Package leaflet: Information for the patient

Dropizol 10 mg/ml oral drops, solution
Morphine in opium tincture

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- 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 you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Dropizol is and what it is used for

Dropizol is an herbal medicinal product that contains morphine.

Dropizol belongs to a group of medicines called antipropulsives, and is used in adults to treat symptoms of severe diarrhoea when use of other anti-diarrhoea treatments have not given sufficient effect.

Dropizol works by inhibiting the movements of the intestine.

2. What you need to know before you take

Dropizol Do not take Dropizol:
- If you are allergic to opium or morphine or any of the other ingredients of this medicine (listed in section 6)
- If you have opiate dependency
- If you suffer from glaucoma (raised pressure in the eye)
- If you have severe liver or kidney disease
- If you have alcohol withdrawal symptoms (delirium tremens).
- If you have a severe head trauma
- If you are at risk of paralytic ileus (obstruction of the intestine due to paralysis of the intestinal muscles)
- If you suffer from acute asthma
- a chronic pulmonary disease that makes it hard to breathe (COPD)
- If you have breathing problems because of severe respiratory depression. Your doctor will have told you if you have any of these conditions. Symptoms may include breathlessness, coughing or breathing more slowly or weakly than expected
- If you have heart failure secondary to lung disease (cor pulmonale)
- If you are breast-feeding

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Dropizol:

- If you are elderly, as elderly people may react differently to this medicine. The dose may need to be adjusted.
- If you have a chronic kidney and/or liver disease. The dose may need to be adjusted.
- If you are addicted to narcotics or alcohol
- If you have gallbladder disease or gallstones
- If you have a head injury or increased pressure in the brain
- If you have reduced consciousness
- If you are taking medication for depression (moclobemide or other MAO-inhibitors) or have stopped using this medication within the last 2 weeks
- If you have reduced adrenal glands function
- If you have underactive thyroid, the dose may need to be adjusted.
- Low blood pressure with decreased blood volume
- Inflammation of the pancreas
- If you have prostatic hyperplasia (enlargement of the prostate) and/or conditions predisposing to urinary retention.
- If you have an infection or inflammation of the intestines since inhibition of peristalsis may increase the risk of uptake of toxins and development of an enlarged colon and perforation of your intestines.
- If you suffer from epilepsy
- If you take other medicines against diarrhea
- If you experience seizures
- If you have a bleeding in your stomach and/or intestines
- If you take medicine against increased blood pressure

If you experience difficulty to urinate a health care professional should be contacted.

Dropizol is not recommended before surgery or within 24 hours after operation due to risk of paralytic ileus. The symptoms of which are nausea and vomiting.

Risk for dependence and tolerance when using the product.

Children and adolescents
Dropizol should not be used in children and adolescents aged below 18 years.

Other medicines and Dropizol
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

It is especially important that you tell your doctor or pharmacist if you are taking:

- Medicines that potentiate the reduced consciousness and difficulty breathing, seen with Dropizol, such as
    - Alcohol
    - Sleeping medicines (e.g. zolpidem) and general anaesthetics (e.g. barbiturates)
    - Medicines to treat depression (Tricyclic antidepressants) or Parkinson's disease (MAO-inhibitors, e.g. safinamide)
    - Antipsychotic medicines with a sedative action (e.g. phenothiazines)
    - Medicines to treat epilepsy (gabapentin)
    - Medicines to relieve nausea and vomiting (e.g. bromopride, meclizine,

metoclopramide)
    - Medicines to relieve allergy (antihistamines, e.g. carbinoxamine, doxylamine)
    - Other opioid pain relievers (e.g. alfentanil, butorphanol, fentanyl, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, oxycodone, oxymorphone, remifentanil, sufentanil, tapentadol, tramadol).
- Medicines that have a similar mode of action as morphine and therefore may increase withdrawal symptioms and reduce therapeutic effect (buprenorphine, nalbuphine, nalmefene, naltrexone pentazocine)
- Medicines to treat alcohol abuse (disulfiram) or medicines to treat certain kinds of infections (metronidazole) as this might cause unpleasant side effects such as flushing, rapid breathing and fast heart rate
- Medicines to treat tuberculosis (rifampicin) decreases the effect of morphine

- Some medicines used to treat blood clots (e.g. clopidogrel, prasugrel, ticagrelor) may have delayed and decreased effect when taken together with opium

- Amphetamine and analogues can reduce the sedative effect of opioids.
- Loxapine and periciazine can increase the sedative effect of opioids.
- Concomitant use of flibanserin and opioids may increase the risk of CNS depression.
- Opioids can increase the plasma concentrations of desmopressin and sertraline
- Zidovudine (medicine to treat or prevent HIV infections).
- Medicines to treat depression (fluoxetine) might reduce the duration of action of morphine

Concomitant use of Dropizol and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However, if your doctor prescribes Dropizol together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor if you experience such symptoms.

Concurrent administration of morphine may increase the effects of drugs that decrease your blood pressure or other drugs with a lowering effect on your blood pressure.

Dropizol with food, drink and alcohol
Dropizol can be taken with food and drink. Dropizol contains alcohol, so extra care should be exercised when consuming alcohol.
See "Dropizol contains ethanol" below.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy:
Do not take Dropizol during pregnancy unless your doctor has told you to. Dropizol should not be taken close to the date to give birth due to the risk of withdrawal symptoms in the neonate.

Breastfeeding:
Dropizol must not be used during breastfeeding.

Fertility:
It is unknown whether morphine may harm your fertility. Fertile men and women should use effective contraception when using Dropizol.

Driving and using machines
Dropizol contains morphine and ethanol and it may cause drowsiness and significantly affect your ability to drive or operate machines.

Do not drive after taking your medicines until you know how they affect you

Dropizol contains ethanol
This medicinal product contains 33 vol % ethanol (alcohol), i.e. up to 260 mg per dose, equivalent to 6.6 ml of beer or 2.8 ml of wine per dose. Harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease, or epilepsy.

3. How to take Dropizol

Always take this medicine exactly as your doctor told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose in adults is:
Adults: 5-10 drops 2-3 times daily.
Single dose should not exceed 1 ml and the total daily dose should not exceed 6 ml.

Elderly: The dosage should be reduced initially.

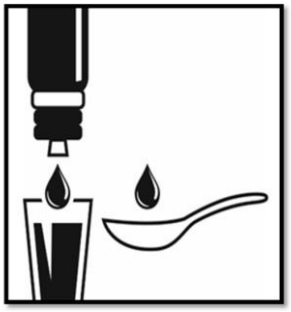
Hepatic impairment: Dropizol should not be used or the dosage should be reduced. Please see section 2 “Do not take” and section 2 “Warnings and precautions”.

Renal impairment: Dropizol should not be used or the dosage should be reduced.
Please see section 2 “Do not take” and section 2 “Warnings and precautions”.

There are 20 drops in 1 ml.

Method of administration:
Oral use.
Dropizol can be used undiluted or mixed in a glass of water. After mixture with water, it should be used immediately. If Dropizol is used undiluted the correct dosage can be administered with a spoon.

1. Opening of the child-resistant closure: Push down and turn.



2. Hold the bottle vertically and drip onto a spoon or into a glass.

Use in children and adolescents
Dropizol should not be used in children and adolescents below 18 years.

If you take more Dropizol than you should
If you take too much Dropizol you may experience small pupils, slow heartrates, low blood pressure, lung edema, breathing difficulties and depressed levels of consciousness which may lead to coma. Call your doctor if you have taken more Dropizol than your doctor has prescribed for you or as stated in this leaflet and you feel uncomfortable.

If you forget to take Dropizol
You should take the missed dose as soon as you remember, unless it is nearly time for the next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Dropizol
Continue taking the medicine as long as your doctor has told you to.
If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

Serious side effects
Common (may affect up to 1 in 10 people):
Difficulty urinating

Uncommon (may affect up to 1 in 100 people):
Shortness of breath fatigue, anxiety, bluish tinge of the lips, fingers and toes, headaches, confusion, seizures and swelling in the legs and feet (Respiratory depression).
Cardiac arrhythmia (fast or slow heartbeat)

Other side effects
Very common (may affect more than 1 in 10 people): Drowsiness and constipation, dry mouth

Common (may affect up to 1 in 10 people):
Dizziness, headache, pupil contraction, nausea and vomiting, loss of appetite, indigestion or discomfort, changes in taste and smell, urticaria sweating, bronchospasm, decreased coughing, asthenia

Uncommon (may affect up to 1 in 100 people):
Facial flushing, itching, spasms in the lower urinary tract, abnormal liver tests

Rare (may affect up to 1 in 1,000 people):
Increase in pancreatic enzymes (seen in a blood test) and inflammation of the pancreas, pain because of kidney stones (renal colic) or gallstones (biliary colic), withdrawal symptoms, orthostatic hypotension (a form of low blood pressure that happens when you stand up from sitting or lying down)

Very rare (may affect up to 1 in 10,000 people):
Difficulty breathing, muscle cramp, seizures, burning and stinging pain, increased sensitivity to pain, blurred vision, double vision, involuntary movement of the eye, a condition where the bowel does not

work properly (ileus), abdominal pain, rash, swelling of the hands, ankles or feet, feeling unwell, shivering, syndrome of inappropriate antidiuretic hormone (SIADH) (symptoms: nausea, malaise, headache, exhaustion and in severe cases may progress to seizures and coma), absence of menstrual bleeding.

Not known (frequency cannot be estimated from the available data)**:**
Adrenal insufficiency (fatigue, weight loss, fainting, low blood sugar, nausea, diarrhea, vomiting and abdominal pain), Euphoria (strong sense of well-being, happiness and excitement), uncontrolled muscle movements, addiction, dysphoric mood (sad, without energy), restlessness, decreased libido or potency, hallucinations, vertigo and fever.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side affects you can help provide more information on the safety of this medicine.

5. How to store Dropizol

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and bottle. The expiry date refers to the last day of that month.

Do not refrigerate or freeze.

After first opening, the bottle may be used for 4 weeks.

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. Contents of the pack and otherinformation

What Dropizol contains
- The active substance is: Opium tincture
  - 1 ml of oral liquid contains 1 ml of tincture from Papaver somniferum L., succus siccum (Opium, raw) corresponding to 10 mg of morphine.

    1 drop contains 50 mg opium tincture equivalent to 0.5 mg (10 mg/ml) anhydrous morphine.

    1 ml contains 20 drops.

  - Extraction solvent: 33 % ethanol (V/V)
- Excipients
- Ethanol 96% V/V
- Purified water

What Dropizol looks like and contents of the pack
Dropizol is a dark, reddish brown liquid. It is available in a brown glass bottle with dropper and a child-resistant closure

Pack sizes 1 x 10 ml, 2 x 10 ml, 3 x 10 ml, 4 x 10 ml, 5 x 10 ml and 10 x 10 ml
Not all pack sizes may be marketed

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Manufacturer
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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This medicinal product is authorised in the Member States of the EEA under the following names:

Danmark: Dropizol
Island: Dropizol
Finland: Dropizol
Norge: Dropizol
Sverige: Dropizol
UK: Dropizol
Austria: Dropizol
Belgium: Dropizole
Czech Republic: Dropizol
Germany: Dropizol
Spain: Dropizol
France: Dropizal
Hungary: Dropizol
Ireland: Dropizol
Italy: Dropizole
Luxembourg: Dropizol
Netherlands: Dropizol
Portugal: Dropizale
Romania: Dropizol
Slovak Republic: Dropizol

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