

Hyoscine butylbromide SXP Injection

Hyoscine butylbromide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Hyoscine butylbromide SXP. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

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

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Hyoscine butylbromide SXP is used for

Hyoscine butylbromide SXP is known as an anticholinergic medicine. It is used:

- To relieve the pain of stomach and bowel cramps by helping your digestive system to relax
- To help relax gallbladder spasms and kidney spasms
- As a diagnostic aid in radiology.

Hyoscine butylbromide SXP reduces the peristalsis (wave-like contractions) of smooth muscle resulting in relief from spasms in

certain organs in the digestive system.

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

Your doctor may have prescribed it for another reason.

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

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

Before you are given Hyoscine butylbromide SXP

When you must not be given it

You will only receive treatment with Hyoscine butylbromide SXP injection if it has been prescribed for you by a doctor.

The medicine will be given to you by a healthcare professional.

You should not be given Hyoscine butylbromide SXP if you have an allergy to:

- any medicine containing hyoscine butylbromide
- 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

You should not be given Hyoscine butylbromide SXP if you have the following medical conditions:

- 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
- megacolon - a condition where the bowel is enlarged
- a suspected or confirmed blockage of the bowel
- paralytic or obstruction ileus - a condition where the bowel is blocked and does not work properly
- tachyarrhythmia – a fast heart rate
- achalasia – a condition that causes difficulty in swallowing food
- prostatic hypertrophy – prostate problems, with urinary retention - inability to completely empty the bladder
- intestinal atony - lack of normal muscle tone or strength in the bowel

Hyoscine butylbromide SXP must not be used when there is a blockage in the stomach or bowel or in certain conditions when there is reduced bowel activity.

These conditions are best explained by your doctor or pharmacist.

Your doctor will not give Hyoscine butylbromide SXP by the intramuscular route if you are taking medicines used to prevent blood clots. In this case, your doctor may choose to give you Hyoscine butylbromide SXP by an intravenous route.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

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

The use of this medicine in children is not recommended.

Safety and effectiveness in children have not been established.

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

Before you are given it

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

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

There is limited information on the use of Hyoscine butylbromide SXP during pregnancy and breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you are given Hyoscine butylbromide SXP.

Taking other medicines

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

Some medicines and Hyoscine butylbromide SXP 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, phenothiazines and MAOI inhibitors
- medicines used to treat allergies such as antihistamines
- medicines for the treatment of depression, heart disease or respiratory disease such as tiotropium, ipratropium, atropine-like compounds, betasympathomimetics and disopyramide
- any other medicine for the treatment of stomach or bowel condition including belladonna alkaloids

These medicines may be affected by Hyoscine butylbromide SXP or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while being given this medicine.

How Hyoscine butylbromide SXP is 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.

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

Safety and effectiveness of Hyoscine butylbromide SXP in children have not been established and is therefore not recommended.

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.

Overdose

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.

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

While you are being given Hyoscine butylbromide SXP

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being given Hyoscine butylbromide SXP.

Tell any other doctors, dentists and pharmacists who treat you that you are being given 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
- abdominal tenderness
- drowsiness

Tell your doctor or pharmacist if the pain is severe or does not improve within 48 hours of taking Hyoscine butylbromide SXP.

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

If you have a heart condition, your doctor will closely monitor you for additional side effects.

Things to be careful of

Be careful driving or operating machinery until you know how Hyoscine butylbromide SXP affects you.

This medicine 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.

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

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given Hyoscine butylbromide SXP.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

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 (blisters on the feet and hands)
- difficulty with passing urine or inability to completely empty the bladder
- eye conditions including temporary blurred vision (due to reduced eye focusing), dilated pupils, visual disturbances
- dizziness
- a drop in blood pressure
- flushing
- shortness of breath

Vary 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 SXP 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).

Allergic reactions can be very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After being given Hyoscine butylbromide SXP

Storage

Hyoscine butylbromide SXP

Injection should be kept in a cool dry place where the temperature stays below 25°C.

Protect from light.

Each ampoule is for single use only and unused contents of opened ampoules must be discarded.

Product description

What it looks like

Hyoscine butylbromide SXP injection 1 mL glass ampoules contain a clear, colourless or almost colourless solution.

Hyoscine butylbromide SXP injection is available in packs of 5 and 10 ampoules. Not all pack sizes may be marketed.

Ingredients

Each Hyoscine butylbromide SXP injections contains 20 mg of hyoscine butylbromide as the active ingredient.

The ampoules also contain the following inactive ingredients:

- sodium chloride
- water for injections
- sodium hydroxide (for pH adjustment)

- hydrochloric acid (for pH adjustment)

Distributor

Hyoscine butylbromide SXP is distributed in Australia by:

Southern Cross Pharma Pty Ltd

Suite 5/118 Church St
Hawthorn VIC 3122

This leaflet was prepared in July 2020.

AUST R 278817

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