# BEATAFED TABLET/ SYRUP

Triprolidine hydrochloride/Pseudoephedrine hydrochloride (2.5mg/60mg, 1.25mg/32mg per 5ml)

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#### What BEATAFED is used for

This medicine is used to relief symptoms associated with the common cold, sinusitis (inflammation of the lining of the sinuses) and allergic conditions including hayfever, allergic asthma, vasomotor (nonallergic) rhinitis, pollenosis (an allergic reaction to pollen), allergic rhinitis (an allergic inflammation of the nasal airways) and urticaria (raised, itchy areas of skin).

# **How BEATAFED works**

The tablet contains pseudoephedrine hydrochloride, a decongestant which works by reducing the swelling of blood vessels inside your nose. This helps to open up your nasal airway, making breathing easier.

Triprolidine is an antihistamine which works by blocking a certain natural substance (histamine) that your body makes during an allergic reaction. It also helps to dry up some body fluids to relieve symptoms such as watery eyes and runny nose.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

#### Before you use BEATAFED

#### - When you must not use it

Do not take this medicine if you have an allergy to:

- Triprolidine hydrochloride, pseudoephedrine hydrochloride
- any of the other ingredients listed at the end of the leaflet
- any other similar medicines

# Do not take BEATAFED if you:

- have very high blood pressure
- have severe heart disease
- are taking, or have taken in the last two weeks, drugs for depression known as monoamine oxidase inhibitors (MAOIs)

If any of these apply to you, get advice from a doctor or pharmacist.

When BEATAFED is used for treatment of cough and cold, it is not to be used in children less than 2 years of age. It is needed to be used with caution and doctor's or pharmacist's advice in children 2 to 6 years of age.

BEATAFED is not recommended in newborn or premature infants. It is used with caution in elderly due to higher risk of side effects.

There is no human study have been done in pregnant women.

Use by nursing mothers is not recommended because triprolidine and pseudoephedrine is distributed into breast milk.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

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

#### - Before you start to use it

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

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

- liver problem
- high blood pressure
- heart disease
- diabetes
- overactive thyroid gland
- glaucoma (increased pressure inside the eyes)
- prostate problem

Ask your doctor or pharmacist for advice before taking this medicine if you are pregnant or breastfeeding.

If you have not told your doctor about any of the above, tell him/her before you start taking BEATAFED.

### - Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and BEATAFED may interfere with each other. These include:

- decongestant
- appetite suppressant
- monoamine oxidase inhibitors
- anti-hypertensive medicines
- other antihistamine
- sedative
- barbiturates
- hypnotics
- tranquilizers

These medicines may be affected by BEATAFED or may affect how well it works.

You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

#### **How to use BEATAFED**

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

#### - How much to use

The recommended dose of BEATAFED is:

Adults and children over 12 years: 1 tablet or 10ml, 3 to 4 times a day.

Children 6-12 years: 5ml to 7.5ml, 3 or 4 times a day.

Children 2-5 years: 2.5ml to 5ml, 3 or 4 times a day.

Use is not recommended in newborn and premature infants because of the higher than usual risk of side effects.

Ask your doctor or pharmacist if you are unsure of the correct dose for you. They will tell you exactly how much to take.

# - When to use it

Take BEATAFED as your doctor has prescribed.

# - How long to use it

Continue taking your medicine for as long as your doctor tells you.

#### - If you forget to use it

Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

# - If you use too much (overdose)

Immediately telephone your doctor for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much BEATAFED.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of overdose include:

- clumsiness or unsteadiness
- severe drowsiness
- severe dryness of mouth, nose or throat
- redness of face
- convulsions
- hallucinations
- increase in blood pressure
- dizziness
- dry skin
- shortness of breath
- slow or fast heartbeat
- excitement

#### While you are using it

# - Things you must do

Always follow your doctor's instructions carefully.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking BEATAFED.

Tell your doctor if you become pregnant or if you are breastfeeding while taking this medicine.

#### - Things you must not do

Do not take BEATAFED to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same conditions as you.

# - Things to be careful of

Be careful of driving or operating machinery until you know how BEATAFED affects you. This medicine may cause drowsiness and dulling of mental alertness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine. If you drink alcohol, dizziness or light-headedness may be worse.

#### Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Some of the common side effects include:

- drowsiness
- nausea
- vomiting
- constipation

#### · stomach pain

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

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 portal.bpfk.gov.my → Reporting).

# Storage and disposal of BEATAFED

#### - Storage

Keep your medicine in the original container. If you take it out of its original container, it may not keep well.

Keep your medicine in a dry place where the temperature stays below  $30^{\circ}$ C. Protect from light.

Do not store BEATAFED or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-ahalf metres above the ground is a good place to store medicines.

#### - Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Medicines should not be disposed of via wastewater or household waste. These measures will help to protect the environment.

#### **Product description**

#### - What it looks like

#### i. BEATAFED TABLET

A 8.0mm diameter, round, flat, marked "UPHA" white tablet.

#### ii. BEATAFED SYRUP

A yellow, fruity flavoured syrup.

#### - Ingredients

- Active ingredients

#### i. BEATAFED TABLET

Each tablet contains 2.5mg
Triprolidine hydrochloride and
60mg Pseudoephedrine
hydrochloride.

#### ii. BEATAFED SYRUP

Each 5ml of syrup contains 1.25mg Triprolidine hydrochloride and 32mg Pseudoephedrine hydrochloride.

# - Inactive ingredients

# i. BEATAFED TABLET

- Sodium starch glycolate
- Microcrystalline cellulose
- Magnesium stearate
- Lactose monohydrate
- Pregelatinised starch

# ii. BEATAFED SYRUP

- Quinoline yellow
- Sugar
- Citric acid
- Chloroform spirit
- Raspberry
- Liquid glucose
- Propylparaben
- Methylparaben
- Saccharin sodium
- Lemon

#### - MAL numbers:

i. BEATAFED TABLET

MAL19860359AZ

ii. BEATAFED SYRUP

MAL19860358AZ

#### Manufacturer

UPHA PHARMACEUTICAL MFG. (M) SDN BHD (53667-M) Lot 2&4, Jalan P/7, Section 13, Bangi Industrial Estate, 43650 Bandar Baru Bangi, Selangor Darul Ehsan.

#### **Product Registration Holder**

UPHA PHARMACEUTICAL MFG. (M) SDN BHD (53667-M) Lot 2&4, Jalan P/7, Section 13, Bangi Industrial Estate, 43650 Bandar Baru Bangi, Selangor Darul Ehsan.

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