

Hyoscine butylbromide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Medsurge Hyoscine Butylbromide solution for injection.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up-to-date information on the medicine.

Those updates may contain important information about the medicine and its use which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given this medicine against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, talk to doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What Hyoscine Butylbromide injection is used for

Hyoscine Butylbromide injection is an anticholinergic medicine. It relieves the pain of stomach and bowel cramps by helping your digestive system to relax.

Hyoscine Butylbromide injection

reduces the peristalsis (wave-like contractions) of smooth muscle resulting in relief from spasms in certain organs in the digestive system.

Your doctor, however, may have prescribed Hyoscine Butylbromide injection for another purpose.

Always consult your doctor or pharmacist if the pain does not improve within 48 hours or if pain worsens after treatment.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is only available with a doctor's prescription.

Before you use Hyoscine Butylbromide injection

When you must not have this medicine

You should not have Hyoscine Butylbromide injection if you are allergic to hyoscine butylbromide or any of the ingredients listed at the end of this leaflet. If you are uncertain as to whether you have such an allergy you should raise this concern with your doctor or pharmacist.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body

- rash, itching or hives on the skin.

You should not take Hyoscine Butylbromide injection if you have:

- myasthenia gravis - a condition in which the muscles become weak and tire easily
- glaucoma - high pressure in the eye
- porphyria – a rare blood pigment disorder
- a suspected or confirmed blockage of the bowel
- a condition where the bowel is blocked and does not work properly (paralytic or obstructive ileus). Symptoms include severe abdominal pain with lack of stools and/or nausea/vomiting
- a very enlarged bowel (megacolon)
- tachyarrhythmia – a fast heart rate
- achalasia – a condition that causes difficulty in swallowing food
- prostatic hypertrophy – prostate problems.

These conditions are best explained by your doctor or pharmacist.

Do not give it to a child under the age of 6 years.

Safety and effectiveness in children younger than 6 years have not been established.

Your doctor will not give Hyoscine Butylbromide injection by the intramuscular route if you are taking medicines used to prevent

Hyoscine butylbromide

blood clots. In this case, your doctor may choose to give you Hyoscine Butylbromide injection by an intravenous route.

Do not use this medicine after the expiry date (EXP) printed on the pack.

If you are given it after the expiry date has passed, it may not work very well.

Do not use this medicine if the packaging is torn or shows signs of tampering or if the injection shows any visible signs of deterioration.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your pharmacist or doctor.

Before you start to have this medicine

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor immediately if your abdominal pain continues or worsens or occurs with symptoms like:

- fever
- nausea
- vomiting
- changes in bowel movements
- fainting
- blood in faeces.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

If you have not told your doctor about any of the above, tell them before you start taking Hyoscine Butylbromide injection.

Taking other medicines

Tell your doctor if you are taking any other medicines including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Hyoscine Butylbromide injection may interfere with each other. These include:

- medicines used to treat or prevent nausea and vomiting such as metoclopramide
- medicines used to treat malaria such as quinine
- medicines used to treat the symptoms of Parkinson's disease such as amantadine
- medicines used to treat some mental conditions such as tri and tetracyclic antidepressants and antipsychotics
- medicines used to treat allergies such as antihistamines
- medicines for the treatment of depression, heart disease or respiratory disease such as tiotropium, ipratropium or atropine-like compounds
- any other medicine for the treatment of stomach or bowel condition.

These medicines may be affected by Hyoscine Butylbromide injection or may affect how well it works. You may need to use different amounts of the medicines or take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using this medicine.

Pregnancy

Ask for your doctor's advice if you are pregnant, or likely to become pregnant during your course of medication. Special care is recommended during pregnancy, particularly in the first three months.

Breastfeeding

Ask for your doctor's advice if you are breastfeeding or likely to breastfeed during the course of your medication. Special care is recommended if you are breastfeeding as no studies have been conducted in nursing women.

Children

Hyoscine Butylbromide injection may be given to children under the advice of your doctor.

Ability to drive or operate machinery

In rare cases, Hyoscine Butylbromide injection may cause drowsiness. If affected, do not drive or operate machinery.

Alcohol

Do not drink alcohol while on medication with Hyoscine Butylbromide injection. Alcohol may increase the chance of side effects such as drowsiness.

How to use Hyoscine Butylbromide injection

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much medicine is given

Hyoscine butylbromide

Adults and adolescents over 12 years:

The recommended dose is one or two ampoules (20 – 40 milligrams). It can be given as a slow intravenous, intramuscular or subcutaneous injection. The maximum dose per day is 100 milligrams (equivalent to five ampoules).

Infants and young children:

The recommended dose in severe cases is 0.3 – 0.6 mg/kg bodyweight, to be administered by slow intravenous, intramuscular or subcutaneous injection several times a day. The maximum daily dose of 1.2 mg/kg should not be exceeded.

Your doctor might prescribe a different dose or duration of treatment to that described here.

If you want more information, ask your doctor.

Hyoscine Butylbromide injection should only be used under the supervision of a doctor and in a setting where appropriate equipment is readily available for diagnosis and patient monitoring.

If you use too much (overdose)

Overdose of Hyoscine Butylbromide injection is unlikely as it is used under medical supervision. If you do receive too much Hyoscine Butylbromide injection, signs may include drowsiness, dry mouth, difficulty passing urine, reddening of the skin, decreased gastrointestinal tract movement, fast heart rate and sight disturbances.

Tell your doctor or healthcare immediately if you experience any signs of overdose.

While you are given Hyoscine Butylbromide

injection

Things you must do

Before you start on a new medicine, remind your doctor and pharmacist that you are being given Hyoscine Butylbromide injection.

Tell any other doctors and pharmacists who treat you that you are having this medicine.

Tell your doctor immediately if your abdominal pain continues or worsens or occurs with symptoms like:

- fever
- nausea
- vomiting
- changes in bowel movements
- fainting
- blood in faeces.

Tell your doctor or pharmacist if you begin taking any other medicine while you are taking Hyoscine Butylbromide injection.

Cramps in the stomach or bowel may be temporary or may signal the presence of a more serious problem.

Always consult your doctor or pharmacist if the pain is severe or does not improve within 48 hours of taking Hyoscine Butylbromide injection.

Things you must not do

Do not drink alcohol while you are being given this medicine.

Side effects

All medicines may have some unwanted side effects. Sometimes they are serious but most of the time they are not. Your doctor has weighed the risks of this medicine against the benefits they expect it will have

for you.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor as soon as possible if you do not feel well while you are having Hyoscine Butylbromide injection.

Do not be alarmed by this list of possible side effects.

Not everybody experiences them.

Many of the side effects listed for Hyoscine Butylbromide injection are due to its anticholinergic properties. If side effects occur, they are usually mild when Hyoscine Butylbromide injection is used at the recommended dose, and may disappear when you have stopped taking Hyoscine Butylbromide injection.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- dry mouth
- fast heart rate
- reduced sweating
- rash
- itching
- redness of the skin
- a skin condition called dyshidrosis
- difficulty passing urine
- allergic reactions (such as skin rashes, or swelling of the face and difficulty in breathing)
- sudden life-threatening allergic reactions (anaphylaxis with episodes of shortness of breath and shock).
- dizziness
- a drop in blood pressure
- flushing

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- temporary blurred vision (due to reduced eye focusing).

Very rarely there have also been isolated reports of coma, hallucinations (seeing, feeling or hearing things that are not there), dystonia (unusual muscle tone causing distortion of the body), confusion, agitation and dizziness.

These side effects were relieved when the patients stopped Hyoscine Butylbromide injection therapy and received appropriate medical treatment.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- allergic reactions (such as skin rashes, or swelling of the face and difficulty in breathing).
- sudden life-threatening allergic reactions (anaphylaxis with episodes of shortness of breath and shock).

The above list includes very serious side effects. You may need urgent medical attention or hospitalization.

When seeking medical attention take this leaflet and any remaining medicine with you to show the doctor.

Unexpected effects, not listed above, can occur with any

medicine. You should tell your doctor or pharmacist if you notice anything unusual, during or after taking Hyoscine Butylbromide injection.

After having it

Storage

Keep the unopened ampoules in a cool, dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom, near a sink or on a windowsill.

Do not leave it in the car.

Heat and damp can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Each ampoule can be used only once and unused contents of opened ampoules must be discarded.

Disposal

If your doctor tells you to stop having this medicine or the medicine has passed the expiry date, ask your pharmacist how to dispose of medicines no longer required.

Product description

What it looks like

Medsurge Hyoscine

Butylbromide solution for injection is available in clear glass ampoules containing a clear, colourless or almost colourless solution in the following presentation and pack sizes.

Presentation	Pack Sizes (Ampoules)
20 mg in 1 mL	5 x 20 mg/1 mL; 10 x 20 mg/1 mL

Not all pack sizes are marketed.

Ingredients

Active ingredient:

1 mL of Medsurge Hyoscine Butylbromide solution for injection 20 mg in 1 mL contains 20 mg of hyoscine butylbromide.

Inactive ingredients:

- sodium chloride
- hydrochloric acid
- sodium hydroxide
- water for injections.

This medicine does not contain lactose, sucrose, gluten, tartrazine or other azo dyes.

Sponsor

New Zealand Sponsor

Medicianz Healthcare Limited
P.O. Box 331054
Takapuna
Auckland 0622
Email: info@medicianz.com.au
Telephone: 0800 788 261

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