

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PART III: PATIENT MEDICATION INFORMATION

Mictoryl[®] **Propiverine hydrochloride modified-release capsules**

Mictoryl[®] Pediatric **Propiverine hydrochloride tablets**

Read this carefully before you start taking **Mictoryl/Mictoryl Pediatric** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Mictoryl/Mictoryl Pediatric**.

What is Mictoryl/Mictoryl Pediatric used for?

Mictoryl is used in adults who have difficulty in controlling their bladder due to bladder overactivity. The symptoms of bladder overactivity include the urgent need to urinate, needing to urinate more often or being unable to hold your urine.

Mictoryl Pediatric is used in children who have difficulty in controlling their bladder due to bladder overactivity. The symptoms of bladder overactivity include the urgent need to urinate, needing to urinate more often or being unable to hold your urine.

How does Mictoryl/Mictoryl Pediatric work?

Mictoryl/Mictoryl Pediatric stops the bladder from contracting and increases the amount of urine that the bladder can hold.

What are the ingredients in Mictoryl/Mictoryl Pediatric?

Medicinal ingredient: propiverine hydrochloride

Mictoryl Non-medicinal ingredients: ammonio methacrylate copolymer type A, ammonio methacrylate copolymer type B, citric acid, gelatin, lactose monohydrate, magnesium stearate, methacrylic acid-methyl methacrylate copolymer (1:1), methacrylic acid-methyl methacrylate copolymer (1:2), povidone, red iron oxide, talc, titanium dioxide, triethyl citrate, yellow iron oxide.

Mictoryl Pediatric Non-medicinal ingredients: acacia gum, calcium carbonate, cellulose powdered, glucose monohydrate, kaolin heavy, lactose monohydrate, macrogol 6000, magnesium stearate, silica colloidal anhydrous, sucrose, talc, titanium dioxide.

Mictoryl comes in the following dosage forms:

Modified-release capsule: 30 mg, 45 mg.

Mictoryl Pediatric comes in the following dosage form:

Tablet: 5 mg.

Do not use Mictoryl/Mictoryl Pediatric if you/your child:

- are allergic (hypersensitive) to propiverine or to any ingredient of Mictoryl/Mictoryl Pediatric; or

- have any of the following conditions:
 - blockage in your intestines (obstruction of the bowel);
 - difficulty in passing urine (obstruction to the bladder outlet);
 - a disease causing muscle weakness (myasthenia gravis);
 - a loss of function of the muscles controlling your bowel movements (intestinal atony);
 - severe inflammation of the bowel (ulcerative colitis) that may lead to diarrhea containing blood and mucus and abdominal pain;
 - a condition involving enlargement of the bowel (toxic megacolon);
 - increased pressure in the eye (uncontrolled angle closure glaucoma);
 - moderate or severe liver disease;
 - fast and irregular heart beat (tachyarrhythmia);
 - rare genetic problems of sugar intolerance (galactose, glucose-galactose malabsorption, or Lapp lactase deficiency);
 - children with rare genetic problems of fructose intolerance or sucrase-isomaltase insufficiency.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Mictoryl/Mictoryl Pediatric. Talk about any health conditions or problems you/your child may have including:

- damage to the nerves that control blood pressure, heart rate, bowel and bladder movements and other bodily functions (autonomic neuropathy)
- kidney problems
- liver problems
- severe heart problems
- enlargement of the prostate
- heartburn and indigestion due to back flow of stomach juice into the throat (hiatus hernia with reflux oesophagitis)

Other warnings you should know about:

Do not take Mictoryl/Mictoryl Pediatric if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby.

Mictoryl/Mictoryl Pediatric can sometimes cause sleepiness and blurred vision. You should not drive or operate machinery if you experience sleepiness and blurred vision.

Children with overactive bladder should not be treated before the age of 5 years. Once treatment starts it should include changes to voiding and drinking habits.

Tell your healthcare professional about all the medicines you/your child take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following drugs may interact with Mictoryl/Mictoryl Pediatric:

- antidepressants (e.g. imipramine, clomipramine and amitriptyline),
- sleeping pills (e.g. benzodiazepines),
- anticholinergics taken by mouth or injection (usually used to treat asthma, stomach cramps, eye problems or urinary incontinence),
- amantadine (used to treat flu and Parkinson's disease),
- neuroleptics such as promazine, olanzapine, quetiapine (drugs used to treat psychotic disorders like schizophrenia or anxiety),
- beta stimulants (drugs used to treat asthma),
- cholinergics used to treat glaucoma (e.g. carbachol, pilocarpine),
- isoniazid (a treatment for tuberculosis), and
- metoclopramide (used to treat nausea and vomiting).

How to take Mictoryl:

Always take Mictoryl exactly how your healthcare professional told you. You should check with your healthcare professional if you are not sure.

Take your capsule at the same time each day. Swallow the capsule whole with a drink of water. Do not crush or chew the capsule. You may take Mictoryl with or without food.

Usual Mictoryl adult dose:

The usual adult dose is one 30 mg capsule daily. The dose can be increased to one 45 mg capsule daily.

The maximum recommended daily dose is 45 mg.

Mictoryl is not recommended for the use in children.

How to take Mictoryl Pediatric:

Always give Mictoryl Pediatric to your child exactly as your healthcare professional told you. Check with your healthcare professional if you are not sure.

Give your child the tablets at the same times each day. Children should swallow the tablets whole with a drink of water at least one hour before meals.

Usual Mictoryl Pediatric dose:

Your child's healthcare professional will tell you how many tablets to give your child based on their body weight. The tablets will be given in two daily doses.

In children or adolescents with a body weight over 35 kg the maximum recommended dose is 30 mg to be given in two daily doses.

Overdose:

If you think you/your child have taken too much Mictoryl/Mictoryl Pediatric, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

Leave out the missed dose completely. Then take your next dose at the right time. Do not take a double dose to make up for a forgotten dose.

What are possible side effects from using Mictoryl/Mictoryl Pediatric?

These are not all the possible side effects you/your child may feel when taking Mictoryl/Mictoryl Pediatric. If you/your child experience any side effects not listed here, contact your healthcare professional.

The following side effects have been reported:

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

Dry mouth

Common (may affect up to 1 in 10 people):

Abnormal vision and difficulty in focussing, fatigue, headache, abdominal pain, indigestion, constipation

Uncommon (may affect up to 1 in 100 people):

Nausea and vomiting, dizziness, trembling (tremor), difficulty in passing urine, flushing, altered sense of taste, decreased blood pressure with drowsiness, itching

Rare (may affect up to 1 in 1000 people):

Rash

Very rare (may affect up to 1 in 10 000 people):

Feeling your heart beat (palpitations), restlessness, confusion

Not known (frequency cannot be estimated from the available data):

Speech disorder

In addition, in studies with children the following side effects were seen: loss of appetite, sleep disturbance and trouble concentrating.

Mictoryl/Mictoryl Pediatric can cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and will interpret the results.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Allergic reaction (rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing)			X
Urinary retention (difficulty emptying the bladder unless known for this problem)		X	
Tachycardia (fast heartbeat)		X	
Hallucination (sensing things that are not real)		X	

If you/your child have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at [MedEffect](http://www.healthcanada.gc.ca/medeffect); (www.healthcanada.gc.ca/medeffect);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Address Locator 0701C
Ottawa, ON
K1A 0K9
Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](http://www.healthcanada.gc.ca/medeffect) (www.healthcanada.gc.ca/medeffect).

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store in the original package at room temperature (15 to 30°C).

Keep out of reach and sight of children.

If you want more information about Mictoryl/Mictoryl Pediatric:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website](#) (www.healthcanada.gc.ca); the manufacturer's website www.duchesnay.com, or by calling 1-888-666-0611.

This leaflet was prepared by Duchesnay Inc.

Last Revised January 15, 2018.