AXCEL DICYCLOMINE-S SYRUP

Dicyclomine Hydrochloride/Simethicone (5mg/50mg)

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What Axcel Dicyclomine-S Syrup is used for

Axcel Dicyclomine-S Syrup is used for the relief of gastrointestinal colic, flatulence and abdominal discomfort due to entrapped gas.

How Axcel Dicyclomine-S Syrup works

Dicyclomine is a medicine for reducing cramps and pain in the digestive tract.

Simethicone lowers surface tension cause bubbles of gas in the digestive tract to coalesce, thus aiding their elimination.

Before you use Axcel Dicyclomine-S Syrup

-When you must not use it

Do not take Axcel Dicyclomine-S Syrup if:

- The infants younger than 6 months.
- You have closed angle glaucoma (a buildup of pressure in the eye).
- You have urinary tract or stomach and intestinal obstruction.
- You have unstable cardiovascular (heart or blood vessel) status in acute bleeding or backflow of gastric content leading to esophagus (food pipe) irritation.
- You suffer from reduced intestinal movement or paralysis.
- You are allergic or hypersensitive to Dicyclomine and other ingredients.
- The ambient temperature is high especially in children.

-Before you start to use it

Tell your doctor if you:

- Have fever, asthma or hiatal hernia (part of the stomach pushes upward into the chest).
- Have serious liver or kidney disease, acute heart attack or high blood pressure.
- Are elderly and in conditions characterized by a faster than normal heart rate & debilitate individuals with long term obstructive lung disease.
- Are pregnant.
- Are allergic to any medicines.

-Taking other medicines

You should tell your doctor or pharmacist if you are taking the following medicine as it may interact with your Axcel Dicyclomine-S Syrup:

- Other parasympatholytics (used to relax smooth muscle, reduce excessive sweat)
- Guanethidine, reserpine (used to treat high blood pressure).
- Histamine (used to treat allergy).
- Antacids (used to treat heartburn and indigestion).

It may still be all right for you to take Axcel Dicyclomine-S Syrup and your doctor will be able to decide what is suitable for you.

How to use Axcel Dicyclomine-S Syrup

-How much to use

For oral use only.

Adults: 10-20ml.

Children (2-12 years): 10ml, (6 months – 2 years): 5 - 10ml, total daily dose should not exceeding 40ml.

-When to use it

To be used 3-4 times a day, 15 minutes before meals. Your doctor will decide when it is appropriate for you to take Axcel Dicyclomine-S Syrup according to the type of condition you have.

-How long to use it

 Take this medicine as stated in the leaflet without exceeding the dosage. Follow any recommendations and advices from your doctor or pharmacist.

-If you forget to use it

 Do not double up the dosage as Axcel Dicyclomine-S Syrup may give you unacceptable side effects.

-If you use too much (overdose)

- It is advisable for you to contact your doctor immediately or go to the Emergency Department of your nearest hospital if you did take Axcel Dicyclomine-S Syrup too much.
- Symptoms of overdose include: faster than normal heart rate, rapid breathing, high fever, central nervous system (CNS) stimulation marked by confusion, excitement, uncoordinated movement and occasionally seizures. Rashes may appear on the face or upper trunk.

While you are using it

-Things you must do

- Discuss with your doctor or pharmacist the dos' and don'ts' while taking this medicine.
- Tell your doctor if unexpectedly you need to take any other medicines.
- Take the Axcel Dicyclomine-S Syrup according to the recommended dosage.
- Tell your doctor or pharmacist if you experience any side effects that are not listed in this leaflet.

-Things you must not do

- Do not take your medicine more than the suggested frequency in a day.
- Do not over dosage the medicine during any single consumption.

-Things to be careful of

 Be careful when driving or operating machinery until you know how Axcel Dicyclomine-S Syrup affects you.

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Side effects

Like all medicines, Axcel Dicyclomine-S Syrup can cause side effects although not everybody gets them. You are advised to consult doctor/ pharmacist for further information. The following side effects have been reported:

- Increase of pressure in the eye especially in individuals with closed- angle glaucoma.
- Dryness of the mouth with difficulty in swallowing and talking.
- Thirst.
- Reduced bronchial secretions.
- Dilatation of the pupils of the eye with loss of accommodation and sensitive to light exposure.
- Flushing and dryness of the skin.
- Transient slow heart rate followed by a faster heartbeat, with feeling of strong and irregular heartbeat.
- Difficulty in urination.
- Reduction in the tone and motility of digestive tract leading to constipation.
- Elevated body temperature.
- Central Nervous System (CNS) stimulation.
- Occasionally vomiting may also occur.

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 npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and disposal of Axcel Dicyclomine-S Syrup

-Storage

Keep Axcel Dicyclomine-S Syrup out of reach of children.

Store below 30°C. Keep container well closed and protect from light.

-Disposal

Do not use Axcel Dicyclomine-S Syrup after the expiry date which is stated on the carton.

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

Axcel Dicyclomine-S Syrup is orange coloured and orange flavoured syrup.

-Ingredients

- Active Ingredient (s):
 Dicyclomine Hydrochloride
 Simethicone
- Inactive Ingredients:
 Refined Sugar, Xanthan Gum,
 Methylparaben, Cremophor RH40,
 Citric Acid, Propylene Glycol,
 Saccharin Sodium, Sunset Yellow,
 Orange Flavor and Purified Water.

-MAL Number MAL19991140AZ

Manufacturer and product registration holder

Kotra Pharma (M) Sdn Bhd No. 1, 2 & 3, Jalan TTC 12, Cheng Industrial Estate,

75250 Melaka, Malaysia.

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