SPAZMOL 20 mg/ml Solution for Injection **DEVATIS**
Hyoscine butylbromide

Consumer Medicine Information (CMI)

What is in this leaflet

Please read this leaflet carefully before you start using SPAZMOL.

This leaflet answers some common questions about SPAZMOL. 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 SPAZMOL against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

What SPAZMOL is used for

SPAZMOL contains Hyoscine butylbromide as the active ingredient.

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

SPAZMOL reduces the peristalsis (wave-like contractions) of smooth muscle resulting in relief from spasms in certain organs in the digestive system.
Your doctor may have prescribed SPAZMOL for another reason. 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 SPAZMOL has been prescribed for you.

This medicine is available only with a doctor's prescription.
There is no evidence that it is addictive.

Before you use SPAZMOL

When you must not use it

You must not be given SPAZMOL if you have had an allergic reaction to:
- **hyoscine butylbromide**
- **any of the ingredients in SPAZMOL.**

These ingredients are listed in full at the end of this leaflet (See *Ingredients*).
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

If you are uncertain as to whether you have such an allergy you should raise this concern with your doctor or pharmacist.

You must not be given SPAZMOL 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.

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

You should not use SPAZMOL if the packaging is torn or shows signs of tampering.
Do not take it 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.

If you are not sure whether you should be given SPAZMOL, talk to your doctor.

Before you start to use it

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 breastfeeding.

If you have not told your doctor about any of the above, tell him/her before you start taking SPAZMOL.

Taking other medicines
Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking SPAZMOL.

Some medicines and SPAZMOL 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 SPAZMOL, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.
Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking 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
SPAZMOL Injection may be given to children under the advice of your doctor.

Ability to drive or operate machinery
In rare cases, SPAZMOL may cause drowsiness. If affected, do not drive or operate machinery.

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

How to use SPAZMOL

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 to use
Adults and adolescents over 12 years:
The recommended dose is 1 or 2 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 5 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. SPAZMOL 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 SPAZMOL injection is unlikely as it is used under medical supervision. If you do receive too much SPAZMOL 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 professional immediately if you experience any signs of overdose.

Immediately telephone your doctor, or the Poisons Information Centre (New Zealand: 0800 POISON or 0800 764 766), or go to the Accident and Emergency department at your nearest hospital, if you think you or anyone else may have been given too much SPAZMOL Injection. Do this even if there are no signs of discomfort or poisoning.

If you forget to take it
It is unlikely as it is used under medical supervision.

How it is given
SPAZMOL Solution for Injection is a sterile solution. It is given slowly by:
- direct injection into a vein,
- deep injection into a large muscle or
- as injection under your skin.

SPAZMOL must only be prepared and given by a doctor or nurse.

While you are using SPAZMOL

Things you must do
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 feces

As mentioned previously, do not drink alcohol. Tell your doctor or pharmacist if you begin taking any other medicine while you are taking SPAZMOL.

Cramps in the stomach or bowel may be temporary or may signal the presence of a more serious problem.
Tell your doctor or pharmacist if the pain is severe or does not improve within 48 hours of taking SPAZMOL.

Tell any other doctors, dentists and pharmacists who are treating you that you are being given SPAZMOL Solution for Injection, especially if you are about to be started on any new medicines.

Tell your doctor immediately if you become pregnant while you are being given SPAZMOL Solution for Injection.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being treated with SPAZMOL.

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Ask for the advice of your doctor or pharmacist if you have any concerns about the effects of taking this medicine.
Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

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

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 SPAZMOL 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.

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 SPAZMOL.

After using SPAZMOL

Storage
Store below 25°C.
Each ampoule can be used only once and unused contents of opened ampoules must be discarded.

Keep the medicine where young children cannot reach it.
A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.

Disposal
Do not use SPAZMOL Solution for Injection after the expiry date, which is stated on the packaging.
If your doctor advises you to stop taking SPAZMOL or the medicine has passed its expiry date, ask your pharmacist how to throw away medicines you no longer use. Do not throw away any medicines via wastewater. These measures will help protect the environment.

Product description

SPAZMOL is the brand name of your injection.

What it looks like
The glass ampoules of injection contain a clear colorless and odorless solution.

SPAZMOL ampoules are sold to pharmacists and hospitals in packs of 3, 5 or 6 ampoules.

Ingredients
Active ingredient(s):
Each SPAZMOL injection contains 20 mg of hyoscine butylbromide in 1 ml of solution.

Inactive ingredients:
The ampoules also contain sodium chloride, hydrochloric acid (for pH adjustment), and water for Injections.

SPAZMOL Solution for Injection does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Sponsor

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