SPAZMOBEST

Training Manual

Understanding pain
Understanding different abdominal pain

"The pain of abdominal cramps is different from headache, or indigestion. For me, it's a special kind of pain. And I think it needs a special kind of treatment."
Each of us has a unique experience of our body and its needs. Pain is often a "message" from our body. It's important to understand what the message means, so we can act to prevent the problem in the future.

Abdominal pain due to cramp

In most cases, abdominal pain is harmless and temporary. Many people experience short-term pain in the abdomen once in a while. Stress, family affairs or eating food that is very spicy, acidic or that has a high fat content can cause temporary pain. But sometimes the pain doesn't go away after a few minutes. Sometimes the muscles of the digestive organs go into spasms, or cramps. These can cause pain in the lower abdomen that lasts up to several hours or even several days. And as anyone who's ever experienced strong abdominal cramps can confirm, they can be severely painful.
At times like these, Spazmobest provides targeted, effective and safe relief from the pain of abdominal cramps.

Irritable Bowel Syndrome (IBS)

"I suffered from stomach cramps for years. Finally, one doctor diagnosed IBS. That was it; now at last I can do something to prevent the pain."
A large number of people suffer from recurring abdominal pain and cramps for which doctors are unable to find a specific physical cause. In some cases, pain and cramps are accompanied by a feeling of fullness, bloating (i.e. the feeling of having the abdomen swelling to larger-than-normal size) and disturbed bowel movements, often alternating between constipation and diarrhea. This collection of symptoms - pain, cramps, bloating and diarrhea/constipation with no evident physical cause - has been given the name Irritable Bowel Syndrome (IBS).
You can learn more about IBS by going to the Irritable Bowel Syndrome section of this website.

Regular discomfort: menstrual pain

Before or during menstruation, pain in the lower abdomen is also quite normal. Hormones cause the muscles of the uterus to contract. The surrounding digestive organs can also start to cramp. Many women therefore experience menstrual pain together with digestive disturbances such as bloating, constipation or diarrhoea. While this is certainly not pleasant, it is an experience shared by many women. Spazmobest is a proven treatment for the pain of menstrual cramps, trusted by millions of women around the world.
Spazmobest

Butylscopolamine — also known as scopolamine butylbromide, butylhyoscine and hyoscine butylbromide — is a peripherally acting antimuscarinic, anticholinergic agent[1] used as an abdominal-specific antispasmodic. It is a quaternary ammonium compound and a semisynthetic derivative of scopolamine. It is marketed under the trade name Buscopan by Boehringer Ingelheim GmbH, Germany, who also offer a combination of butylscopolamine and paracetamol, marketed under the name Buscopan Plus (in some countries as Buscapina, Buscopan Compositum).

Butylscopolamine is used to treat pain and discomfort caused by abdominal cramps, menstrual cramps, or other spasmodic activity in the digestive system. It is also effective at preventing bladder spasms. It is not an analgesic in the normal sense, since it doesn't 'mask' or 'cover over' the pain, but rather works to prevent painful cramps and spasms from occurring in the first place. The attachment of the butyl-bromide moiety effectively prevents the movement of this drug across the blood–brain barrier, effectively minimising undesirable CNS side-effects associated with scopolamine/hyoscine.

\[
[7(S)-(1\alpha,2\beta,4\beta,5\alpha,7\beta)]-9\text{-butyl}-7-(3\text{-hydroxy-}
\text{1-oxo-2-phenylpropoxy})-9\text{-methyl-3-oxa-}
9\text{-azonitricyclo[3.3.1.0(2,4)]nonane}
\]
INDICATIONS

Spazmobest Tablets are indicated for Gastric and duodenal ulcers, gastrointestinal spasm and hypermotility, pylorospasm in infants, post-operative vomiting, Spastic constipation, biliary dyskinesia and spasm of the urinary tract, delayed relaxation of the lower uterine segment, dysmenorrhoea. It is also indicated in radiologic and endoscopic diagnostic procedures of gastrointestinal tract to reduce spasm.

DOSAGE AND METHOD OF ADMINISTRATION

Spazmobest Tablets are for oral administration only.

Spazmobest Tablets should be swallowed whole with adequate water.

**Adults:** 10-20 mg 3-5 times daily

**Paediatrics:** Not recommended under 6 years

**Elderly:** Reduced dose may be necessary

PHARMACOLOGICAL PROPERTIES

Pharmacodynamics

Hyoscine Butylbromide exerts a spasmolytic action on the smooth muscle of the gastrointestinal, biliary and genito-urinary tracts. As a quaternary ammonium derivative, hyoscine butylbromide does not enter the central nervous system. Therefore, anticholinergic side effects at the central nervous system do not occur. Peripheral anticholinergic action results from a ganglion-blocking action within the visceral wall as well as from an anti-muscarinic activity.

Pharmacokinetics

**Absorption:** As a quaternary ammonium compound, hyoscine butylbromide is highly polar and hence only partially absorbed following oral (8%) or rectal (3%) administration. After oral administration of single doses of hyoscine butylbromide in the range of 20 to 400 mg, mean peak plasma concentrations between 0.11 ng/mL and 2.04 ng/mL were found at approximately 2 hours. In the same dose range, the observed mean AUC0-tz-values varied from 0.37 to 10.7 ng h/mL. The median absolute bioavailabilities of different dosage forms, i.e. coated tablets, suppositories and oral solution, containing 100 mg of hyoscine butylbromide each were found to be less than 1%.
**Distribution:** Because of its high affinity for muscarinic receptors and nicotinic receptors, hyoscine butylbromide is mainly distributed on muscle cells of the abdominal and pelvic area as well as in the intramural ganglia of the abdominal organs. Plasma protein binding (albumin) of hyoscine butylbromide is approximately 4.4%. Animal studies demonstrate that hyoscine butylbromide does not pass the blood-brain barrier, but no clinical data to this effect is available. Hyoscine butylbromide (1 mM) has been observed to interact with the choline transport (1.4 nM) in epithelial cells of human placenta *in vitro.*

**Metabolism and Elimination**

Following oral administration of single doses in the range of 100 to 400 mg, the terminal elimination half-lives ranged from 6.2 to 10.6 hours. The main metabolic pathway is the hydrolytic cleavage of the ester bond. Orally administered hyoscine butylbromide is excreted in the faeces and in the urine. Studies in man show that 2 to 5% of radioactive doses is eliminated renally after oral, and 0.7 to 1.6% after rectal administration. Approximately 90% of recovered radioactivity can be found in the faeces after oral administration. The urinary excretion of hyoscine butylbromide is less than 0.1% of the dose. The mean apparent oral clearances after oral doses of 100 to 400 mg range from 881 to 1420 L/min, whereas the corresponding volumes of distribution for the same range vary from 6.13 to 11.3 x 10^5 L, probably due to very low systemic availability. The metabolites excreted via the renal route bind poorly to the muscarinic receptors and are therefore not considered to contribute to the effect of the hyoscine butylbromide.

**CONTRAINDICATIONS**

Spazmobest Tablets should not be administered to patients with Myasthenia Gravis, Narrow angle glaucoma, retention of urine (Prostate hypertrophy), Mechanical Stenosis in the region of G.I.T., Tachycardia, Megacolon.

In addition, they should not be given to patients with a known hypersensitivity to hyoscine butylbromide or any other component of the product.

**DRUG INTERACTIONS**

The anticholinergic effect of drugs such as tri- and tetracyclic antidepressants, antihistamines, quinidine, amantadine, antipsychotics (e.g. butyrophenones, phenothiazines), disopyramide and other anticholinergics (e.g. tiotropium, ipratropium, atropine-like compounds) may be intensified by Spazmobest.

Concomitant treatment with dopamine antagonists such as metoclopramide may result in diminution of the effects of both drugs on the gastrointestinal tract.
The tachycardic effects of beta-adrenergic agents may be enhanced by Spazmobest.

Absorption of concomitantly administered oral drug is delayed.

**PREGNANCY, LACTATION AND FERTILITY**

**Pregnancy**

There are limited data from the use of hyoscine butylbromide in pregnant women. Animal studies are insufficient with respect to reproductive toxicity. As a precautionary measure Spazmobest is not recommended during pregnancy.

**Lactation**

There is insufficient information on the excretion of hyoscine butylbromide and its metabolites in human milk. A risk to the breastfeeding child cannot be excluded. Use of Hyoscine Butylbromide during breastfeeding is not recommended.

**Fertility**

No studies on the effects on human fertility have been conducted.

**SIDE- EFFECTS**

Many of the listed side-effects can be assigned to the anticholinergic properties of Spazmobest.

Side-effects include: Increased pulse rate, skin reactions(e.g. urticaria, pruritis), dry mouth, urinary retention, vision disturbances.

**OVERDOSAGE**

**Symptoms:**

Serious signs of poisoning following acute overdosage have not been observed in man. In the case of overdosage, anticholinergic effects 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.

**Therapy:**

In the case of oral poisoning, gastric lavage with medicinal charcoal should be followed by magnesium sulphate (15%). Symptoms of spazmobest overdosage 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. Catheterisation may be required for urinary retention.

In addition, appropriate supportive measures should be administered as required.

**SPECIAL WARNINGS AND PRECAUTIONS FOR USE**

In case severe, unexplained abdominal pain persists or worsens, or occurs together with symptoms like fever, nausea, vomiting, changes in bowel movements, abdominal tenderness, decreased blood pressure, fainting, or blood in stool, medical advice should immediately be sought.

Spazmobest Tablets should be used with caution in conditions characterised by tachycardia such as thyrotoxicosis, cardiac insufficiency or failure and in cardiac surgery where it may further accelerate the heart rate. Due to the risk of anticholinergic complications, caution should be used in patients susceptible to intestinal or urinary outlet obstructions.

Because of the possibility that anticholinergics may reduce sweating, Spazmobest should be administered with caution to patients with pyrexia.

Elevation of intraocular pressure may be produced by the administration of anticholinergic agents such as Spazmobest in patients with undiagnosed and therefore untreated narrow angle glaucoma. Therefore, patients should seek urgent ophthalmological advice in case they develop a painful, red eye with loss of vision whilst or after taking Spazmobest.

Effects on Ability to drive and use machines: No studies on the effects on the ability to drive and use machines have been performed. Because of possible visual accommodation disturbances patients should not drive or operate machinery if affected.

**Special warnings if you are taking Spazmobest Tablets for Irritable Bowel Syndrome.**

If this is the first time you have had symptoms of Irritable Bowel Syndrome, consult your doctor before using any treatment.

If any of the following apply to you do not take Spazmobest Tablets. It may not be the right treatment for you. See your doctor as soon as possible.

- you are aged 40 years or over
- you have passed blood from the bowel
• you are feeling sick or vomiting
• you have lost your appetite or lost weight
• you are looking pale and feeling tired
• you are suffering from severe constipation
• you have a fever
• you have recently travelled abroad
• you have abnormal vaginal bleeding or discharge
• you have difficulty or pain passing urine

Consult your doctor if you have developed new symptoms, or if your symptoms worsen, or if they do not improve after 2 weeks of treatment.

Special Precautions for storage
Store in a cool and dry place, protected from light
Do not use preparation after expiry date, indicated on the pack

Manufactured by:
Simpex pharma Pvt. Ltd.

Head office: B-4/160, Safdarjung Enclave, New Delhi- 110 029, India.

Works: C-7 to C-13 & C-59 to C-64, Sigaddi Growth Center (SIDCUL)

Sigaddi, Kotdwar - 246149, Distt: Pauri Garhwal, Uttarakhand, India.
FAQ’s

What is Spazmobest?
Spazmobest is an antispasmodic medication which specifically relieves abdominal discomfort and pain due to cramps and spasms.

Spazmobest offers a targeted relief of your abdominal discomfort and cramps. It acts where the pain develops - in the abdomen. Spazmobest works directly on the muscles of your bowel to relieve the cramps and spasm that cause the discomfort. With Spazmobest, you can be confident that you are targeting the cause of your discomfort and cramps and thus that you efficaciously solve the problem avoiding simply masking it.
Spazmobest is one of the most used and trusted medicines in this indication.

What is the difference between Spazmobest and a pain killer?
Spazmobest acts only where the cramps and pains occur - in the abdomen. Many analgesics act by reducing the pain awareness by blocking the pain signals, thereby masking the pain. Therefore, analgesics act in the whole body, they enter the blood stream and thus offer a greater potential for unpleasant side-effects. Compared to analgesics, Buscopan® only acts where the pain occurs and treats the cause of the pain. As it does not enter the blood stream, it has practically no side-effects.

Can a take more than normal dose to get relief faster?
This is not recommended. An increase of the recommended dosage in general will not accelerate the effect and can perhaps even have negative effects. The dosage that is indicated on the instruction leaflet or that has been recommended by your doctor or pharmacist is best for the type and severity of your ailment potential causes and helpful treatments for this very common health problem.

Is it safe to take Spazmobest during pregnancy or lactation?
As with all medication, you should ask for your doctor’s advice if you are pregnant, likely to become pregnant or are breastfeeding or likely to breastfeeding during the course of your medication.
Long experience has shown no evidence of ill effects during human pregnancy. However, the usual precautions regarding the use of drugs in pregnancy, especially during the first trimester, should be observed.
Adverse effects on the newborn have not been reported. However, safety during lactation has not yet been established.

How do I take Spazmobest?
It is recommended to take Spazmobest un chewed and with enough water (usually a full glass). For more information, please refer to the package instruction leaflet of your country. If in doubt, please consult your doctor.

What causes abdominal pain and cramps?
Common causes of stomach pain include:

- Sensitivity to certain foods which trigger stomach pain, such as fatty, spicy or rich foods, caffeine, alcohol and acidic citrus fruits.
- A hectic, stress-filled lifestyle, skipping meals, eating on the run and the anxieties which can cause a nervous stomach.
- A change from your normal daily routine, for example when travelling, which can unbalance your digestive system.

Given the large number of organs in this part of the body, the symptoms can obviously be caused by a wide variety of factors. In almost all cases, abdominal cramps and associated symptoms such as flatulence, a sensation of fullness, constipation or diarrhoea can be significantly alleviated with Spazmobest

When should I see my doctor about my abdominal cramps?
You should be especially cautious if your ailment lasts longer than several days or if the pain is more severe, if you have a fever, if you notice blood on your stools, or if you notice sudden weight loss. You should then consult a doctor and ask for advice.

Does Spazmobest also relieve cramps outside the gastrointestinal tract?
No. Spazmobest is specially developed to relax the muscles of the digestive tract. Therefore, it acts only where abdominal cramps and pains occur. As it is barely absorbed, it does not enter the blood stream and thus has no effects on organs outside the gastrointestinal tract.

What is the difference between abdominal cramps and IBS?
In addition to abdominal pain and cramp, IBS patients suffer often from symptoms of diarrhoea and/or constipation and/or flatulence.

Is there any connection between IBS and cancer?
No. IBS is a functional disorder of the bowel and is not related to cancer or tumour growth nor to any other illness. In fact, being diagnosed with IBS may mean that you have had examinations and tests which can positively rule out cancer.

Does IBS get better as you get older?
IBS can affect people of all ages; however, the symptoms usually become less severe as people get older. The reason for this is not fully understood but leading a less stressful lifestyle, and learning to avoid trigger factors may help to reduce symptoms.
Does IBS reduce the life expectancy?

No. IBS is not a life threatening disease.

I have heard that oral contraceptives may help with period pain. Is this true?

This is true for some women. Sometimes a few months on an oral contraceptive can sort out the problem. Of course, for women who require protection from pregnancy this can be a good solution to two needs. To find out whether this would be a suitable option for you, you should consult your doctor.

I'm worried about my period pain; should I see my doctor?

If you are worried about your health, it is always advisable to discuss it with your healthcare professional. This is especially true if you notice changes such as any of the following:

• more painful cramps
• irregular periods
• heavier bleeding
• fever or weight loss