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## PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

### Novitropan 5 mg Tablets

#### Composition:

Each tablet contains: Oxybutynin Chloride 5 mg

Inactive ingredients in the preparation – see section 6. Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or 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 ailment is similar.

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

#### 1. WHAT IS THE MEDICINE INTENDED FOR?

To alleviate symptoms caused by urinary incontinence (e.g., urgency, frequency, leakage, urge incontinence, dysuria) in adults and children.

**Therapeutic group:** anticholinergic

#### 2. BEFORE USING THE MEDICINE:

##### **❗ Do not use the medicine if:**

- there is a known sensitivity to one of the medicine's ingredients (see further information in section 6).
- you suffer from glaucoma (high intraocular pressure), from ocular disease, from partial or complete intestinal obstruction, from gastrointestinal problems including colitis, from myasthenia gravis (severe muscle weakness), from urinary tract obstruction that impedes urination, from severe bleeding.

#### Special warnings regarding use of the medicine:

##### **❗ Do not use the medicine without consulting the doctor before beginning treatment:**

- if you are pregnant, planning to become pregnant, breastfeeding or planning to breastfeed.
- if you suffer or have suffered in the past from impaired function of:
  - the heart and/or vascular system, e.g., hypertension, the liver, the kidney, the thyroid gland (hyperthyroidism), enlarged prostate gland, autonomic neuropathy (an illness that affects the nervous system), colitis or diarrhea, irregular heartbeat, increased or rapid heartbeat, hiatus hernia (sometimes accompanied by digestive difficulty or heartburn).
- if you are 65 years old or more.

- The medicine suppresses the sweat mechanisms. Therefore, take extra care during the hot summer days or in hot climates or during exercise, to avoid developing fever or heat stroke. Consult the doctor if your body temperature rises or you suffer from fever.

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

- sedatives which may cause drowsiness, or for treating nausea or vertigo (dizziness), such as: chlorpromazine or prochlorperazine.
- antipsychotic medicines, such as: clozapine, phenothiazine; haloperidol, benperidol (medicines from the butyrophenones family).
- antidepressants, such as: amitriptyline, imipramine and doxepin (tricyclic antidepressants).
- certain antihistamines used for treating hay fever.
- hyoscine - muscle relaxant.
- amantadine (for treating Parkinson's disease or certain viral infections).
- digoxin (for treating heart problems).
- levodopa for treating Parkinson's disease.
- other medicines from the anticholinergic group or antimuscarinic group, such as:
  - certain medicines for treating irritable bowel syndrome.
  - medicines given for treatment of motion sickness.
  - medicines for treating asthma.
  - medicines for treating urinary incontinence.
  - medicines for treating Parkinson's disease.

##### **❗ Use of the medicine and food:**

Novitropan tablets can be taken with or without food.

##### **❗ Use of the medicine and alcohol consumption:**

**Do not drink wine** or alcoholic beverages during treatment with the medicine.

##### **❗ Pregnancy and breastfeeding:**

**Do not use the medicine without consulting the doctor before starting treatment:**

- if you are pregnant or planning to become pregnant.
- if you are breastfeeding or planning to breastfeed, since the medicine passes into the breast milk and may affect your child.

##### **❗ Driving and operating machinery:**

Use of this medicine may cause drowsiness or blurred vision. In such cases, avoid driving a car or operating machinery. In any case, caution is required when driving a car, operating machinery and when engaging in any activity which requires alertness and sharp vision.

##### **❗ Important information about some of the ingredients of the medicine:**

The preparation contains lactose and may cause an allergic reaction in people sensitive to lactose.

Each tablet of Novitropan contains approximately 100 mg of lactose.

#### 3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's

instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

The dosage and treatment regimen will be determined by the doctor only.

The usual dosage is generally:

**Adults:** One tablet 2-3 times per day.

Maximum dosage per day is 4 tablets.

**Children over 5 years of age:** One tablet twice a day.

Maximum dosage per day is 3 tablets.

If Novitropan is intended for treating bed-wetting, take the last dose at bedtime.

##### **Do not exceed the recommended dose.**

Swallow the medicine with water.

Do not chew; the tablet is intended to be swallowed. Do not halve. To help swallowing, the tablet may be halved and then used immediately. Once the tablet is halved, both its halves should be swallowed together immediately. No information is available regarding crushing/pulverizing the tablet.

##### **If you accidentally take more Novitropan than necessary:**

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you. **Do not induce vomiting** unless explicitly instructed to do so by the doctor.

Overdose may cause: restlessness, over excitement, hot flushes (especially on the face), dizziness, fast/irregular and/or forceful heartbeat, troubled breathing, numbness in hands or feet, coma, loss of balance, confusion, drowsiness, fever, hallucinations, nervousness, nausea, vomiting.

##### **If you forget to take Novitropan:**

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 - do not take a double dose. Take the next dose at the scheduled time and consult the doctor. Adhere to the treatment recommended by the doctor.

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

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

**If you have further questions regarding use of the medicine, consult a doctor or pharmacist.**

#### 4. SIDE EFFECTS:

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

**If you experience the following side effects, stop treatment with Novitropan tablets and inform your doctor immediately or proceed to the emergency room of the nearest hospital:** Allergic reactions (rash, swelling of the face, lips, tongue or throat that may cause difficulty swallowing or breathing); decreased sweating, which may cause the development of fever or heat stroke; numbness

in the hands or feet; hives; fainting; jaundice

**If you experience the following side effects, contact your doctor or pharmacist immediately:** Fast or irregular heartbeat; hot flushes (appearing especially in children); dizziness; unusual fatigue or weakness; restlessness or trouble sleeping; hallucinations; nightmares; confusion, nervousness (anxiety), severe suspiciousness (paranoia); unusual excitement; convulsions; eye problems, including: dry eyes, glaucoma, blurred vision, eye pain; dysuria; skin rash; decreased flow of breast milk; impotence

**Refer to your doctor or pharmacist if one of the following effects concerns you:**

Nausea, vomiting; dry mouth, nose and throat; drowsiness; constipation; decreased sweating; diarrhea; indigestion, stomach pain, heartburn; loss of appetite; dry skin/rash, increased sensitivity upon sun exposure; headache

**These side effects are usually mild.**

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

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](http://www.health.gov.il)), which will direct you to the online form for reporting side effects, or by clicking on the following link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

#### 5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, like any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date that appears on the package. The expiry date refers to the last day of that month.
- Store at a temperature below 25°C.

#### 6. FURTHER INFORMATION:

- In addition to the active ingredient, the medicine also contains:
  - Lactose, Maize Starch, Povidone, Calcium Carboxy Methyl Cellulose, Magnesium Stearate, FD&C blue no. 2.
- What the medicine looks like and the contents of the package:
  - The tablet is light blue, biconvex, with a score line on one side.
  - Packages of 10, 20, 30, 50, 100 tablets are available. Not all package sizes may be marketed.
- Registration Holder/Manufacturer and address: CTS Chemical Industries Ltd., 3 Hakidma Street, Kiryat Malachi, Israel
- This leaflet was checked and approved by the Ministry of Health in August 2014
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 1155725985