You have a raised body temperature or fever
- You will be taking this medicine in a hot climate
- Ditropan may reduce the amount of saliva resulting in tooth decay or fungal infection of the mouth

Ditropan can cause glaucoma (increased pressure in the eye) please contact your doctor immediately if you suffer any blurred vision, loss of vision or have any pain in the eye.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Ditropan Tablets.

Other medicines and Ditropan Tablets

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Ditropan Tablets can affect the way some other medicines work. Also some medicines can affect the way Ditropan Tablets works.

In particular, tell your doctor if you are taking any of the following:

- Other anticholinergic or antimuscarinic medicines - such as some medicines for irritable bowel syndrome, asthma or incontinence, motion sickness or movement disorders associated with Parkinson's disease
- Medicines used to make you feel sleepy (sedatives) or if you are feeling sick (nausea) or have vertigo - such as prochlorperazine or chlorpromazine

- Medicines used to treat certain mental illnesses· such as clozapine, phenothiazines, haloperidol or benperidol (butyrophenones)
- Medicines for depression - such as amitriptyline, imipramine or dosulepin ('tricyclic antidepressants')
- Amantadine· used in Parkinson's disease or to treat and prevent some virus infections
- L·dopa - used to treat Parkinson's disease
- Digoxin· used to treat heart problems
- Medicines for stomach and bowel related problems - such as Domperidone, Metoclopramide, Bethanechol.

Pregnancy, breast-feeding and fertility

Talk to your doctor before taking this medicine if:

- You are pregnant, might become pregnant or think you may be pregnant.
- You are breast-feeding or planning to breast-feed. This is because small amounts may pass into mothers' milk. Breast feeding while using oxybutynin is therefore not recommended.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

You may feel drowsy or have blurred vision while you are taking this medicine. If this happens, do not drive or use any tools or machines.

Important information about some of the ingredients of Ditropan Tablets

This medicine contains:

- **Lactose:** If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking this medicine.

3. How to take Ditropan Tablets

Always take Ditropan Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth
- Swallow the tablets with a glass of water
- Do not give this medicine to children under 5 years old
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor

How much to take

Your doctor will decide the dose appropriate for you.

Adults

- The usual dose is one 5mg tablet two or three times each day

- Your doctor may decide to increase to the maximum dose of 5mg four times each day

Elderly

- The usual dose is 2.5mg twice each day
- Your doctor may decide to increase this to 5mg twice each day

Children (over 5 years)

- The usual dose is one 2.5mg tablet twice each day
- Your doctor may decide to increase this to one 5mg two or three times each day
- If you are giving it to a child to prevent bedwetting, give the last dose just before bedtime

If you take more Ditropan Tablets than you should

If you take more Ditropan Tablets than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken.

Taking too much Ditropan Tablets can be very dangerous. You may become very restless or excited, flushed or get dizzy or light-headed. Your heart beat may become very fast, uneven or forceful. You may get breathing problems or numbness or go into a coma.

If you forget to take Ditropan Tablets

If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. **Do not** take a double dose to make up for a forgotten dose.

If you stop taking Ditropan Tablets

Keep taking Ditropan Tablets until your doctor tells you to stop. Do not stop taking Ditropan Tablets just because you feel better.

4. Possible side effects

Like all medicines Ditropan Tablets can cause side effects, although not everybody gets them. Children are at higher risk of the effects.

Stop taking Ditropan Tablets and see a doctor or go to a hospital straight away if:

Frequency unknown

- You have an **allergic reaction**. The signs may include: a rash, swallowing or breathing problems, swelling of your, lips, face, throat or tongue
- You may feel reduced sweating, leading to overheating in hot environments

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:

Very common (affects more than 1 in 10 people)

- Constipation
- Nausea
- Dry mouth

- Dry skin, rash or skin that is more sensitive to the sun
- Headache
- Somnolence (feeling drowsy or sleepy)
- Dizziness
- Blurring of vision

Common (affects 1 to 10 people in a 100 people)

- Dry eyes
- Diarrhoea
- Being sick (vomiting)
- Confusion
- Flushing especially in children

Uncommon (affects 1 to 10 people in a 1,000)

- Stomach pain
- Loss of appetite (anorexia)
- Difficulty in swallowing (dysphagia)

Frequency not known: frequency cannot be estimated from the available data

- Increased pressure in the eyes sometimes sudden and painful with blurred vision or loss of vision (glaucoma)
- Indigestion or heartburn (acid reflux)
- Urinary tract infection
- Heat stroke
- Difficulty passing water (urine)
- Agitation
- Anxiety
- Becoming dependent on Ditropan
- Feeling excessive suspicious and distrustful of others
- Mental Health disorders
- Seeing or hearing things that are not there (hallucinations)
- Drowsiness
- Nightmares
- Fits (convulsions)
- Depression
- Increased heart beat (tachycardia)
- Irregular heart beat (arrhythmia)
- Dilation of pupil (mydriasis)
- Itchy, lumpy rash (urticaria)
- Absence of sweating (hypohidrosis)
- Skin that is more sensitive to the sun (photosensitivity)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the Yellow card Scheme Website:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ditropan Tablets

Keep this medicine in a safe place where children cannot see or reach it.

Do not use Ditropan Tablets after the expiry date which is stated on the blister or carton after EXP.

The expiry date refers to the last day of that month.

Store below 30°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Ditropan Tablets contains

- Each tablet contains 2.5 mg or 5mg of the active substance, oxybutynin hydrochloride.
- The other ingredients lactose, cellulose, calcium stearate and indigo carmine (E132).

What Ditropan Tablets looks like and contents of the pack

- Ditropan® 2.5mg Tablets are pale blue oval bi-convex tablets with OXB2.5 on one side.
- Ditropan® 5mg Tablets are pale blue circular tablets with OXB5 on one side and a break-line on the other side
- Supplied in blisters packs of 6, 21 or 84 tablets. Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Neon Healthcare Limited

Mill Studio

Crane Mead

Ware

SG12 9PY

United Kingdom

Manufacturer

Sanofi Winthrop Industrie

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37000 Tours

France

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

This leaflet was last revised in October 2020