1.3.2.1 Patient Information Leaflet

# PATIENT INFORMATION LEAFLET

## SCHEDULING STATUS

S6

**Dropizol 10 mg/ml** oral drops, solution

Morphine, 1 drop contains 50 mg opium tincture corresponding to 0,5 mg (10 mg/ml) anhydrous morphine.

**Read all of this leaflet carefully before you start taking Dropizol**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- Dropizol has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

**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**.**


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6. Contents of the pack and other information.

## 1. What Dropizol is and what it is used for

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 certain tumours. Dropizol should only be used if other diarrhoea-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 hypersensitive (allergic) to morphine or any of the other ingredients of Dropizol.
- 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**

**Take special care / Special care should be taken with 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.
- If you have low blood pressure with decreased blood volume.
- If you have 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.



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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**.**

***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.

**Other medicines and Dropizol**

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

- 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 symptioms 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 and drink and alcohol**

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

**Pregnancy and breastfeeding and fertility**

If you are pregnant or breastfeeding, 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. Particular care should be taken in pregnant women. Dropizol should not be taken in the last trimester due to the risk of drowsiness and difficulty breathing in the neoborn 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 machinery**

Dropizol **may affect** mental and/or physical abilities to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing, operating machines/equipment (see 'Possible side- effects')

**3. How to take Dropizol**

Do not share medicines prescribed for you with any other person.



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

The usual 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 “Do not take” and section “Warnings and precautions”.

Renal impairment: Dropizol should not be used or the dosage should be reduced.

Please see section “Do not take” and section “Warnings and precautions”. There are about 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.



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**Use in children and adolescents**

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

If you have the impression that the effect of Dropizol is too strong or too weak, tell your doctor or pharmacist.

**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.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

**If you forget to take a dose of 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 forgotten individual doses.

**If you stop taking Dropizol**

Continue the medicine as long as your doctor has told you so.

**4. Possible side effects**

Dropizol can have side effects.

Not all side effects reported for Dropizol are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Dropizol, please consult your healthcare professional for advice.

**If any of the following happens, stop taking Dropizol and tell your doctor immediately or go to the casualty department at your nearest hospital:**

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to Dropizol. You may need urgent medical attention or hospitalisation.

**Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:**

- Shortness of breath and difficulty breathing.

These are all serious side effects. You may need urgent medical attention.

**Tell your doctor if you notice any of the following:**

The following side effects have been reported frequently:

- Drowsiness and constipation.
- Dry mouth.
- Dizziness.

- Pupil contraction.
- Nausea and vomiting.
- Difficulty urinating.
- Bronchospasm (when the airways contract).
- Decreased coughing
- Asthenia (decreased muscle strength).

The following side effects have been reported less frequently:

- Itching.
- Spasms in the lower urinary tract.
- Abnormal liver tests
- Orthostatic hypotension (a form of low blood pressure that happens when you stand up from sitting or lying down)

The following side effects have been reported but the frequency is unknown:

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

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via **v**ia the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of Dropizol.



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## 5. How to store Dropizol

- Keep out of the reach of children.
- Store at or below 25 °C.
- Store in the original container.
- Do not store in a bathroom
- Do not use after the expiry date stated on the bottle
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## 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 20 drops.

  Extraction solvent: 33 % ethanol (V/V)
- The other ingredients are ethanol 96 % *v/v* and purified water.

**What Dropizol looks like and contents of the pack**

Dropizol is a dark, reddish brown liquid, oral drop solution and is packed in a brown glass bottle with a white LDPE dropper and white polypropylene (PP) child-resistant closure.

Pack sizes of 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.

**Holder of Certificate of Registration and Manufacturer**

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**Access to the corresponding Professional Information**

Can be obtained on the SAHPRA website



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