

PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS

(PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Novitropan 5 mg tablets

Each tablet contains: oxybutynin chloride 5 mg

Inactive ingredients and allergens in the preparation – see the subsection "Important information about some of the ingredients of the medicine" and section 6.

Read the entire leaflet carefully before using the medicine.

This leaflet contains concise information about the medicine.

If you have any other questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

This medicine is usually not recommended for infants and children under 5 years of age.

1. What is the medicine intended for?

For the relief of symptoms caused by urinary incontinence (such as: urgency, frequency, leakage, inability to control the bladder, difficulty urinating) in adults and children.

Therapeutic class: anticholinergic and antispasmodic.

The medicine works by relaxing the muscles of the bladder and stopping sudden muscle contractions, and thus helps controlling the release of urine.

2. Before using the medicine

⚠ Do not use this medicine if you have:

- Sensitivity (allergy) to the active ingredient or to any of the other ingredients this medicine contains (see section 6). Signs of an allergic reaction include: rash, swallowing difficulties or breathing difficulties, swelling of the lips, face, throat or tongue
- A rare muscle disease called myasthenia gravis
- Glaucoma (increased intraocular pressure), sometimes painful or sudden, accompanied by blurred vision or loss of vision
- Blockage, perforation or problem in the function of the gut (stomach or intestine)
- Severe ulcerative colitis
- Sudden widening of the colon which causes abdominal pain, fever or shock (called toxic megacolon)
- Blockage in the urinary tract which makes it difficult to pass urine

⚠ Special warnings regarding the use of the medicine: Before treatment with Novitropan, inform the doctor if:

- You have kidney or liver problems
- You have autonomic neuropathy – a disease that affects the nervous system (such as: Parkinson's disease)
- You have an overactive thyroid (hyperthyroidism)
- You have a heart disease or hypertension

- You have an irregular heartbeat (palpitations, arrhythmias) and/or increased or rapid heartbeat
- You have an enlarged prostate gland
- You have a problem in your gut or a disease called ulcerative colitis
- You have indigestion or heartburn caused by a hiatus hernia, esophageal reflux or if you are using medical preparations that can cause or worsen esophagitis
- You have a high body temperature or fever
- You will be taking this medicine in a hot climate

⚠ Additional warnings:

Novitropan may reduce the amount of saliva, which may cause tooth decay or fungal infection in the mouth.

Novitropan may cause glaucoma (increased intraocular pressure). Refer to the doctor immediately if you suffer from blurred vision, loss of vision or if you suffer from any pain in the eye.

Novitropan may cause hallucinations, agitation, confusion or drowsiness, and the doctor may consider monitoring you.

⚠ The elderly:

Patients above the age of 65 should take the medicine with caution, because of the risk of cognitive impairment and because these patients are at increased risk of side effects.

⚠ Children:

Under 5 years of age: this medicine is usually not recommended for infants and children under 5 years of age.

Above 5 years of age: treat children with caution, as they may be more sensitive to the effects of the medicine and because they are at increased risk of side effects.

⚠ Drug interactions:

If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. Especially if you are taking:

- Other medicines from the group of anticholinergics or antimuscarinics, such as: certain medicines for the treatment of irritable bowel syndrome, asthma, urinary incontinence, seasickness, movement disorders associated with Parkinson's disease
- Sedatives that cause a sense of sleepiness
- Medicines to treat nausea and vomiting, such as: chlorpromazine or prochlorperazine
- Antipsychotics, such as: clozapine, phenothiazines, haloperidol or benperidol (medicines from the group of butyrophenones)
- Medicines for the treatment of dementia, such as: donepezil, rivastigmine, galantamine or tacrine (cholinesterase inhibitors)
- Antidepressants, such as: amitriptyline, imipramine or dosulepin (tricyclic antidepressants)
- Amantadine, for the treatment of Parkinson's disease or for certain viral infections
- L-dopa or biperiden, for the treatment of Parkinson's disease

- Digoxin or quinidine, for the treatment of cardiac problems
- Atropine, used for the treatment of various poisonings, a slow heart rate, certain eye conditions or is given during surgery
- Medicines for the treatment of problems related to the stomach or bowel, such as: domperidone, metoclopramide, bethanechol
- Certain antihistamine medicines for the treatment of allergy symptoms
- CYP3A4 enzyme inhibitors, such as: ketoconazole, itraconazole or fluconazole, that are used for the treatment of fungal infections, erythromycin or other macrolide antibiotics that are used for the treatment of bacterial infections

⚠ Use of the medicine and food:

Novitropan tablets may be taken with or without food.

⚠ Use of the medicine and alcohol consumption:

Alcohol consumption during treatment with Novitropan may cause sleepiness.

⚠ Pregnancy, breastfeeding and fertility:

Do not use this medicine without consulting a doctor before starting the treatment if you are pregnant, think you may be pregnant, are planning to become pregnant, or are breastfeeding.

Small amounts of the medicine may pass into breastmilk, and therefore breastfeeding while taking Novitropan is not recommended.

⚠ Driving and operating machinery:

Using this medicine may cause sleepiness or blurred vision. In such cases, avoid driving or operating machinery. Children should be cautioned against riding a bicycle or playing near a road etc.

⚠ Important information about some ingredients of the medicine:

This preparation contains lactose. If you have been told by the doctor that you have an intolerance to some sugars, refer to the doctor before using this medical preparation.

3. How should you use the medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the medicine.

The dosage and treatment regimen will be determined by the doctor only. The generally accepted dosage is:

Adults: one tablet 2-3 times per day.

The maximum daily dosage is 4 tablets.

Children above 5 years of age: one tablet twice a day.

The maximum daily dosage is 3 tablets.

If Novitropan is intended for the treatment of night time bedwetting, the last dose should be taken before bedtime.

Do not exceed the recommended dose.

Swallow the medicine with water.

The tablet is intended to be swallowed. Do not chew. The tablet can be halved. No information is available regarding crushing/ pulverizing the tablet.

If you accidentally take a higher dosage, this may be very dangerous and you may suffer from restlessness, a feeling of overexcitement, flushing, dizziness, fast/irregular/strong heartbeat and a drop in blood pressure. You may experience breathing problems, loss of sensation or coma.

If you took an overdose or if a child swallowed this medicine by mistake, go to the doctor or to a hospital emergency room immediately and take the package of the medicine with you.

If you forgot to take this medicine at the required time, take a dose as soon as you remember. However, if it is already time for the next dose, skip the forgotten dose. Do not take a double dose in order to compensate for a forgotten dose.

Follow the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor or pharmacist.

Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.

If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Novitropan may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Stop using the medicine and refer immediately to a doctor or a hospital emergency room if you experience:

Side effects with unknown frequency (effects whose frequency has not yet been determined):

- **An allergic reaction.** Signs of an allergic reaction include: rash, swallowing difficulties or breathing difficulties, swelling of the lips, face, throat or tongue.
- Reduced sweating that leads to overheating in hot environments.

Additional side effects:

Very common side effects - side effects that occur in more than one user out of ten:

- Constipation
- Nausea
- Dry mouth
- Dry skin
- Headache
- Somnolence
- Dizziness
- Blurred vision

Common side effects - side effects that occur in 1-10 users out of 100:

- Dryness in the eyes
- Diarrhea
- Vomiting
- Confusion
- Flushing (appears especially in children)

- Inability to completely empty the bladder

Uncommon side effects - side effects that occur in 1-10 users out of 1,000:

- Abdominal pain
- Lack of appetite
- Difficulty swallowing

Side effects with unknown frequency (effects whose frequency has not yet been determined):

- Increased eye pressure, sometimes sudden and painful, which may appear with blurred vision or with loss of vision (glaucoma)

- Indigestion or heartburn (acid reflux)
- Urinary tract infection
- Heatstroke
- Difficulty urinating
- Unusual excitement

- Anxiety

- Dependence on the medicine Novitropan, if there is a history of medicine or substance dependence

- Excessive suspicion in others
- Mental disorders (especially in the elderly)
- Seeing or hearing non-existing things (hallucinations)

- Drowsiness
- Nightmares
- Convulsions
- Depression

- Fast heartbeat (tachycardia)
- Irregular heartbeat (arrhythmia)
- Dilated pupils

- Itchy rash with blisters (urticaria)
- Absence of sweating
- Increased sensitivity upon exposure to the sun

- Disorientation
- Cognitive disorders

- Nose bleeding
- Angioedema

- Muscle weakness, pain or contractions

Side effects in children:

Children are at increased risk of side effects.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link "report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il/>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

- Do not use the medicine after the expiry date (exp.) appearing on the package. The expiry date refers to the last day of that month.

- Store at a temperature below 25°C.

6. Additional information

In addition to the active ingredient, the medicine also contains:

Lactose, Maize Starch, Povidone, Calcium Carboxy methyl cellulose, Magnesium Stearate, FDC blue no. 2.

What does the medicine look like and what are the contents of the package?

- Light blue biconvex tablet, with a score line on one side.
- The package contains 10, 20, 30, 50 or 100 tablets.
- Not all package sizes may be marketed.

Name and address of the manufacturer/marketing

authorization holder: CTS Chemical Industries Ltd., 3 Hakidma St., Kiryat Malachi.

This leaflet was revised in 12/2022 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the national drug registry of the Ministry of Health: 1155725985



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