SPASIL TABLET

Diphenoxylate hydrochloride / Atropine sulphate (2.5mg / 0.025mg)

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What SPASIL is used for

SPASIL is used for symptomatic treatment of diarrhoea.

SPASIL can be given after the colostomy or ileostomy surgery to reduce the frequency and fluidity of the stools.

How SPASIL works

SPASIL contains the active ingredients diphenoxylate hydrochloride and atropine sulphate.

Diphenoxylate hydrochloride reduces diarrhoea by slowing down the movement of the intestines. Because diphenoxylate hydrochloride is an opioid, it may be abused by taking it in doses that are larger than prescribed. Therefore, a small amount of atropine sulphate is included in SPASIL to prevent drug abuse.

Before you use SPASIL

- *When you must not use it*

Do not take SPASIL if you:

• are allergic to diphenoxylate hydrochloride, atropine sulphate or any ingredients in the formulation.
• have jaundice (yellowing of skin and whites of eye).
• have intestinal obstruction, ulcers and inflammation in the digestive tract.
• have diarrhoea caused by pseudomembranous enterocolitis. This is a potentially serious infection of the gut, which may occur following antibiotic treatment.
• have a raised pressure in your skull or head injury.
• have muscle weakness including those affecting your intestinal movement.
• have prostatic enlargement.

- *Before you start to use it*

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

Tell your doctor if you have any other medical conditions, especially:
- Liver disease
- Kidney disease
- Down's syndrome
- History of drug abuse

Appropriate fluid and electrolyte therapy should be taken to prevent dehydration due to diarrhoea. Oral rehydration therapy including oral rehydration salts remains the most effective treatment for dehydration due to diarrhoea. The intake of as much of these fluids as possible is therefore imperative.

If you are not sure whether you should start taking this medicine, consult your doctor.

- *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 may interfere with SPASIL. These include:
• Medicines used to treat depression known as monoamine oxidase inhibitors (MAOIs) or tricyclic antidepressants
• Medicines for vomiting and feeling sick, e.g. domperidone, metoclopramide
• Medicines which increase muscle contraction, e.g. neostigmine/pyridostigmine, bethanecol/carbachol
• Amantadine and levodopa (used to treat Parkinson's disease)
• Sedative and non-sedative antihistamines (used to treat allergies), e.g. terfenadine
• Medicines used to treat mental disorders, e.g. clozapine, phenothiazines, olanzapine, remoxipride, zotepine
• Disopyramide (used to treat irregular heartbeat)
• Nefopam (a pain killer)
• Glyceryl trinitrate (a medicine given under the tongue for angina chest pain)
• Ketoconazole (used to treat fungal infections)
• Cisapride (used to treat heartburn caused by gastroesophageal reflux disease)

- *Pregnancy and lactation*

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding. Your doctor can discuss with you the risks and benefits involved.

SPASIL should be used during pregnancy only if the anticipated benefit justifies the potential risk to the foetus.

SPASIL is not recommended for nursing mother. SPASIL passes into breast milk, so if you take SPASIL while breastfeeding, your baby may have some effects from it.

How to use SPASIL

Follow all directions given to you by doctor and pharmacist carefully. Check with your doctor or pharmacist if you are not sure.

- *How much to use*

Adults

The recommended dose is 1 to 2 tablets 3 to 4 times a day until the diarrhoea is under control. Do not exceed 8 tablets in a day (24 hours).

Children

6 to 8 years of age: 1 tablet 3 times daily.
9 to 12 years of age: 1 tablet 4 times daily.

Not recommended for children under 6 years of age.

- *When to use it*

Take SPASIL 3 to 4 times daily or follow the frequency as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- *How long to use it*

Take SPASIL for the duration as your doctor tells you.

Your doctor may want you to stop taking SPASIL when your bowel movements return to normal. If your diarrhoea contains blood or lasts for more than 3 days, tell your doctor.

- *If you forget to use it*

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- *If you use too much (overdose)*

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Initial symptoms of overdosage may include dryness of the skin and mucous membranes, flushing, pinpoint pupils, abnormal high body temperature, and abnormal rapid heart rate followed by lethargy or coma, low muscle tone reflexes, involuntary movement of eyes and respiratory depression.

While you are using it

- *Things you must do*

• Your body can lose large amounts of fluids and salts when you have diarrhoea. You need to replace the fluid by drinking more liquid than usual.
• If you are about to be started on any new medicine, tell your doctor or pharmacist that you are taking SPASIL.
• If you become pregnant while taking SPASIL, tell your doctor immediately.

- *Things you must not do*

• Do not stop taking the medicine unless advised by your doctor.
• Do not give this medication to anyone else, even if they have the same condition as you.

- *Things to be careful of*

Some of the undesirable effects such as sedation, drowsiness or dizziness may affect the ability to drive or operate machines. Be careful when driving or operating machinery until you know how SPASIL affects you.

Side effects

Like all medicines, SPASIL may cause side effects in some patients although not everyone will get it.

If you experience any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face, gum or lips, rash or itching (especially affecting your whole body) you should see a doctor immediately.

The following side effects may occur:
• numbness in hands and feet
• depression
• feeling tired
• confusion
• drowsiness
• dizziness
• restlessness
• headache
• difficulty sleeping
• nausea, vomiting, abdominal discomfort
• eating disorder
• constipation
• flushing
• dryness of skin and mouth
• irregular heartbeat
• unusually high body temperature
• urinary retention
• blurry vision and sensitive towards light

Other side effects not listed above may occur in some people. Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of SPASIL

- *Storage*

Store in a cool dry place, below 30°C.
Keep in the original package in order to protect from light and moisture.

Do not use SPASIL after the expiry date which is stated on the carton and blister.

Do not store SPASIL or any other medicines in the bathroom, near a sink or leave it at the window sill or in the car.

Keep out of the reach of children.

- *Disposal*

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- *What it looks like*

SPASIL is a white, round, biconvex tablet embossed with “SPS” on one side and with a bisect on the other side.

- *Ingredients*

- Active ingredient

Diphenoxylate hydrochloride 2.5mg
Atropine sulphate 0.025mg

- Inactive ingredients

Cornstarch, lactose monohydrate, povidone K-90, talcum, colloidal silicon dioxide, magnesium stearate.

- *Packing*

Aluminium foil strip of 10 tablets, pack in box of 10 and 100 strips.

- *MAL Number*

MAL19921520AZ

Manufacturer

Sriprasit Pharma Co., Ltd.
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Product Registration Holder

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