

CONSUMER INFORMATION
Product Monograph Part III

TROSEC™
trospium chloride
20 mg coated tablets

Oryx Pharmaceuticals Inc.

Submission Control No. 095373

The Consumer Information Section (Part III) of the Product Monograph for TROSEC has been submitted by the drug sponsor and is attached for your information.

The attached version accompanied the Notice of Compliance issued on January 10, 2006 and does not necessarily reflect the most current information for the product.

For the most up-to-date product information, please consult your health care professional.

Due to the fact that the information originated with an organization that is not subject to the *Official Languages Act*, the document may only appear in the language in which it was written. Translations of the document are the responsibility of the sponsor involved.

PART III: CONSUMER INFORMATION

**TROSEC™
Trospium Chloride**

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

ABOUT THIS MEDICATION

What the medication is used for:

TROSEC is an antispasmodic agent used to treat overactive bladder. Patients with overactive bladder have these symptoms: a strong need to urinate right away (urgency) with or without urge incontinence (leaking or wetting accidents caused by a sudden, unstoppable urge to urinate), usually with a need to urinate often (frequent bathroom visits), and nocturia (having to urinate frequently during the night).

What it does:

The term "overactive bladder" refers to the involuntary spasm of the bladder muscle (detrusor). Overactive bladder happens when you cannot control your bladder muscle contractions. When these muscle contractions happen too often or cannot be controlled, you get symptoms of overactive bladder (see "What the medication is used for:").

TROSEC blocks involuntary contractions of the bladder muscle (detrusor) which allows the muscle to relax giving you better control of your bladder.

TROSEC reduces (see also "What this medication is used for:):

- the strong need to urinate right away
- the number of bathroom visits during the day or night
- the number of wetting accidents

You should begin to notice an improvement in your symptoms in about a week.

When it should not be used:

TROSEC should not be used by patients with or at risk for:

- an inability to empty the bladder (urinary retention);
- delayed emptying of the stomach (gastric retention);
- an eye problem called "uncontrolled narrow-angle glaucoma";
- a history of any allergic or other severe reaction to TROSEC or any of its components.

What the medicinal ingredient is:

Trospium chloride

What the nonmedicinal ingredients are:

calcium carbonate, carboxymethylcellulose sodium, carnauba wax, colloidal silicon dioxide, croscarmellose sodium, ferric oxide, lactose monohydrate, microcrystalline cellulose, polyethylene glycol 8000, povidone, stearic acid, sucrose, talc, titanium dioxide, wheat starch, white wax.

What dosage forms it comes in:

TROSEC is available as a coated tablet (20 mg).

WARNINGS AND PRECAUTIONS

BEFORE you use TROSEC talk to your doctor or pharmacist if:

- you have trouble emptying your bladder (slow urinary stream), because of the risk of urinary retention;
- you have delayed or slow emptying of your stomach because of the risk of gastric retention;
- you have ulcerative colitis (ulcers in the large intestine or colon), intestinal atony or myasthenia gravis (muscle weakness);
- you have an eye problem called "narrow-angle glaucoma" that is being treated;
- you have liver or kidney disease (see **PROPER USE OF THIS MEDICATION**, Usual dose);
- you have congestive heart failure, hypokalemia (low potassium), or other conditions which may increase the risk of TROSEC affecting your heart rate;
- you are pregnant, planning on becoming pregnant or are breast feeding;

The safety and effectiveness of TROSEC has not been studied in children.

Although uncommon, TROSEC may cause blurred vision and/or drowsiness in some people. Until you know how TROSEC affects you, caution should be exercised when driving or operating heavy machinery.

Consumption of alcohol while taking TROSEC may make drowsiness worse.

Due to decreased sweating, heat prostration (overheating of the body) can occur when drugs such as TROSEC are used in a hot environment.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with TROSEC include: anticholinergic agents (such as amantadine, tricyclic antidepressants, quinidine, antihistamines, and disopyramide), beta agonists (such as salbutamol or formoterol), prokinetic agents (such as metoclopramide) and drugs that are

eliminated by active renal secretion (such as digoxin, procainamide, pancuronium, morphine, vancomycin, metformin and tenofovir).

Tell your doctor or pharmacist about every medication you are taking including those you are taking without a prescription as well as any natural health products (herbal or vitamins).

Interactions with herbal medicines have not been studied.

Taking TROSEC with food reduces the amount of medication that will get into your body. (see "PROPER USE OF THIS MEDICATION")

environment. Be sure to consume adequate amounts of liquid if you are in a hot environment for a prolonged period of time.

Tell your doctor or pharmacist if you have any side effects that bother you or don't go away.

The following events have rarely been reported during TROSEC use: Anaphylactic and Stevens-Johnson reactions (rare, life-threatening, allergic reactions), tachycardia (rapid heartbeat), syncope (fainting), rhabdomyolysis (destruction of muscle tissue), and hypertensive crisis (sudden, marked increase in blood pressure). If you think you are experiencing any of these rare effects, stop taking TROSEC immediately and go to the emergency room.

PROPER USE OF THIS MEDICATION

Usual dose:

Take one TROSEC 20 mg tablet twice a day on an empty stomach at least one hour before meals. For patients with kidney disease the recommended dose of TROSEC is 20 mg once a day. In geriatric patients 75 years of age and older, the dose may be reduced to 20 mg once daily if twice daily dosing is not well tolerated.

TROSEC has not been studied in children.

Overdose:

Overdosage with TROSEC may result in severe anticholinergic effects such as rapid and irregular heartbeat, flushed face, fever, ringing in the ears, and muscle spasms.

If you think you have taken an overdose of TROSEC, go to your nearest emergency room immediately. If possible, bring the package with you.

Missed Dose:

If you miss a dose, take your next dose at the usual time (on an empty stomach at least 1 hour before your next meal). Do not double the next dose to make up for the missed dose.

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 call your doctor or pharmacist
		Only if severe	In all cases	
Uncommon	Urinary retention (inability to empty your bladder)			✓
	Constipation	✓		

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

HOW TO STORE IT

Store at controlled room temperature 15° to 30°C.

Keep out of reach of children.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Common side effects:

In clinical studies, the most common side effects with TROSEC were dry mouth, constipation and abdominal pain.

Other side effects:

The following less common events may also occur with the use of TROSEC: dyspepsia (upset stomach), nausea, dizziness, flatulence, chest pain, dry eyes, blurred vision, increased heart rate, palpitation urinary retention, and heat prostration.

Due to decreased sweating, heat prostration (overheating of the body) can occur when drugs such as TROSEC are used in a hot

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs . If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

toll-free telephone: 866-234-2345

toll-free fax 866-678-6789

By email: cadrmp@hc-sc.gc.ca

By regular mail:

Canadian Adverse Drug Reaction Monitoring Program
(CADRMP)

Health Canada

Address Locator: 0201C2

Ottawa, ON K1A 1B9

NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.oryxpharma.com>

or by contacting the sponsor, Oryx Pharmaceuticals Inc., at:
1-866-260-6291

This leaflet was prepared by Oryx Pharmaceuticals Inc. (A
Subsidiary of Filiale d'Arrow Pharmaceuticals Inc.)

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