

1.3.2 PATIENT INFORMATION LEAFLET**SCHEDULING STATUS****S3****PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM****DITROPAN**, 5 mg, tablets**Read all of this leaflet carefully before you start taking DITROPAN**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- DITROPAN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT DITROPAN CONTAINS

- The active substance is oxybutynin hydrochloride, 5 mg per tablet.
- The other ingredients are calcium stearate, cellulose (microcrystalline), Indigo carmine aluminium lake (E132) and lactose (anhydrous).
- Contains sugar (anhydrous lactose).

WHAT DITROPAN IS USED FOR

DITROPAN is used to decrease the urgency and the frequency of urination.

DITROPAN is also used to decrease bed-wetting in children older than 5 years.

BEFORE YOU TAKE DITROPAN**Do not take DITROPAN:**

- if you are hypersensitive (allergic) to oxybutynin hydrochloride or any of the other ingredients of DITROPAN. Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue

- if you have increased pressure in the eye (glaucoma)
- if your stomach or intestine are blocked, perforated or not working properly
- if you have a severe form of a condition known as ‘ulcerative colitis’
- if you have a rare muscle illness called ‘myasthenia gravis’
- if you have a blockage of your bladder that makes it difficult for you to pass water(urine)
- if you have severe bleeding
- if you have a hypotonic neurogenic bladder (an enlarged bladder in which the emptying reflex becomes hyperactive)
- if you are pregnant or breastfeeding (see ‘HUMAN REPRODUCTION’)
- if your child is under the age of 5 years
- if you are an elderly man, have Parkinson’s disease or have an enlarged prostate gland.

Special care should be taken with DITROPAN:

- if you have liver or kidney problems
- if you have a heart disease
- if you have high blood pressure
- if you have an irregular heartbeat (palpitations) and/or increased or rapid heartbeat
- if you are 65 years of age or older
- if you have an overactive thyroid gland (‘Hyperthyroidism’)
- if you are taking this medicine in a hot climate
- if you have a raised body temperature or fever
- if you have indigestion or heartburn caused by a ‘hiatus hernia’ (where part of your stomach pushes through the diaphragm)
- when given to a child over the age of 5 years.

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

Taking DITROPAN with food and drink:

- DITROPAN may be taken with or without food.

Pregnancy and Breastfeeding

You should not take DITROPAN if you are pregnant. If you are taking DITROPAN, you should not breastfeed your baby.

If you are pregnant or breastfeeding your baby while taking DITROPAN, please consult your doctor, pharmacist or other healthcare professional for advice.

Small amounts of oxybutynin may pass into breast milk. Breastfeeding while using oxybutynin is therefore not recommended.

Driving and using machinery

- DITROPAN may make you feel drowsy/sleepy or blur your vision
- do not drive because DITROPAN could interfere with your ability to drive safely
- do not operate any tools of machines.

Important information about some of the ingredients of DITROPAN:

DITROPAN contains lactose. If you have been told by your doctor that you cannot tolerate or digest some sugars, talk to your doctor before taking DITROPAN.

Taking other medicines with DITROPAN:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of DITROPAN with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

Tell your doctor if you are taking any of the following:

- other anticholinergic or antimuscarinic medicines (medicines used 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 scopolamine)
- medicines used to treat certain mental illnesses (such as phenothiazines, butyrophenones)
- medicines used for depression (such as 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)
- antihistamine (used for relief of allergies)
- prokinetic medicines (used to control acid reflux)

HOW TO TAKE DITROPAN

Do not share medicines prescribed for you with any other person.

Always take DITROPAN exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure

The usual dose for adults is one 5 mg tablet two to three times a day. The maximum recommended dose is one 5 mg tablet four times a day.

The usual dose for children over the age of 5 years is one 5 mg tablet twice daily. The maximum recommended dose is one 5 mg tablet three times a day. The use of DITROPAN in children under the age of 5 years is not recommended.

The usual dose in frail elderly patients is 5 mg twice daily.

Your doctor may decide to test your bladder function at the beginning of treatment and again at regular intervals.

Your doctor will tell you how long your treatment with DITROPAN will last. Do not stop treatment early, even if you start to feel better.

If you have the impression that the effect of DITROPAN is too strong or too weak, tell your doctor or pharmacist.

Swallow the tablet with a glass of water.

Do not crush or chew the tablet.

If you take more DITROPAN than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center.

When taking too many DITROPAN tablets you may become very restless, excited or confused, flushed or get dizzy or lightheaded. Your heartbeat may become very fast, uneven or forceful. You may have breathing problems or numbness in the hands or feet.

If you forget to take a dose of DITROPAN:

Do not take a double dose to make up for forgotten individual doses.

If you forget a dose, take it as soon as you remember. 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.

Effects when treatment with DITROPAN is stopped:

Keep taking DITROPAN tablets until your doctor tells you to stop.

POSSIBLE SIDE EFFECTS

DITROPAN can have side effects.

Not all side effects reported for DITROPAN are included in this leaflet. Should your general health worsen while taking DITROPAN, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking DITROPAN and tell your doctor immediately or go to the emergency department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing, rash or itching. These are all very serious side effects. If you have them, you may have had a serious allergic reaction to DITROPAN. You may need urgent medical attention or hospitalisation
- reduced sweating, leading to overheating in hot environments.

Tell your doctor immediately or go to the emergency department at your nearest hospital if you notice any of the following:

- chest pain, changes in the way your heart beats (for example, if you notice it beating faster)
- less urine than is normal for you

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

Tell your doctor if you notice any of the following:

- blurring of vision, increased pressure in the eye (glaucoma), enlargement of the pupil of the eye, dry eyes.
- diarrhoea or constipation
- feeling sick, being sick or stomach pain
- difficulty swallowing
- thirst
- indigestion or heartburn (acid reflux)

- dry mouth
- loss of appetite (anorexia)
- agitation or anxiety
- headache
- dizziness, drowsiness or confusion
- feeling depressed
- seeing or hearing things that are not there (hallucinations)
- nightmares
- fits (convulsions)
- flushing
- difficulty passing water (urine)
- dry skin, rash or skin that is more sensitive to the sun
- producing less or no breast milk
- you cannot stop taking DITROPAN especially if you have a history of drug or substance abuse.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF DITROPAN

Keep all medicines out of the reach and sight of children.

Store at or below 25 °C.

Keep the container in the outer carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF DITROPAN

20 or 100 tablets packed in securitainers or blister packs.

IDENTIFICATION OF DITROPAN

Light blue, round, biconvex tablet with "OXB5" engraved on one side with scored line on reverse side.

L/5.4/104

Each tablet contains 5 mg oxybutynin chloride

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REGISTRATION NUMBERS

L/5.4/104

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