

**Composition:**

**Capsules:** Each DOLOSCOP Capsule contains:

Hyoscine-N-Butylbromide 10 mg and Paracetamol 400 mg.

**Suppositories:** Each DOLOSCOP Suppository contains:

Hyoscine-N-Butylbromide 10 mg and Paracetamol 500 mg.

**Mechanism of Action:**

Hyoscine-N-Butylbromide has an antispasmodic action on smooth muscles of the gastrointestinal tract, biliary tract and urogenital tract. Peripheral anti-cholinergic effects are due to ganglion blocking within the visceral wall and to antimuscarinic effects.

Paracetamol is an effective analgesic and antipyretic. It works by inhibiting the synthesis of prostaglandins in the central nervous system and to a lesser extent through a peripheral effect by blocking the generation of pain impulses.

**Pharmacokinetics:**

**Hyoscine-N-Butylbromide:** Is a quaternary ammonium compound, it is highly polar and hence only partially absorbed following oral (8%) or rectal (3%) administration. It peak plasma concentration maximum within 0.25 - 2 hours. Plasma protein binding (albumin) is approximately 4.4%. It is metabolized mainly via the hydrolytic portion of the ester bond, excreted in faeces and urine.

**Paracetamol:** Paracetamol is rapidly and almost completely absorbed in the small intestine. After oral administration, the maximum concentration in plasma is reached after oral administration 0.5-2 hours.

After rectal administration, Paracetamol is absorbed, giving 30 to 40% bioavailability. The maximum concentration in plasma is reached after administration of 1.3-3.5 hours. Paracetamol diffuses rapidly into all tissues. The binding to plasma proteins is low between (5-20%). Paracetamol is mainly metabolized in the liver and is half-life of its elimination is approximately two hours.

**Indications:**

DOLOSCOP is indicated for patients who suffer from spasms of the gastrointestinal tract, biliary tract, and urogenital tracts (such as female dysmenorrhea).

**Contraindications:**

- Hypersensitivity to the active ingredients or to any of the components of the product.
- Mechanical narrowing of the gastrointestinal tract.
- Megacolon.
- Urinary retention with sub-bladder obstruction (such as a prostate adenoma).
- Narrow angle glaucoma.
- Tachycardia.
- Myasthenia gravis.

**Warnings & Precautions:**

- If severe abdominal pain persists or worsens or is accompanied by other symptoms such as fever, nausea, vomiting, changes in bowel motility, low blood pressure, fainting, or blood in the stool, a doctor should be consulted immediately.

- DOLOSCOP should be used with caution in patients with:

- Hepatic dysfunction (due to chronic alcohol abuse or hepatitis).
  - Deficiency of the enzyme glucose-6-phosphate dehydrogenase.
- Blood counts, hepatic and renal function should be monitored with prolonged use.

**Pregnancy & Lactation:**

**Pregnancy:** There are no adequate data on the use of DOLOSCOP during pregnancy. You should not take DOLOSCOP without consulting the doctor.

**Lactation:** For Hyoscine-N-Butylbromide, the safety of its use during lactation has not been established. However, no harmful effects on a nursing infant have been reported. Paracetamol enters breast milk, but is not likely to affect the infant when therapeutic doses are used.

**Driving & Using Machines:**

No studies have been performed on the effects on the ability to drive or use machines. Caution should be exercised in patients with visual disturbances.

**Drug Interactions:**

- Concomitant use with anticholinergics, amantadine, tricyclic and tetracyclic antidepressants, neuroleptics, quinidine, antihistamines, disopyramide, as well as the tachycardic effect of  $\beta$ -sympathomimetics, may increase the anticholinergic effects.

- Concomitant use with dopamine antagonists such as metoclopramide can lead to a combined weakening of the effect on the motility of the gastrointestinal tract.

- Concomitant use with probenecid leads to decreased clearance of Paracetamol, therefore the dose of Paracetamol should be reduced.

- Concomitant and prolonged use with anticoagulants such as warfarin and other coumarins may enhance the anticoagulant effect and thus increase the risk of bleeding.

- Caution should be exercised with concomitant use with flucloxacillin due to the possibility of metabolic acidosis.

**Side Effects:**

Many of the known undesirable effects are due to the anticholinergic properties of Hyoscine-N-Butylbromide. These anticholinergic effects are generally mild, such as: dizziness, fatigue, mouth dryness (inhibition of salivary secretion), diarrhea, nausea, vomiting, stomach upset, shortness of breath.

Rare: hypotension, flushing of the skin, irregular heartbeat, urinary retention.

**Dosage & Administration:****Capsules:**

- Adults: One or two capsules, three times a day.
- The total daily dose should not exceed 6 capsules.
- The capsules should not be chewed, but should be swallowed whole with a sufficient amount of water.
- DOLOSCOP can be used in children older than 10 years, if necessary.

**Suppositories:**

One suppository, three times daily.

**Overdose:****Symptoms:**

- (Hyoscine-N-Butylbromide): In case of overdose, anticholinergic effects are observed (e.g. urinary retention, dry mouth, flushing of the skin, tachycardia, inhibition of gastrointestinal motility, visual disturbances).

- Symptoms of a Paracetamol overdose usually appear within the first 24 hours and include pallor, nausea, vomiting, loss of appetite, and abdominal pain. Paracetamol overdose may cause hepatic cytolysis which can lead to hepatocellular failure, gastrointestinal bleeding, metabolic acidosis, encephalopathy, coma and death.

**Treatment:**

- (Hyoscine-N-Butylbromide): Symptoms of overdose respond to parasympathomimetics. Cardiovascular complications should be treated according to the usual clinical principles. In the event of respiratory paralysis, intubation and artificial respiration should be considered. In the event of an overdose in patients with glaucoma, pilocarpine should be given. In addition, appropriate supportive measures should be used in each case.

- Paracetamol: If a Paracetamol overdose is suspected, N-acetyl cysteine should be administered intravenously within the first 10 hours (it can be effective for up to 48 hours) after the overdose. Plasma Paracetamol concentration can be reduced by hemodialysis.

**Storage:**

Keep out of reach of children. Store in a dry place, at a temperature below 25 °C.

**Packaging:**

**Capsules:** Each DOLOSCOP carton box contains 10 or 20 Capsules in one or two blister strips.

**Suppositories:** Each DOLOSCOP carton box contains 10 Suppositories in two PVC/PE strips.

- A medicament is a product which affects your health, and it's 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 exist in medicine, it's benefits and risks.  
- Do not repeat the same prescription without consulting your doctor.  
- KEEP THE MEDICAMENTS OUT OF REACH OF CHILDREN  
- Council of Arab Health Ministries, Union of Arab Pharmaceuticals

