

DITROPAN[®]

OXYBUTYNYN 5 mg

scored tablets

Read all of this leaflet carefully before you start taking this medicine

- Keep this leaflet. You may need to read it again
- If you have any further questions or are unsure of anything, ask your doctor or pharmacist for more information.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

In this package leaflet:

1. What DITROPAN is and what it is used for
2. What you need to know before you take DITROPAN
3. How to take DITROPAN
4. Possible side effects
5. How to store DITROPAN
6. Other information

1. WHAT Ditropan IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group

UROLOGICAL MEDICINE / URINARY ANTISPASMODIC

Therapeutic indications

This medicine can be used:

- in adults and children 5 years or older, to treat:
 - loss of control in passing urine during the day or night (urinary incontinence)
 - an immediate need to urinate (urge to void) and excessive frequency of urination in patients with an unstable bladder, which may result from instability of unknown origin of the bladder muscle (idiopathic detrusor instability) or bladder disorders linked to certain diseases of the nervous system (neurogenic bladder disorders).
- in children over 5 years of age, to treat:
 - nighttime bedwetting when other treatments have not worked.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE Ditropan

If you have been told by your doctor that you are intolerant to some sugars, contact him/her before taking this medicine.

Contraindications

Do not take DITROPAN:

- if you are allergic to oxybutynin and/or any of the other ingredients of this medicine,
- if you have a risk of urinary retention (difficulty in emptying the bladder) linked to urethro-prostatic disorders,
- if you have a blockage of matter and gas in part of the intestine (intestinal occlusion),
- if part of your intestine is dilated (toxic megacolon),
- if you have a marked reduction in intestinal tone (intestinal atony),
- if you have serious inflammation of the colon (ulcerative colitis),
- if you have a muscle disorder called "myasthenia gravis",
- if you know you are at risk for closed-angle glaucoma (increased pressure in the eye)

Appropriate precautions for use; special warnings

Take special care with DITROPAN:

Warnings and precautions

Your doctor will need to see you after 4 to 6 weeks to reassess your treatment.

Oxybutynin should not be used to treat urinary incontinence caused by exertion.

Oxybutynin can stimulate an already overactive thyroid gland (hyperthyroidism), aggravate certain cardiac disorders (coronary artery disease, congestive heart failure, arrhythmia, tachycardia), and increase

the volume of an already enlarged prostate gland (prostatic hypertrophy). Tell your doctor if you have any of these disorders.

Using oxybutynin for a long time may cause discomfort because of a reduction in the flow of saliva and thus promote tooth decay, damage to the tissue supporting the teeth (periodontal destruction), or mouth infection caused by certain microscopic fungi (oral candidiasis).

In hot environments, oxybutynin therapy can result in reduced sweating, leading to heat stroke. This risk is higher in younger and older age groups (infants, children, elderly people) and in patients with chronic disease (particularly cardiovascular, renal or neuropsychiatric disorders).

This medicine is not recommended if you have galactose intolerance, glucose-galactose malabsorption syndrome, or Lapp lactase deficiency (rare hereditary diseases).

Precautions for use

This medicine must be used with caution in elderly people and children. It is not recommended for use in children less than 5 years of age.

Inform your doctor in the following situations:

- neurological disorder,
- hiatus hernia or other gastrointestinal disease,
- liver or kidney disease,
- urinary tract infection,
- known heart rate disorder,
- known brain disease.

Taking or using other medicines

If you are taking or have recently taken any other medicines including non-prescription medicines, tell your doctor or pharmacist.

Pregnancy – Breast-feeding

This medicine should not be taken during pregnancy unless otherwise specified by your doctor.

It should not be taken while breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

This medicine may cause drowsiness or blurred vision. Driving, using machines and carrying out dangerous tasks should be avoided.

List of excipients with a specific effect: lactose.

3. HOW TO TAKE Ditropan

Taking this medicine

Adults

The starting dose is ½ tablet, 3 times a day.

The usual dose is 1 tablet, twice or 3 times a day.

Your doctor may decide to increase the dosage up to a maximum of 1 tablet, 4 times a day.

If you are elderly, the starting dose is ½ tablet, twice a day. The usual dose is 1 tablet, twice a day.

Children

Children over 5 years of age: the starting dose is ½ tablet, twice a day.

The usual dose is:

½ tablet, 3 times a day from 5 to 9 years of age,

1 tablet, twice a day from 9 to 12 years of age,

1 tablet, 3 times a day from 12 years of age.

Use of this medicine is not recommended in children below the age of 5 years.

How DITROPAN should be taken

Oral use.

Tablets may be swallowed on an empty stomach with a glass of water, or may also be taken during meals or with a glass of milk in case of stomach pain.

Duration of treatment

STRICTLY FOLLOW YOUR DOCTOR'S PRESCRIPTION

If you take more DITROPAN than you should:

Contact your doctor or a hospital immediately.

If you forget to take DITROPAN:

If you forget to take a dose, take your tablet as soon as possible and then carry on your treatment as normal.

POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects although not everybody gets them.

The most frequently reported side effects include: dry mouth, constipation, blurred vision, dilation of the pupils (mydriasis), accelerated heart rate (tachycardia), nausea, abdominal discomfort, redness of the face, agitation, difficulty urinating (micturition disorders).

Less frequently reported side effects include: headache, urinary retention, dizziness, drowsiness, dry skin, diarrhea, heart rate disorders (arrhythmia), certain eye disorders (intraocular hypertension, glaucoma and dry eyes), indigestion or heartburn (gastroesophageal reflux), convulsions, hallucinations and nightmares, mental confusion, anxiety and delusion (a set of personality disorders), allergic reactions such as skin rash, hives and angioedema.

If you notice any side effects not listed in this leaflet, or if any of the side effects become serious, tell your doctor or pharmacist.

5. HOW TO STORE Ditropan

KEEP THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN.

Do not use DITROPAN after the expiry date indicated on the outer packaging.

Store at a temperature no higher than 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. OTHER INFORMATION

What DITROPAN contains

The active substance is:

Oxybutynin hydrochloride 5.00 mg
for 1 scored tablet.

The other ingredients are:

Indigotine-aluminum lake, microcrystalline cellulose, calcium stearate, anhydrous lactose.

What DITROPAN looks like and contents of the pack

This medicine is presented as scored tablets. Box of 60.

Marketing Authorization Holder and Operating Company sanofi-aventis France

1-13, boulevard Romain Rolland - 75014 Paris – France

Manufacturer

SANOFI WINTHROP INDUSTRIE

30 - 36, avenue Gustave Eiffel - 37100 Tours - France

This leaflet was last approved in: September 2012

THIS MEDICAMENT

Is a product, which affects your health, and its consumption contrary to instructions is dangerous for you.

Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

The doctor and the pharmacist are the experts in medicines, their benefits and risks.

Do not by yourself interrupt the period of treatment prescribed.

Do not repeat the same prescription without consulting your doctor.

Keep all medicaments out of reach of children.

Council of Arab Health Ministers, Union of Arab Pharmacists.