

PART III: CONSUMER INFORMATION

Pr**DITROPAN XL**[®]
oxybutynin chloride
Extended-release Tablets

This leaflet is Part III of a three-part “Product Monograph” published when DITROPAN XL[®] was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about DITROPAN XL[®]. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

DITROPAN XL[®] is used to relieve the symptoms of overactive bladder which include the frequent and urgent need to urinate with or without urine leakage.

DITROPAN XL[®] use in patients under 18 years of age has not been established.

What it does:

DITROPAN XL[®] relaxes the smooth muscle of the bladder which results in a decreased urgency and frequency of urination and episodes of urine leakage.

When it should not be used:

Do **not** take DITROPAN XL[®] if you:

- have difficulty urinating, or stomach problems affecting passage and digestion of food
- have uncontrolled narrow-angle glaucoma (high pressure and pain in the eyes)
- are allergic to oxybutynin chloride or any of the other ingredients in DITROPAN XL[®] (see **What the nonmedicinal ingredients are**).

What the medicinal ingredient is:

oxybutynin chloride

What the nonmedicinal ingredients are:

butylated hydroxytoluene, cellulose acetate, hydroxypropyl methylcellulose, lactose, magnesium stearate, polyethylene glycol, polyethylene oxide, polysorbate 80, propylene glycol, sodium chloride, synthetic iron oxides and titanium dioxide

What dosage forms it comes in:

extended-release tablets: 5 and 10 mg

WARNINGS AND PRECAUTIONS

BEFORE you use DITROPAN XL[®], talk to your doctor or pharmacist if you:

- have stomach or intestine (gut) problems affecting passage and digestion of food
- have glaucoma (high pressure and pain in the eyes)
- have gastroesophageal reflux (heartburn) or are taking drugs (such as bisphosphonates which are used to prevent bone thinning and fractures caused by osteoporosis) that can

- worsen esophagitis (inflammation of the tube that connects the mouth and the stomach)
- have ulcerative colitis (inflammatory bowel disease)
- have myasthenia gravis (a muscle weakening disease)
- have heart problems
- have kidney and liver problems
- take certain drugs for treatment of dementia (such as Alzheimer’s disease)
- have autonomic neuropathy (a nerve disorder that affects heart rate, blood pressure, sweating and digestion)
- have Parkinson’s disease
- have difficulty urinating
- are pregnant or trying to become pregnant
- are breast-feeding
- have one of the following rare hereditary diseases:
 - Galactose intolerance
 - Lapp lactase deficiency
 - Glucose-galactose malabsorption

Because lactose is a non-medicinal ingredient in DITROPAN XL[®].

DITROPAN XL[®] is contained within a nonabsorbable shell designed to release the drug at a controlled rate. It is normal that the shell that looks like a tablet may pass through the stomach and intestine and appears in the stool.

In hot weather, DITROPAN XL[®] can cause heat prostration (fever and heat stroke due to decreased sweating).

Driving and using machines: DITROPAN XL[®] may produce drowsiness or blurred vision. Do not drive or operate machinery until you know how the medication affects you.

Alcohol may add to the drowsiness caused by DITROPAN XL[®].

DITROPAN XL[®] may cause central nervous system (CNS) effects (symptoms referring to changes in thinking or emotions) such as anxiety, nervousness, difficulty remembering, seeing or hearing things that are not actually there, and trouble thinking clearly or making decisions. If you experience any CNS effects, please contact your doctor immediately.

DITROPAN XL[®] may cause severe allergic reactions such as swelling of the face, lips, tongue, and upper airway that may become life-threatening.

INTERACTIONS WITH THIS MEDICATION

Always tell your doctor about all medicines you are taking. Your doctor will decide if it is safe for you to use DITROPAN XL[®] with other medicines. If you take any of the following medicines with DITROPAN XL[®], it may affect how well they work or increase the likelihood of side effects:

- drugs that could result in serious adverse effects if small changes in dosage occur (such as digoxin for heart problems)
- other anticholinergic drugs, used to treat a number of different medical conditions (a few examples are atropine for glaucoma or hyoscine for nausea), or drugs with similar undesired effects (such as dry mouth, constipation, drowsiness and blurred vision)
- certain antibiotics (such as erythromycin and clarithromycin)

- certain drugs for the treatment of fungal infections (such as oral ketoconazole, itraconazole, and miconazole)
- drugs used to help empty the stomach and move foods through the gut (such as domperidone and metoclopramide)

PROPER USE OF THIS MEDICATION

DITROPAN XL® tablets should be swallowed whole with water or liquids. **Do not chew, divide, or crush the tablets.**

DITROPAN XL® may be taken with or without food.

Take DITROPAN XL® by mouth once daily.

Usual adult dose:

The recommended starting dose of DITROPAN XL® is 5 or 10 mg once daily at a consistent time each day. The maximum daily dose is 30 mg. Your dose may be adjusted as recommended by your doctor.

Overdose:

If you take too much DITROPAN XL®, you may experience: nervous system excitation (such as restlessness, tremor, irritability, confusion, and hallucinations), flushing (usually of the face or neck), fever, dehydration, heart beat irregularities, vomiting, and difficulty emptying your bladder completely.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed dose:

If you miss a dose, take it as soon as you remember. If it is almost time for the next dose, do not take the missed dose. Instead, take the next scheduled dose. Do not try to make up for the missed dose by taking a double dose next time.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, DITROPAN XL® can cause side effects, although not everyone gets them. The following side effects may occur with this medicine:

Very common side effects (may affect more than 1 in 10 people):

- Dry mouth

Common side effects (affects less than 1 in 10 people):

- Pain passing urine
- Delay when starting to pass urine
- Bladder cannot be fully emptied (residual urine)
- Urinary tract infection
- Stuffy nose (rhinitis)
- Back pain, joint pain
- Swelling feet and hands (retaining water)
- Constipation, diarrhea, indigestion, nausea, vomiting, stomach pain, flatulence, heartburn
- Problems sleeping

- Feeling sleepy, feeling tired
- Cough, sore or dry throat, dry nose
- Change in the way things taste
- Dry eyes, blurred eye sight
- Dry skin, itching
- Feeling dizzy
- Headache
- Chest pain
- Confusion, depression, nervousness

Uncommon side effects (affects less than 1 in 100 people):

- Abdominal discomfort
- Frequent bowel movements
- Hoarseness, throat irritation
- Flushing, hot flush
- Chest discomfort
- Mucosal dryness (multiple sites)
- Loss of appetite

The following side effects have been reported with the use of DITROPAN XL®:

- Central nervous system (CNS) effects, their symptoms include anxiety, agitation, difficulty remembering
- Difficulty getting or keeping an erection
- Skin rash, swelling of the skin, hives
- Falling

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Common	High Blood Pressure: headache, vision problems, dizziness, shortness of breath		✓	
Uncommon	Seeing or hearing things that are not really there			✓
	Feeling agitated, behaving irrationally and thinking abnormally			✓
Rare	Convulsions			✓
Very Rare	Fast or uneven heartbeat		✓	

	Angioedema and Severe Allergic Reactions: swelling of the face, eyes, or tongue, difficulty swallowing, wheezing, hives and generalized itching, rash, fever, abdominal cramps, chest discomfort or tightness, difficulty breathing, unconsciousness			✓
	Glaucoma: increased pressure in your eyes, eye pain			✓

This is not a complete list of side effects. For any unexpected effects while taking DITROPAN XL®, contact your doctor or pharmacist.

HOW TO STORE IT

Store between 15 and 30°C. Protect from moisture and humidity. Keep out of reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting>
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect® Canada Web site at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full Product Monograph prepared for health professionals can be found at:
<http://www.janssen.com/canada>
 or by contacting the sponsor, Janssen Inc., at:
 1-800-567-3331 or 1-800-387-8781.

This leaflet was prepared by
 Janssen Inc.
 Toronto, Ontario M3C 1L9

Last revised: August 2018

All trademarks used under license.