# SEDILIX-RX LINCTUS

Dextromethorphan hydrobromide/Phenylephrine hydrochloride/Promethazine hydrochloride (15mg/5mg/3.125mg per 5ml)

#### What is in this leaflet:

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

#### What is Sedilix-Rx Linctus used for

Sedilix-Rx Linctus is used:

- for the relief of dry irritating coughs such as those associated with common cold or upper respiratory tract infections.
- to relief nose congestion, sneezing and rhinorrhea (runny nose) associated with allergy and common cold.

# **How Sedilix-Rx Linctus works**

Dextromethorphan Hydrobromide is a cough suppressant which acts centrally to raise the threshold for coughing.

Phenylephrine Hydrochloride decongestant which works by reducing swelling of the blood vessels in the air passages, thereby making it easier to breathe.

Promethazine Hydrochloride is an antihistamine and works by blocking a certain natural substances (histamine) that your body makes during an allergic reaction.

# Before you use Sedilix-Rx Linctus

#### When you must not use it

Do not use Sedilix-Rx Linctus if you are allergic to any ingredients in this medicine.

This product contains promethazine hydrochloride. It should not be used in pediatric patients less than 2 years of age because of the potential for fatal respiratory depression. To be used with cautions, and as advised by the physician/pharmacist for children age 2 to 6 years.

#### Before you start to use it

Tell your doctor or pharmacist before using Sedilix-Rx Linctus if you:

- are pregnant or plan to get pregnant.
- are breast-feeding or plan to start breast-feeding.
- have persistent cough due to smoking, lung disease or asthma.
- are coughing with excessive secretions.

- have liver, lungs, heart or metabolic problems, e.g. asthma, high blood pressure, high blood sugar, overactive of thyroid gland.
- are taking drugs for antidepressant, e.g. **MAOIs** (monoamine oxidase inhibitors) or within 2 weeks from stopping such treatment.
- have epilepsy (seizure).
- have prostate enlargement and/or bladder disorder.
- have glaucoma (increased pressure in
- have gastrointestinal problems.

#### Taking other medicines

Tell your doctor or pharmacist if you are taking or having recently taken any other medicines. This includes any medicines which you have bought without a prescription.

Sedilix-Rx Linctus may react with betahistine, certain hypnotic and anxiolytic metoclopromide medication, and antiparkinson medicines.

#### **How to use Sedilix-Rx Linctus**

How much to use

- Adult and children over 12 years 10ml every 6 hours.
- Children 6 to 12 years 5ml every 6 hours.
- Children 2 to 5 years 2.5ml every 6 hours.

#### When to use it

Follow the prescription from your doctor or pharmacist.

#### How long to use it

Follow the prescription from your doctor or pharmacist. Ask your doctor or pharmacist before prolonged use of this medicine. If symptoms do not improve within one week or accompanied with high fever, consult a physician before continuing use.

# If you forget to use it

Use it as soon as you remember, unless it is nearly time for your next dose, skip the missed dose. Then go on as before. Never double up on the next dose to make up for the one missed.

#### 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.

Symptoms of overdose include difficulty in breathing, paranoid psychosis, delusions, hallucinations, convulsions, high blood pressure and slow heart rate.

### While you are using Sedilix-Rx Linctus Things you must do

- Always wash your hand before handling the medicine.
- Take the medicine at the same time each day.
- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Sedilix-Rx Linctus.

#### Things you must not do

- Do not take any new medicines without consulting your doctor.
- Do not give Sedilix-Rx Linctus to anyone else, even if they have the same symptoms or condition as you.
- Do not use this medicine by yourself without prescription from your doctor or pharmacist.

# Things to be careful of

- This medicine may cause drowsiness. If affected, do not drive motor vehicles or operate machinery.
- Do not drink alcohol or take any medicines that may produce drowsiness while taking this medicine.

#### Side effects

- Drowsiness, dizziness
- Constipation
- Dry mouth
- Gastrointestinal discomfort
- Sleeplessness, restlessness
- Mental disruption
- Irregular heart beat
- Tightness of chest
- Rashes
- Blood disorders
- Thickening of secretions

This is not a complete list of side effects. Seek immediate medical attention if you experience any side effects or allergic reactions.

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)

# SEDILIX-RX LINCTUS

Dextromethorphan hydrobromide/Phenylephrine hydrochloride/Promethazine hydrochloride (15mg/5mg/3.125mg per 5ml)

# Storage and disposal of Sedilix-Rx Linctus

**Storage** 

Store in a cool place below 25 °C. Keep out of the reach of the children.

Do not use this medicine after expiry date.

#### 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**

How it looks like

Brown, clear syrup with cherry flavour.

#### **Ingredients**

Active ingredients
Dextromethorphan Hydrobromide,
Phenylephrine Hydrochloride,
Promethazine Hydrochloride.

# **Inactive Ingredients**

Chloroform Spirit, Saccharin Sodium, Syrup, Citric Acid Anhydrous, Fruity Flavour, Sodium Sulphite, Liquid Caramel, Glycerin, Menthol, Sorbitol Solution 70%, Purified Water, ascorbic Acid, Sodium Metabisulphite, Sodium Benzoate.

### MAL number

MAL07061427A

# **Manufacturer and Product Registration Holder**

Xepa-Soul Pattinson (Malaysia) Sdn Bhd 1-5 Cheng Industrial Estate, 75250 Melaka, Malaysia.

#### Date of revision

18 August 2015

# **Serial Number**

BPFK(R4/1)180815/00253