SPASMIN TABLET

Dicyclomine hydrochloride (20mg)

- What is in this leaflet
- 1. What Spasmin is used for
- 2. How Spasmin works
- 3. Before you use Spasmin
- 4. How to use Spasmin
- 5. While you are using it
- 6. Side effects
- 7. Storage and Disposal of Spasmin
- 8. Product description
- 9. Manufacturer and Product Registration holder
- 10.Date of revision

What Spasmin is used for

For treatment of irritable bowel syndrome, spasm related constipation, colon inflammation, pyloric sphincter and biliary movement disorder.

How Spasmin works

Dicyclomine is a medicine which has a direct action in reducing spasm and pain of the gastrointestinal tract.

Before you use Spasmin

- <u>When you must not use it</u>
- Do not take Spasmin if allergic to dicyclomine or to other ingredients in the product.
- Not recommended for use in:
- enlargement of the prostate gland
- intestinal obstruction due to paralysis of the intestinal muscles
- pyloric stenosis (blockage of stomach to the intestines).
- in infants under the age of six months.

- Before you start to use it

Be careful when using:

- in the elderly
- glaucoma (increased eye pressure)
- urinary retention, obstructive uropathy (blocking of normal urine flow)
- fever
- heart disease, increased heart rate
- over active thyroid gland
- histal hernia (displacement of stomach) with back flow of stomach contents into the esophagus, intestinal obstruction
- acute bleeding with unstable heart and blood status
- kidney or liver function impairment
- myasthenia gravis (muscle weakness)
- colon ulcer and inflammation

- Taking other medicines

- Tell the doctor if you are taking:
- narcotic analgesics (for pain)
- antimuscarinic medicine
- amantadine (antiviral)
- monoamine oxidase (MAO) inhibitors
- phenothiazines or tricyclic antidepressant
- antacid or antidiarrhoeal
- antihistamine

How to use Spasmin

- <u>How much to use</u>
- Adults: oral, 10 20mg, the dosage being adjusted as needed and tolerated up to 160mg daily.

Children over 2 years: oral, 10mg, the dosage being adjusted as needed and tolerated, or as directed by physician. Follow all directions given by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- <u>When to use it</u> Use three or four times a day or as directed by the doctor or pharmacist.

- <u>*How long to use it*</u> Continue medication as directed by doctor.

- <u>If you forget to use it</u>

Consult your doctor or pharmacist on what you should do 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. Signs of overdose include increased heart rate, rapid breathing, increased body temperature, restlessness, confusion and excitement, hallucinations (hear, smell, taste or feel things that do not exist) leading to delirium (confused state), rash on face and upper body, central nervous system depression and circulatory failure.

While you are using Spasmin

- <u>Things you must do</u>

Take your medicine exactly as the doctor has told you.

Tell the doctor, dentist and pharmacist treating you that you are taking Spasmin. Tell the doctor immediately if you are pregnant while taking this medication.

- <u>Things you must not do</u>

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist. Do not give Spasmin to anyone else, even if they have the same symptoms or condition as you.

- <u>Things to be careful of</u> Safety for use in pregnancy and breast feeding has not been established.

Side effects

Spasmin can cause side effects. Visit your doctor or pharmacist immediately if you experience dryness of mouth, thirst, dilatation of the eye pupils, flushing and dryness of skin, feeling pounding of heartbeats, difficulty urinating, constipation, vomiting, blurred vision, giddiness and staggering.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website <u>npra.moh.gov.my</u> (Public \rightarrow Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of Spasmin

- <u>Storage</u>

Store in a cool, dry place below 30°C. Protect from light. Keep out of reach of children.

- <u>Disposal</u>

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

Product description

<u>What it looks like</u> Blue, oblong and top-scored tablet.

- <u>Ingredients</u>
- Active ingredient: dicyclomine hydrochloride
- Inactive ingredients: lactose monohydrate, cornstarch, indigo carmine lake, polyvinylpyrrolidone and magnesium stearate

- <u>MAL number:</u>

MAL19930132AZ

Manufacturer and Product Registration Holder

Prime Pharmaceutical Sdn. Bhd. 1505, Lorong Perusahaan Utama 1 Taman Perindustrian Bukit Tengah 14000 Bukit Mertajam, Penang, Malaysia.

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