AXCEL BROMHEXINE (CHILDREN) SYRUP

Bromhexine Hydrochloride (4mg/5ml)

What is in this leaflet

- 1. What Axcel Bromhexine (Children) Syrup Is Used For.
- 2. How Axcel Bromhexine (Children) Syrup Works.
- 3. Before You Use Axcel Bromhexine (Children) Syrup.
- 4. How to Take Axcel Bromhexine (Children) Syrup.
- 5. While You Are Using It.
- 6. Side Effects.
- 7. Storage and Disposal of Axcel Bromhexine (Children) Syrup.
- 8. Product Description.
- 9. Manufacturer and Product Registration Holder.
- 10. Date of revision

What Axcel Bromhexine (Children) Syrup is used for

Axcel Bromhexine (Children) Syrup is a mucolytic (agent which dissolve thick mucus) expectorant used in the treatment of respiratory disorders associated with productive cough.

How Axcel Bromhexine (Children) Syrup works

Bromhexine Hydrochloride is a mucolytic (agent which dissolve thick mucus) expectorant which works by breaking mucus down so that it is easier to cough out.

Before you use Axcel Bromhexine (Children) Syrup

-When you must not use it

Do not take Axcel Bromhexine (Children) Syrup if:

• It is not prescribed by a qualified doctor or pharmacist for you.

-Before you start to use it

Tell your doctor if:

- You have allergic to any medicines.
- You have a history of gastric ulceration.
- You are pregnant or nursing mother.

-Taking other medicines

You should tell your doctor or pharmacist if you are taking the following medicine as it may interact with your Axcel Bromhexine (Children) Syrup:

• Erythromycin, Cephalexin and Amoxicillin.

It may still be all right for you to take Axcel Bromhexine (Children) Syrup and your doctor will be able to decide what is suitable for you.

How to use Axcel Bromhexine (Children) Syrup

<u>-How much to use</u> For oral administration only. To be taken 3 times a day. Children under 2 years: 1.25ml (1mg) Children 2-6 years: 2.5ml (2mg) Children 7-12 years: 5ml (4mg) Adult & Children more than 12 years: 10ml (8mg)

-When to use it

You should take medicine equally spaced times in the day.

Your doctor will decide when it is appropriate for you to take Axcel Bromhexine (Children) 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 Bromhexine (Children) Syrup may give you unacceptable side effects.

-If you use too much (overdose)

- In cases of overdosage occur, it should be managed symptomatically.
- It is advisable for you to contact and inform your doctor if you did take Axcel Bromhexine (Children) Syrup too much.

While you are using it

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

- 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 Bromhexine (Children) 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

• Avoid prolonged use with high dosage.

Side effects

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

Stomach and intestinal disturbances.Abnormal liver test results.

Axcel Bromhexine (Children) Syrup may cause severe allergy and serious skin reactions. Stop using Axcel Bromhexine (Children) Syrup and seek medical assistance immediately if you experience any of the following symptoms:

- Severe allergy: breathing difficulties, light headedness, skin swellings or rash.
- Severe skin reaction: skin reddening, blisters, rash, fever, sore throat or eye irritation.

You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by visiting the website <u>npra.moh.gov.my</u> (Consumers \rightarrow Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI))

Storage and disposal of Axcel Bromhexine (Children) Syrup -Storage

Keep Axcel Bromhexine (Children) Syrup out of reach of children. Store below 30°C. Keep container well closed and protect from light.

AXCEL BROMHEXINE (CHILDREN) SYRUP

Bromhexine Hydrochloride (4mg/5ml)

-Disposal

Do not use Axcel Bromhexine (Children) Syrup after the expiry date which is stated on the carton.

Product description

<u>-What it looks like</u> Axcel Bromhexine (Children) Syrup is a colorless to pale-yellowish liquid with fruity flavoured Syrup.

-Ingredients

- Active Ingredient (s): Bromhexine Hydrochloride

- Inactive Ingredients: Carboxymethylcellulose Sodium, Citric Acid Anhydrous, Maltitol, Sodium Chloride, Polysorbate 80, Glycerin, Sorbitol, Sodium Benzoate, Cherry Flavour, Purified Water

<u>-MAL Number</u> MAL19911419XZ

Manufacturerandproductregistration holderKotra Pharma (M) Sdn BhdNo. 1, 2 & 3, Jalan TTC 12,Cheng Industrial Estate,75250 Melaka, Malaysia.

Date of revision 01/06/2020

Serial number NPRA(R4/1)180418/00110