

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **Ditropan® tablets 2.5 mg and Ditropan® tablets 5 mg**

Oxybutynin hydrochloride

**Read all of this leaflet carefully before you start taking this medicine, because it contains important information for you.**

- 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.

#### **What is in this leaflet**

1. What Ditropan tablets are and what they are used for
2. What you need to know before you take Ditropan tablets
3. How to use 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 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 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**

- if you are allergic to oxybutynin hydrochloride or any of the other ingredients of this medicine (listed in section 6).

*Signs of an allergic reaction include:* a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

- if you have a rare muscle illness called 'Myasthenia gravis'.
- if you have glaucoma (increased pressure in the eye, sometimes sudden and painful with blurred vision or loss of vision).
- if your gut (stomach or intestine) is blocked, perforated or not working properly.
- if you have a severe form of a condition known as 'ulcerative colitis'.
- if you have sudden widening of the colon, which causes abdominal pain, fever or shock known as 'toxic megacolon'.
- if 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.

#### Especially be careful if

- you have kidney or liver problems.
- you have an illness affecting the nerves called 'autonomic neuropathy' (e.g. Parkinson's disease).
- you have an overactive thyroid gland (Hyperthyroidism).
- you have heart disease or high blood pressure.
- you have an irregular heartbeat (palpitations, arrhythmias) and/or increased or rapid heartbeat.
- you have an enlarged prostate gland (prostatic hypertrophy).
- you have gastro-intestinal disorders or a disease called ulcerative colitis.
- you have indigestion or heart burn caused by a 'hiatus hernia' (where part of your stomach pushes through the diaphragm), gastro-oesophageal reflux and/or you are using medicinal products that can cause or worsen oesophagitis.
- you have a raised body temperature or fever.
- you will be taking this medicine in a hot climate.

Ditropan tablets may reduce the amount of saliva resulting in tooth decay or fungal infection of the mouth.

Ditropan tablets 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.

Ditropan tablets can cause hallucinations, agitation, confusion or somnolence so that your doctor might consider to monitor you.

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

### **Elderly**

People 65 years of age or older should take Ditropan tablets with caution, because of the risk of cognitive impairment and being at a greater risk of occurrence of adverse reactions.

## **Children**

### *Children under 5 years of age*

The use of Ditropan tablets is not recommended in children under 5 years of age.

### *Children 5 years of age or older*

Ditropan tablets should be taken with caution as they may be more sensitive to the effects of the product and at a greater risk of occurrence of adverse reactions.

## **Other medicines and Ditropan tablets**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other 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).
- Medicines used to treat nausea and vomiting (prochlorperazine or chlorpromazine).
- Medicines used to treat certain mental illnesses such as clozapine, phenothiazines, haloperidol or benperidol (butyrophenones).
- Medicines used to treat dementia e. g. donepezil, rivastigmine, galantamine or tacrine (cholinesterase inhibitors).
- 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 or biperidin used to treat Parkinson's disease.
- Digoxin or quinidine used to treat heart problems.
- Atropine which is used to treat certain types of poisonings, a slow heart rate, some eye conditions or is given during surgery.
- Medicines for stomach and bowel related problems - such as domperidone, metoclopramide, bethanechol.
- Medicines to treat allergic symptoms (antihistamines).
- CYP3A inhibitor e. g. ketoconazole, itraconazole or fluconazole used to treat fungal infections or erythromycin or other macrolide antibiotics used to treat bacterial infections.

## **Ditropan tablets with alcohol**

If you drink alcohol while using Ditropan tablets, you may become very drowsy.

## **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

While breast-feeding, small amounts may pass into mothers' milk. Breast-feeding while using this medicine is therefore not recommended.

#### **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.

#### **Ditropan tablets contain lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

#### **Ditropan tablets contain sodium**

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

### **3. How to take Ditropan tablets**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

#### Posology

Your doctor will decide the dose appropriate for you.

#### *Adults*

The recommended dose is one 5 mg tablet two or three times each day. Your doctor may decide to increase to the maximum dose of 5 mg four times each day.

#### *Elderly*

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

#### *Use in children and adolescents*

##### *Children 5 years of age or older*

The recommended dose is one 2.5 mg tablet twice each day. Your doctor may decide to increase this to one 5 mg two or three times each day.

If you are giving it to a child to prevent bedwetting, give the last dose just before bedtime.

#### Method of administration

For oral use.

Swallow the tablets with a glass of water as they may taste unpleasant.

If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor.

#### **If you use 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 heartbeat may become very fast, uneven, or forceful or your blood pressure drops. 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.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### **4. Possible side effects**

Like all medicines, this medicine 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 not known (frequency cannot be estimated from the available data):

- 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
- 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
- inability to completely empty the bladder (urinary retention)
- a forceful heartbeat that may be rapid or irregular

**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 tablets if there is a history of drug or substance abuse
- feeling excessive suspicious and distrustful of others
- mental Health disorders (especially in the elderly)
- seeing or hearing things that are not there (hallucinations)
- drowsiness
- nightmares
- fits (convulsions)
- depression
- increased heartbeat (tachycardia)
- irregular heartbeat (arrhythmia)
- dilation of pupil (mydriasis)
- itchy, lumpy rash (urticaria)
- absence of sweating (hypohidrosis)
- skin that is more sensitive to the sun (photosensitivity)
- disorientation
- cognitive disorders
- nosebleed
- angioedema
- muscle weakness, pain or cramps

## **Additional side effects in children**

Children are at higher risk of the effects.

## **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. 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](http://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 out of the sight and reach of children.

Do not use this medicine 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.

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**

- The active substance is 2.5 mg or 5 mg oxybutynin hydrochloride in each tablet.
- The other ingredients are lactose, cellulose, calcium stearate, and indigo carmine (E132).

### **What Ditropan tablets look like and contents of the packs**

Ditropan 2.5 mg tablets are pale blue oval bi-convex tablets with OXB2.5 on one side.

Ditropan 5 mg tablets are pale blue circular bi-convex tablets with OXB5 on one side and a break-line on the other side.

Supplied in PVC/aluminium blisters in cartons containing 6, 21, or 84 tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorisation Holder**

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**This leaflet was last revised in October 2023.**