

Package leaflet: Information for the user

Ditropan®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 only. Do not pass it on to others. It may harm them, even if their signs of illness 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. See section 4.

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1 What Ditropan Tablets are and what they are used for

What Ditropan Tablets are

Ditropan Tablets contain 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 to treat:
- * Loss of control in passing water (urinary incontinence)
 - * Increased need or urgency to pass water (urine)
 - * Night time bedwetting in children 5 years or older, when other treatments have not worked

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

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

2 What you need to know before you take Ditropan Tablets

Do not take this medicine and tell your doctor if:

- * 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
- * You have a rare muscle illness called 'Myasthenia gravis'
- * You have increased pressure in the eye (glaucoma)
- * Your gut (stomach or intestine) is blocked or perforated or not working properly
- * You have a severe form of a condition known as 'ulcerative colitis'
- * You have a blockage that makes it difficult for you to pass water (urine)
- * The patient is a child under 5 years of age
- * You have a fever, high body temperature or you are in a hot environment.
- * You currently suffer from a condition known as hiatus hernia whereby part of your stomach protrudes into the upper abdomen
- * If you have had surgery of the small intestine
- * If you have severe / life threatening inflammation of the colon (toxic megacolon / severe ulcerative colitis)

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.

Take special care with Ditropan Tablets

Check with your doctor or pharmacist before taking your medicine if:

- * You have kidney or liver problems
- * You are 65 years of age or older. The product should be used with caution in elderly due to the risk of cognitive impairment such as memory loss, etc..
- * The person taking the medicine is a child (use is not recommended under 5 years of age)
- * Children over 5 may be more sensitive to the effects of the product
- * You have an illness affecting the nerves called 'autonomic neuropathy'
- * You have Parkinson's disease
- * You have an overactive thyroid gland ('Hyperthyroidism')
- * You have heart disease or high blood pressure
- * You have an irregular heartbeat (palpitations) and/or increased or rapid heart beat

- * You have an enlarged prostate gland
- * You suffer from gastrointestinal disorders
- * You have indigestion or heart burn caused by a 'hiatus hernia' (where part of your stomach pushes through the diaphragm)
- * You suffer from ulcerative colitis
- * You have porphyria, a rare blood disorder
- * You will be taking this medicine in a hot climate. Ditropan can make you more prone to decreased sweating which can cause heat stroke. If you develop a fever while taking this medicine contact your doctor or hospital immediately to seek medical advice.
- * You suffer from liver enzyme disorders
- * Ditropan may reduce the amount of saliva resulting in tooth decay or fungal infection of the mouth.

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

Taking other medicines

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 work.

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

- * Other anticholinergic medicines - such as some medicines for irritable bowel syndrome, asthma or incontinence
- * Medicines that help the stomach empty more quickly
- * 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 haloperidol or benzeridol (butyrophenones)
- * Medicines for depression - such as amitriptyline, imipramine or dosulepin ('tricyclic antidepressants')
- * Bisphosphonates, as the risk of oesophagitis (inflammation of the lining of the oesophagus) may be increased
- * Amantadine - used in Parkinson's disease or to treat and prevent some virus infections
- * L-dopa, biperiden - used to treat Parkinson's disease
- * Quinidine, digoxin - used to treat heart problems
- * Some anti-histamines
- * Alcohol - as drowsiness may be increased
- * CYP 3A4 inhibitors
- * Cholinesterase inhibitors - used in the treatment of Alzheimer's

Pregnancy and breast-feeding

- 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.
- Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding. It is not recommended to use Ditropan during pregnancy or while 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

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 one 2.5mg tablet twice each day
- * Your doctor may decide to increase this to 5mg twice each day

Ditropan® 5mg Tablets

(oxybutynin hydrochloride)

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 tablet 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 many 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.

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 feel overheated, develop a fever or feel reduced sweating. This could be signs of heat stroke.

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 (feeling sick)
- * 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 unknown

- * Increased pressure in the eyes (glaucoma)
- * Indigestion or heartburn (acid reflux)
- * Urinary tract infection
- * Heat stroke
- * Difficulty passing water (urine)
- * Agitation
- * Anxiety
- * Becoming dependent on Ditropan
- * Feeling excessively 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)

- * Dilatation 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971 Fax: +353 1 6762517 Website: www.hpra.ie e-mail: medsafety@hpra.ie

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

5 How to store Ditropan Tablets

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Keep this medicine out of the sight and reach of children. Do not store above 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information.

What Ditropan Tablets contain

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

What Ditropan Tablets look like and contents of the pack

- * 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 84 tablets.

The Parallel Product Authorisation Holder is:

LTT Pharma Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

Repackaged by:

Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

The manufacturer is:

Sanofi Winthrop Industrie, 30-36 avenue Gustave Eiffel, 37000 Tours, France.

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for help.