



Package leaflet: Information for the user
Hyoscine butylbromide 20 mg/ml solution for injection

Hyoscine butylbromide

Read all of this leaflet carefully before you start using 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, 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 Hyoscine butylbromide is and what it is used for
2. What you need to know before you are given Hyoscine butylbromide
3. How Hyoscine butylbromide will be given
4. Possible side effects
5. How to store Hyoscine butylbromide
6. Contents of the pack and other information

1. What Hyoscine butylbromide is and what it is used for

The name of the medicine is Hyoscine butylbromide 20 mg/ml solution for injection (called hyoscine butylbromide throughout this leaflet). Hyoscine butylbromide belongs to a group of medicines called 'antispasmodics'. These medicines relieve spasms (cramp-like contractions) of internal organs and alleviate related spastic pain.

This medicine is used to relieve spasms of smooth muscles of gastrointestinal tract and urogenital tract (stomach, intestines, biliary tract, pancreas and urinary tract).

Hyoscine butylbromide can also be used in diagnostic and therapeutic medical procedures where spasm may be a problem (e.g. barium enema).

2. What you need to know before you are given Hyoscine butylbromide

You should not be given Hyoscine butylbromide

- if you are allergic to hyoscine butylbromide or any of the other ingredients of this medicine (listed in section 6)
- if you have glaucoma (eye disease)
- if you have enlarged prostate gland and have difficulty or pain passing urine
- if you have gut blockage problems
- if you have obstruction of the intestine due to paralysis of the intestinal muscles (paralytic ileus)
- if you have abnormally enlarged bowel (megacolon)
- if you have increased heart rate
- if you have a condition called 'myasthenia gravis' (characterised by extreme muscle weakness).

You should not be given hyoscine butylbromide injection into the muscle if you are taking medicines to prevent blood clots forming (blood thinners) as haematoma (bruising) may occur.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before being given this medicine:

- if you have unexplained abdominal pain which persists or worsens or occurs with fever, feeling sick, being sick, changes in your bowel movements, abdominal tenderness, low blood pressure, feeling faint or blood in stool

The following information is intended for healthcare professionals only:

Hyoscine butylbromide 20 mg/ml solution for injection

Method of administration

For intravenous and intramuscular injection. Hyoscine butylbromide 20 mg/ml solution for injection may be used diluted, see instructions below.

Posology

Adults: One ampoule (20 mg) intravenously or intramuscularly, repeated after half an hour if necessary. Intravenous injection should be performed 'slowly' (in rare cases a marked drop in blood pressure and even shock may be produced by hyoscine injection). When used in endoscopy this dose may need to be repeated more frequently. Maximum daily dose is 100 mg (5 ampoules).

Elderly: No specific information on the use of this medicine in the elderly is available. Clinical trials have included patients over 65 years and no adverse reactions specific to this age group have been reported.

Paediatric population: Not recommended.

Hyoscine butylbromide injection should not be used on a continuous daily basis or for extended

- if you have increased levels of thyroid hormones in blood
- if you have heart problems such as abnormally rapid heartbeats, heart failure or you are going to have cardiac surgery
- if you have fever.

If you are not sure if any of the above apply to you, talk to your doctor, pharmacist or nurse before receiving this medicine.

You should seek medical attention straight away if you develop a painful, red eye with loss of vision after the injection of hyoscine butylbromide. This may be a sign of elevated pressure inside the eye due to a narrow angle glaucoma so far undiagnosed and thus untreated.

Allergic reactions have been observed after injection of hyoscine butylbromide (see section 4). Therefore, you will be monitored after injection of hyoscine butylbromide and treated appropriately in case such reactions occur.

Other medicines and Hyoscine butylbromide

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription and herbal medicines.

In particular tell your doctor or pharmacist if you are taking any of the following:

- medicines for depression called 'tricyclic antidepressants' or 'tetracyclic antidepressants' (such as doxepin or mirtazapine)
- medicines to treat allergies (antihistamines)
- medicines to treat mental illness (such as fluphenazine or haloperidol)
- medicines to treat heart rhythm disorders (quinidine or disopyramide)
- amantadine (used to treat Parkinson's disease)
- medicines for treating breathing disorders (such as tiotropium, ipratropium, atropine-like medicines)
- metoclopramide (used to treat nausea, vomiting or gastrointestinal disorders).

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before you are being given this medicine.

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 for advice before this medicine is being given to you.

There are limited data on the use of hyoscine butylbromide in pregnant or breast-feeding women. As a precautionary measure, this medicine is not recommended during pregnancy and breast-feeding.

There are no data on the effects on human fertility.

Driving and using machines

Some people may experience sight problems or dizziness after being treated with this medicine. If you are affected, wait until your sight returns to normal or you stop feeling dizzy before driving or using machines.

Hyoscine butylbromide contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How Hyoscine butylbromide will be given

Hyoscine butylbromide will be given to you by a doctor or nurse as a slow injection into your vein or muscle. The medicine may be diluted with other solutions if needed. The dosage will be determined by a doctor.

periods without investigating the cause of abdominal pain.

Overdose

Symptoms: Serious signs of poisoning following acute overdosage have not been observed in man. In the case of overdose, anticholinergic symptoms such as urinary retention, dry mouth, reddening of the skin, tachycardia, inhibition of gastrointestinal motility and transient visual disturbances may occur, and Cheynes-Stokes respiration has been reported.

Treatment: Symptoms of hyoscine butylbromide overdose respond to parasympathomimetics. For patients with glaucoma, pilocarpine should be given locally. Cardiovascular complications should be treated according to usual therapeutic principles. In case of respiratory paralysis, intubation and artificial respiration should be considered. Catheterisation may be required for urinary retention. In addition, appropriate supportive measures should be used as required.

Shelf life

Unopened ampoule: 5 years

Shelf life after first opening: The medicinal product should be used immediately after opening the ampoule.

Shelf life after dilution: Chemical and physical in-use stability has been demonstrated for

This medicine should not be used every day for long periods of time.

Adults

You will usually be given one ampoule (20 mg), but you may be given a further ampoule after half an hour if required. If you are being given hyoscine butylbromide as part of an endoscopy your dose may need to be given more often. Maximum daily dose is 5 ampoules (100 mg).

Elderly

No specific information on the use of this medicine in the elderly is available. No adverse reactions specific to this age group have been reported.

This medicine is not recommended for use in children.

If you have been given too much Hyoscine butylbromide

If you think that you have been given too much medicine talk to your doctor or nurse immediately. The following symptoms may occur: dry mouth, reddening of the skin, difficulty passing urine, increased heart rate and visual disturbances.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Tell your doctor or nurse immediately if you notice any of the following side effects. These may be serious and you may need urgent medical treatment:

- Sudden difficulty breathing, feeling faint or dizzy, or skin reactions (e.g. hives, rash, skin redness, itching). These may be symptoms of severe allergic reaction (anaphylactic reaction and anaphylactic shock) that sometimes may have with fatal consequences
- Painful, red eye with loss of vision

Other side effects

Common (may affect up to 1 in 10 people)

- Blurred vision
- Increased heart rate
- Dizziness
- Dry mouth
- Constipation

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

- Hypersensitivity reactions
- Difficulty breathing
- Skin reactions (hives, rash, skin redness, itching)
- Dilated pupils
- Increased pressure inside the eye
- Low blood pressure
- Flushing
- Small blisters on hands and feet
- Difficulty passing urine

Pain at the site of injection may occur if you have been given this medicine into a muscle.

Although unlikely, in certain circumstances it may be possible that hyoscine butylbromide may pass into the brain and cause side effects (such as confusion).

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 Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information

24 hours at 25°C and 2-8°C.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

Instructions for use and other handling

For single use only. Once opened, any unused portion should be discarded.

The medicinal product is to be visually inspected prior to use. Only clear solutions free from particles should be used.

May be diluted with glucose or with sodium chloride 0.9% solution for injection.

Instruction of ampoule opening

- 1) Turn the ampoule with coloured point up. If there is any solution in the upper part of the ampoule, gently tap with your finger to get all the solution to the lower part of the ampoule.
- 2) Use both hands to open; while holding the lower part of the ampoule in one hand, use the other hand to break off the upper part of the ampoule in the direction away from the coloured point (see the pictures below).

on the safety of this medicine.

5. How to store Hyoscine butylbromide

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

This medicinal product does not require any special storage conditions.

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

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 Hyoscine butylbromide contains

– The active substance is hyoscine butylbromide.

Each ampoule (1 ml) contains 20 mg of hyoscine butylbromide.

– The other ingredients are sodium chloride, hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment), water for injections.

What Hyoscine butylbromide looks like and contents of the pack

Clear, colourless or almost colourless solution free from visible particles.

Type I clear glass ampoules of 1 ml. Ampoules are packed in PVC liners. Liners are packed into cardboard carton.

Pack sizes: 5 or 10 ampoules

Not all pack sizes may be marketed.

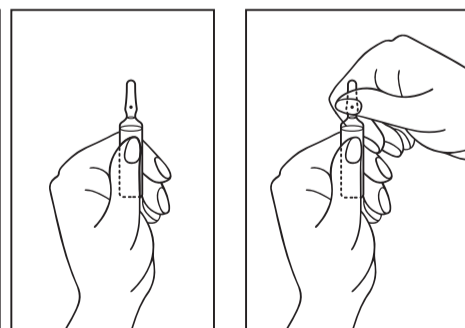
Marketing Authorisation Holder and Manufacturer

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This leaflet was last revised in 11/2023



Place for AS Kalceks internal code
Place for manufacturer internal code



Any unused medicinal product or waste material should be disposed of in accordance with local requirements.