## BENNATUSS EXPECTORANT

Diphenhydramine Hydrochloride / Ammonium Chloride/ Sodium Citrate (12.5mg/130mg/60mg per 5ml)

#### What is in this leaflet

- 1. What BENNATUSS EXPECTORANT is used for
- 2. How BENNATUSS EXPECTORANT works
- 3. Before you use BENNATUSS EXPECTORANT
- 4. How to use BENNATUSS EXPECTORANT
- 5. While you are using it
- 6. Side effects
- 7. Storage and disposal of BENNATUSS EXPECTORANT
- 8. Product description
- 9. Manufacturer and Product Registration Holder
- 10. Date of revision

This leaflet answers some common questions about BENNATUSS EXPECTORANT. It does not contain all the available information. It does not take the place of talking to your pharmacist or doctor.

All medicines have risks and benefits. Your pharmacist or doctor has weighed the risks of you taking BENNATUSS EXPECTORANT against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your pharmacist or doctor.

Keep this leaflet with the medicine.

You may need to read it again.

What BENNATUSS
EXPECTORANT is used for
BENNATUSS EXPECTORANT
is used for the relief the cough and
nasal congestion due to the
common cold or to allergy.

How BENNATUSS
EXPECTORANT works
BENNATUSS EXPECTORANT
contains diphenhydramine
hydrochloride, ammonium
chloride and sodium citrate as

active ingredients.

Diphenhydramine is an ethanolamine derivative with the properties of the antihistamines. It works by blocking the action of histamine, a substance in the body that causes allergic symptoms.

Ammonium chloride acts as an expectorant in cough medicine. Its expectorant action is caused by irritative action on the bronchial mucosa. This causes the production of excess respiratory tract fluid which presumably is easier to cough up.

Sodium citrate is a directly acting expectorant. It breaks down mucus, so that coughing up phlegm is easier.

Ask your pharmacist or doctor if you have any questions about this medicine.

# Before you use BENNATUSS EXPECTORANT

-When you must not use it Do not take BENNATUSS EXPECTORANT if:

 You are allergic (hypersensitive) to diphenhydramine or other antihistamines of similar chemical structure or ammonium chloride or to any of the other ingredients in this medicine.

#### -Before you start to use it

Tell your pharmacist or doctor if you have or have had any of the following medical conditions:

- Lower respiratory disease including asthma
- •Impaired liver or kidney function
- •Increase intraocular pressure (inside the eye)
- Hyperthyroidism (thyroid gland produces excessive amounts of hormone)
- Cardiovascular (heart and blood vessels) disease
- •High blood pressure
- •Narrow angle glaucoma (buildup of fluid in the eye)
- Peptic ulcer (painful sores or ulcers in the lining of the stomach)

- Pyloroduodenal obstruction (gastric outlet obstruction)
- Symptomatic prostatic hypertrophy (enlargement of prostate)
- •Bladder neck obstruction

Pregnancy and breast feeding: Do not take BENNATUSS EXPECTORANT if you are pregnant, trying to get pregnant, think you may be pregnant or if you are breast-feeding.

There was a significant incidence of cleft palate and cleft with other defects in children whose mothers had taken diphenhydramine during pregnancy. Use during pregnancy only if clearly needed.

Contraindicated for use in nursing mothers due to increased risk of antihistaminic side effects in newborns and infants.

Ask your doctor or pharmacist for advice before taking any medicine.

### -Taking other medicines

Tell your doctor if you are taking any other medicines, such as monoamine oxidase therapy (antidepressant treatment) including any product you buy without a prescription from a pharmacy, supermarket or health food shop.

# How to use BENNATUSS EXPECTORANT

-How much to use

Dose to be taken undiluted every 4 hours.

Adult: 5ml to 10ml

**Children:** 2.5ml to 5ml

Not to be used in children less than 2 years of age.

To be used with caution and doctor's advice in children 2 to 6 years of age.

## **BENNATUSS EXPECTORANT**

Diphenhydramine Hydrochloride / Ammonium Chloride/ Sodium Citrate (12.5mg/130mg/60mg per 5ml)

#### <u>-When to use it</u>

Use as directed by your doctor or pharmacist.

<u>-How long to use it</u> Continue taking BENNATUSS EXPECTORANT for as long as your doctor recommends.

#### -If you forget to use it

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)

Overdose reactions may vary from central nervous system depression to stimulation. Atropine like signs and symptoms may also occur such as;

- Dry mouth
- Fixed dilated pupils
- Flushing (sudden reddening of the face, neck, or upper chest)
- Gastrointestinal symptoms

# While you are using BENNATUSS EXPECTORANT

<u>-Things you must do</u> Take your medicine exactly as

your doctor has told you.

Tell all the doctors, dentists and

pharmacists treating you that you are taking BENNATUSS EXPECTORANT.

# -Things you must not do Do not take any new medicines

without consulting your doctor

Do not give BENNATUSS EXPECTORANT to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of Antihistamines may cause drowsiness. Do not drink alcohol while taking BENNATUSS EXPECTORANT as antihistamines may increase the effects of alcohol.

Do not driving a car or operate machinery or do activities requiring mental alertness while taking BENNATUSS EXPECTORANT.

#### Side effects

Like other medicines, BENNATUSS EXPECTORANT can cause some side effects. However if they occur some may be serious and need medical attention.

The most common side effects of antihistamines are:

- Sedation
- Inability to concentrate
- Lassitude (lack of energy)
- Dizziness
- High blood pressure
- Muscular weakness
- Incoordinations

Other side effects include gastrointestinal disturbances such as:

- Nausea
- Vomiting
- Diarrhoea
- Constipation
- Epigastric (upper middle region of the abdomen, immediately below the ribs) pain

Antihistamines may also produce:

- Headache
- Blurred vision
- Tinnitus(ringing in the ears)
- Elation
- Depression
- Irritability
- Nightmares
- Anorexia
- Difficulty in urination
- Dryness of mouth
- Tightness of chest
- Tingling
- Heaviness and weakness of the hands

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

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 <a href="mailto:portal.bpfk.gov.my">portal.bpfk.gov.my</a> (Consumers → Reporting)

## Storage and disposal of BENNATUSS EXPECTORANT

-Storage

Store below 30°C.
Keep container well closed.
Protect from light.
Keep out of reach of children.

### -Disposal

Dispose the medicine after the expiry date. 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

BENNATUSS EXPECTORANT is a reddish brown syrupy liquid with a mixture of raspberry, cherry and butterscotch flavor and odour.

BENNATUSS EXPECTORANT available in bottle of 90ml.

### -Ingredients

-Active ingredient(s): Each 5ml contains Diphenhydramine Hydrochloride 12.5mg, Ammonium Chloride 130mg and 60mg Sodium Citrate

-Inactive ingredients: Sodium Benzoate, Sodium Saccharin, Sucrose, Butterscotch Flavour, Ponceau 4R, Cherry Flavour, Vanilin, Sorbitol 70% Solution, Chloroform Spirit, Liquid Glucose, Menthol Crystal, Citric Acid Anhydrous, Raspberry Flavour, Liquid Caramel and Purified Water.

# **BENNATUSS EXPECTORANT**

Diphenhydramine Hydrochloride / Ammonium Chloride/ Sodium Citrate (12.5mg/130mg/60mg per 5ml)

<u>-MAL number:</u> MAL19871715A

#### Manufacturer

HOE Pharmaceuticals Sdn. Bhd. Lot 10, Jalan Sultan Mohamed 6, Bandar Sultan Suleiman, 42000 Port Klang, Selangor, Malaysia.

## **Product Registration Holder:**

HOE Pharmaceuticals Sdn. Bhd. Lot 10, Jalan Sultan Mohamed 6, Bandar Sultan Suleiman, 42000 Port Klang, Selangor, Malaysia.

## Date of revision

-18/05/2015

### **Serial Number**

BPFK (R4/1)180515/00109