

TUSS-DEX SYRUP

Triprolidine hydrochloride (1.25mg/5ml), pseudoephedrine hydrochloride (30mg/5ml), dextromethorphan hydrobromide (15mg/5ml)

What is in this leaflet

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

What *Tuss-Dex* is used for

For relief of dry cough due to minor throat and respiratory irritation, nasal and sinus congestion, sneezing and runny nose associated with the common cold and allergic rhinitis.

How *Tuss-Dex* works

Tuss-Dex contains pseudoephedrine hydrochloride, which is a decongestant that relieves nasal and sinus congestion and triprolidine hydrochloride which is an antihistamine that helps stop sneezing, runny nose and watery eyes. Dextromethorphan suppresses cough.

Before you use *Tuss-Dex*

- When you must not use it

- Do not take *Tuss-Dex* if
- if allergic to other antihistamine or to its active ingredients or to other ingredients in it.
 - If you are taking, or have taken in the last two weeks, medicines for depression known as monoamine oxidase inhibitors (MAOIs).

- Before you start to use it

Please inform doctor before you start to use *Tuss-Dex* Syrup if you have high blood pressure or heart disease, asthma, liver problems, glaucoma (increased pressure in the eye), hyperthyroidism (overactive thyroid gland) and prostate enlargement.

Safety for use in pregnancy has not been established. It should not be used in nursing mothers. Get advice from a doctor or pharmacist if cough persists after medication has been used for 7 days. Do not use in children less than 2 years of age, and to be used with caution and on doctor's or pharmacist's advice in children 2 to 6 years of age.

- Taking other medicines

Tell your doctor if you are taking:

- alcohol

- medicines used to help you relax, sleep or relieve anxiety such as central nervous system depressants
- medicines used to treat depression such as monoamine oxidase (MAO) inhibitors
- medicines used to manage heart conditions such as Atropine

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

How to use *Tuss-Dex*

- How much to use

Adults: 2 teaspoonfuls (10ml) three or four times a day as needed, not exceeding 40ml per day. Children 6 – 12 years: 1 teaspoonful (5ml) three or four times a day as needed, not exceeding 20ml per day. Children 2 – 5 years: oral, ½ teaspoonful (2.5ml) three to four times a day, not exceeding 10ml per day.

Follow all directions given to you 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.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking *Tuss-Dex* 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)

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 may include unsteadiness, flushing, shortness of breath, hallucinations (hearing voices or seeing things which are not there),

drowsiness, fits, severe dryness of mouth, nose or throat, continuing headache and unusually slow or fast heartbeat, confusion, unusual excitement, nervousness, restlessness or severe irritability.

While you are using *Tuss-Dex*

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking *Tuss-Dex*.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

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 *Tuss-Dex* to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Caution when driving or doing jobs requiring alertness because of possible drowsiness. Avoid alcoholic beverages.

Side effects

Like all medicines, *Tuss-Dex* can cause side effects, although not everybody gets them. Visit the doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Drowsiness, lassitude, dizziness, nausea, vomiting, gastric pain, blurred vision, confusion, difficulty in urination, feeling of fast heart rate, headache, ringing sound of the ears, dryness of mouth, anorexia (eating disorder) and restlessness may occur occasionally.

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 (Consumers → Reporting)

Storage and Disposal of *Tuss-Dex*

- Storage

Store in a cool, dry place, below 25°C. Protect from light.

Keep out of reach and sight of children.

- Disposal

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?*

Brown coloured, sour plum flavoured syrup.

- *Ingredients*

- Active ingredients: triprolidine hydrochloride, pseudoephedrine hydrochloride and dextromethorphan hydrobromide.

- Inactive ingredients: methyl parabens propyl parabens, sour plum flavor, liquid glucose, liquid caramel, sodium citrate, sodium chloride, sodium carboxy methylcellulose, water and syrup.

- *MAL number:*

MAL19930042AZ

Manufacturer and Product Registration

Holder

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

Date of revision

14/04/2016

Serial number

BPFK(R4/1)140416/00109