

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I given Hyoscine Butylbromide Injection?

Hyoscine Butylbromide Injection contains the active ingredient hyoscine butylbromide. Hyoscine butylbromide is an anticholinergic medicine. Hyoscine Butylbromide Injection is used to relieve the pain of stomach and bowel cramps by helping your digestive system to relax. It is also used to help relax gallbladder spasms and kidney spasms, and as a diagnostic aid in radiology.

For more information, see Section [1. Why am I given Hyoscine Butylbromide Injection?](#) in the full CMI.

2. What should I know before I receive Hyoscine Butylbromide Injection?

Do not use if you have ever had an allergic reaction to hyoscine butylbromide or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I receive Hyoscine Butylbromide Injection?](#) in the full CMI.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking or using any other medicines including any that you get without a prescription from your pharmacy, supermarket, or health food shop. Hyoscine Butylbromide Injection must not be given in the muscle if you are being treated with anticoagulant medicines.

For more information see Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I receive Hyoscine Butylbromide Injection?

- Your doctor will decide what dose you will receive and the duration of treatment.
- Hyoscine Butylbromide Injection is administered by a doctor or nurse. It is given by deep injection into a muscle (e.g. the buttock, upper leg or upper arm) or slow injection into a vein.

More instructions can be found in Section [4. How do I receive Hyoscine Butylbromide Injection?](#) in the full CMI.

5. What should I know after being given Hyoscine Butylbromide Injection?

Things you should do	<ul style="list-style-type: none">• Call your doctor straight away if the pain is severe or does not improve within 48 hours of being given Hyoscine Butylbromide Injection.• Before you take any other medicine, talk to your doctor or pharmacist.• Remind any doctor, dentist, or pharmacist you visit that you have received Hyoscine Butylbromide Injection.
Things you should not do	<ul style="list-style-type: none">• Do not drink alcohol after receiving Hyoscine Butylbromide Injection.
Driving or using machines	<ul style="list-style-type: none">• In rare cases, Hyoscine Butylbromide injection may cause drowsiness. If affected, do not drive or operate machinery.
Drinking alcohol	<ul style="list-style-type: none">• Drinking alcohol while on Hyoscine Butylbromide Injection may increase the chance of side effects such as drowsiness.
Looking after your medicine	<ul style="list-style-type: none">• Store below 25°C. Protect from light.• Store in a cool, dry place away from moisture, heat, or sunlight.

For more information, see Section [5. What should I know after being given Hyoscine Butylbromide Injection?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects include redness of the skin, itching, a skin condition called dyshidrosis, rash, abnormal sweating, reduced sweating, fast heart rate, drop in blood pressure, dry mouth, flushing, difficulty with passing urine, shortness of breath, dizziness, and temporary blurred vision due to reduce eye focusing. Serious side effects are allergic reactions (such as skin rashes, or swelling of the face and difficulty in breathing) and sudden life-threatening allergic reactions (anaphylaxis with episodes of shortness of breath and shock). For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Active ingredient(s): *hyoscine butylbromide*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Hyoscine Butylbromide Injection. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Hyoscine Butylbromide Injection.**

Where to find information in this leaflet:

- [1. Why am I given Hyoscine Butylbromide Injection?](#)
- [2. What should I know before I am given Hyoscine Butylbromide Injection?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I receive Hyoscine Butylbromide Injection?](#)
- [5. What should I know after being given Hyoscine Butylbromide Injection?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I given Hyoscine Butylbromide Injection?

Hyoscine Butylbromide Injection contains the active ingredient **hyoscine butylbromide**. Hyoscine butylbromide is an anticholinergic medicine. **Hyoscine Butylbromide Injection is used to relieve the pain of stomach and bowel cramps by helping your digestive system to relax. It is also used to help relax gallbladder spasms and kidney spasms, and as a diagnostic aid in radiology.**

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

2. What should I know before I receive Hyoscine Butylbromide Injection?

Warnings

Do not receive Hyoscine Butylbromide Injection if:

- you are allergic to hyoscine butylbromide, or any of the ingredients listed at the end of this leaflet.
- 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
- Always check the ingredients to make sure you can use this medicine.
- you have myasthenia gravis - a condition in which the muscles become weak and tire easily.
- you have glaucoma - high pressure in the eye
- you have porphyria - a rare blood pigment disorder
- you have a suspected or confirmed blockage of the bowel or stomach
- you have a weakened intestinal muscles (intestinal atony)

- you have 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.
- you have a very enlarged bowel (megacolon)
- you have a fast heart rate (tachyarrhythmia)
- you have a condition that causes difficulty in swallowing food (achalasia)
- you have prostate problems - prostatic hypertrophy
- you are taking anticoagulants medicines and Hyoscine Butylbromide Injection will be given in the muscle

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

Check with your doctor if you:

- you have any other medical conditions
- you take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or plan to breastfeed.

3. What if I am taking other medicines?

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

Hyoscine Butylbromide Injection must not be given in the muscle if you are being treated with anticoagulant medicines.

Some medicines and Hyoscine Butylbromide Injection may interfere with each other:

- 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 conditions
- medicine used to treat certain conditions, such as disopyramide

Check with your doctor, or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Hyoscine Butylbromide Injection.

4. How do I receive Hyoscine Butylbromide Injection?

How much to be given

- Your doctor will decide what dose you will receive. This depends on your condition and other factors.
- The recommended dose is one or two ampoules (20 – 40 milligrams)
The maximum dose per day is 100 milligrams (equivalent to five ampoules).

Your doctor might prescribe a different dose or duration of treatment. If you need further information, ask your doctor or pharmacist.

Do not use it for extended periods.

Worsening or persistent stomach pain should be investigated by your doctor to determine the cause of the pain.

How it is given

This medicine should only be given by a doctor or nurse and in a setting where appropriate equipment is readily available for diagnosis and patient monitoring.

The injections can be given deeply into a muscle (e.g. the buttock, upper leg, or upper arm) or can be given as a slow injection into the vein.

If you receive too much Hyoscine Butylbromide Injection

These injections are given under medical supervision and it is very unlikely that you will be given too much.

Symptoms of an overdose may include drowsiness, dry mouth, difficulty passing urine, reddening of the skin, decreased gastrointestinal tract movement, fast heart rate and sight disturbances.

If you think that you have been given too much Hyoscine Butylbromide Injection, you may need urgent medical attention.

Tell your doctor or medical staff immediately if you feel you have been given too much Hyoscine Butylbromide Injection.

You should do this even if there are no signs of discomfort or poisoning.

If you experience any signs of overdose after you leave the doctor or nurse, you should immediately:

- phone the Poisons Information Centre (by calling **13 11 26** if you are in Australia), or
- phone the National Poisons Information Centre (by calling **0800 POISON** or **0800 764 766** if you are in New Zealand), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

5. What should I know after being given Hyoscine Butylbromide Injection?

Things you should do

Before you take any other medicine, talk to your doctor or pharmacist.

Call your doctor straight away if:

- **the pain is severe or does not improve within 48 hours of being given Hyoscine Butylbromide Injection.**
Cramps in the stomach or bowel may be temporary or may signal the presence of a more serious problem.
- **you develop painful, red eye/s with loss of vision.**

Remind any doctor, dentist, or pharmacist you visit that you have received Hyoscine Butylbromide Injection.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Hyoscine Butylbromide Injection affects you.

Hyoscine Butylbromide Injection may cause dizziness, tiredness, drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery, or do anything else that could be dangerous.

Drinking alcohol

Do not drink alcohol after receiving Hyoscine Butylbromide Injection.

Alcohol may increase the chance of side effects such as drowsiness.

Looking after your medicine

- Store below 25°C. Protect from light.

Store it in a cool dry place away from moisture, heat or sunlight; for example:

- do not store it in the bathroom or near a sink, or
- do not store it in the car or on windowsills.

Keep it where young children cannot reach it.

Each ampoule is for single use only.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects

Less serious side effects

Less serious side effects	What to do
<p>Skin-related</p> <ul style="list-style-type: none"> Redness of the skin Itching A skin condition called dyshidrosis (small blisters on the hands and feet) Rash Abnormal sweating Reduced sweating <p>Heart- related</p> <ul style="list-style-type: none"> Fast heart rate Drop in blood pressure <p>Others</p> <ul style="list-style-type: none"> Dry mouth Flushing Difficulty with passing urine Shortness of breath Dizziness Temporary blurred vision due to reduce eye focusing 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Very rarely there have also been isolated reports of:

- coma,
- hallucinations (seeing, feeling, or hearing things that are not there),
- unusual muscle tone causing distortion of the body (dystonia),
- confusion,
- agitation, and
- dizziness.

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

Serious side effects

Serious side effects	What to do
<p>Allergy- related</p> <ul style="list-style-type: none"> 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) 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Hyoscine Butylbromide Injection contains

Active ingredient (main ingredient)	20 mg of hyoscine butylbromide per ampoule
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> sodium chloride hydrochloric acid sodium hydroxide water for injections Hyoscine Butylbromide Injection does not contain preservative.
Potential allergens	Not applicable

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

Do not take this medicine if you are allergic to any of these ingredients.

What Hyoscine Butylbromide Injection looks like

Hyoscine Butylbromide Injection is available in clear glass ampoules containing a clear, colourless or almost colourless solution in following pack-size:

Presentation

20 mg in 1 mL

Pack Sizes**(Ampoules)**

5 x 20 mg/1 mL;

10 x 20 mg/1 mL

Not all pack sizes are marketed.

Australian Registration Number(s):

Medsurge Hyoscine Butylbromide,

20 mg/1 mL: AUST R 326541

Medicianz Hyoscine Butylbromide

20 mg/1 mL: AUST R 326542

Who distributes Hyoscine Butylbromide Injection

Medsurge Pharma Pty Ltd

Unit 1&2, 6-7 Gilda Court

Mulgrave, Victoria 3170

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