

## **B. PACKAGE LEAFLET**

## 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
2. What you need to know before you take Dropizol
3. How to take Dropizol
4. Possible side effects
5. How to store Dropizol
6. Contents of the pack and other information

#### 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 severe diarrhoea such as diarrhoea caused by cancer medication, radiation ~~for cancer~~ or certain tumours.

Dropizol should only be used if other diarrhea-stopping treatments have not given sufficient effect. It 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)

##### 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 suffer from acute asthma, COPD (a chronic pulmonary disease that makes it hard to breathe) or other respiratory diseases, or you have difficulty breathing
- 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 have heart failure secondary to lung disease
- If you have severe heart and lung disorder
- 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
- Infection 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 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 and general anesthetics (e.g. barbiturates)
  - Medicines to treat depression or Parkinson's disease (MAO-inhibitors)
  - Antipsychotic medicines with a sedative action (e.g. fentiazines)
  - Medicines to treat epilepsy (gabapentin)
  - Medicines to relieve nausea and vomiting
  - Medicines to relieve allergy (antihistamines)
  - Other opioid pain relievers
- Medicines that have a similar mode of action as morphine and therefore may increase withdrawal symptoms and reduce therapeutic effect (buprenorphine, nalbuphine, 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 used for anaesthesia, trouble sleeping and to relieve anxiety (midazolam) as this may increase the respiratory side effects seen with Dropizol.
- Medicines to treat tuberculosis (rifampicin) decreases the effect of morphine
- Cimetidine may increase the effect of morphine
- Zidovudine (medicine to treat or prevent HIV infections).
- Medicines to treat depression (fluoxetine) might reduce the duration of action of morphine

### **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.

### **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. Take with caution in pregnant women. Dropizol should not be taken in the last trimester due to the risk of drowsiness and difficulty breathing in the infant at birth or withdrawal symptoms in the neonate.

#### Breastfeeding:

Dropizol should not be used during breastfeeding, as opium passes into human milk.

#### 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 V/V % ethanol (alcohol), i.e. up to 330 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 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 is about 19 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.

### **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 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 the medicine as long as your doctor has told you so.**

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**

**Uncommon** (may affect up to 1 in 100 people):

Shortness of breath and difficulty breathing.

### **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, pupil contraction, nausea and vomiting, difficulty urinating, bronchospasm, decreased coughing, asthenia

**Uncommon** (may affect up to 1 in 100 people):

Itching, spasms in the lower urinary tract, abnormal liver tests

**Rare** (may affect up to 1 in 1,000 people):

Orthostatic hypotension (a form of low blood pressure that happens when you stand up from sitting or lying down)

**Not known** (frequency cannot be estimated from the available data):

Euphoria (strong sense of well-being, happiness and excitement), cardiac arrhythmia (fast or slow heartbeat) and uncontrolled muscle movements

### **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 HPRÁ Pharmacovigilance, Earlsfort Terrace IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: [www.hpra.ie](http://www.hpra.ie), e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

. By reporting side effects 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.

This medicinal product does not require any special storage conditions.

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 other information**

### **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 19 drops.
- Extraction solvent: 33 % ethanol (V/V)

### **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-proof locker.

Pack sizes 1 x 10 ml, 3 x 10 ml and 10 x 10 ml.

Not all pack sizes may be marketed

### **Marketing Authorisation Holder and**

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

**Ireland**

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

Austria:	Dropizol
Belgium:	Dropizol
Czech Republic:	Dropizol
Denmark:	Dropizol
Finland:	Dropizol
France:	Dropizol
Germany:	Dropizol
Hungary:	Dropizol
Iceland:	Dropizol
Ireland:	Dropizol
Italy:	Dropizol
Luxembourg:	Dropizol
Norway:	Dropizol
Portugal:	Dropizol
Romania:	Dropizol
Slovak republic:	Dropizol
Spain:	Dropizol
Sweden:	Dropizol
The Netherlands:	Dropizol
United Kingdom:	Dropizol

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