# PHOLCODYL SYRUP

Pholcodine (5ml/5mg)

#### What is in this leaflet

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

10.Date of revision

# What Pholcodyl Syrup is used for

It is used for relief of unproductive cough associated with common cold and infections of the upper respiratory tract.

#### How Pholcodyl Syrup works

The active ingredient in the medicine is Pholcodine. Pholcodine is an opioid chemically related to morphine. Pholcodine is a cough suppressant and has a mild sedative effect which relieves local irritation of the respiratory tract. Pholcodine acts primarily on the central nervous system (CNS) causing depression of the cough reflex which is due partly to the direct effect on the cough centre in the medulla (a part of brain).

# Before you use Pholcodyl Syrup

# - When you must not use it

Do not take this medicine if you are hypersensitive to pholcodine or any of the other ingredients listed at the end of the leaflet.

#### Pregnancy and breastfeeding

You should check with your doctor if you are or think you may be pregnant, planning to become pregnant or if you are breastfeeding.

It is not recommended for pregnant women and nursing mothers unless the expected benefit outweighs any potential risks.

# - Before you start to use it

Tell your doctor before taking this medicine if you have:

- asthma
- liver problem

# - Taking other medicines

There are a few medicines which may interact with Pholcodyl Syrup. It is important to tell your doctor or pharmacist about all the medicines that you are taking, including those obtained without doctor's prescription.

You should talk to your doctor or pharmacist if you are taking:-

• Central Nervous System (CNS) depressants such as alcohol, antihistamines, sedatives, hypnotics and tricyclic antidepressants.

#### How to use Pholcodyl Syrup

#### - How much to use

You should take Pholcodyl Syrup exactly as advised by your doctor or pharmacist. The amount you take each day will depend on your condition. Do not take more or less than what your doctor prescribes.

#### Children:

2 - 5 years: 1 ml per year of age, every 8 to 10 hours

5 - 14 years: 5 - 7.5 ml, every 8 to 10 hours.

#### Adults

10 - 15 ml, every 8 to 10 hours.

Not recommended for children < 2 years except on the advice of a physician.

#### - When to use it

Use Pholcodyl Syrup when needed and according to doctor's prescription.

#### - How long to use it

It is important to take Pholcodyl Syrup as long as your doctor prescribes.

#### - 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.

Symptoms of overdose include drowsiness, restlessness, excitement, ataxia (lack of muscle control) and respiratory depression (breathing problem).

# While you are using it

# - 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 Pholcodyl Syrup.

• 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.
- Do not give Pholcodyl Syrup to anyone else, even if they have the same symptoms or condition as you.

# - Things to be careful of

Be careful when engaging in activities requiring mental alertness such as driving a car or operating machinery until you know how this medicine affects you.

#### **Side effects**

Like all medicines, Pholcodyl Syrup can cause side effects, although not everybody gets them. The side effects are nausea and vomiting occasionally occur.

Any other effects not listed above may also occur in some people. Please refer to your doctor or pharmacist if you experience any other symptoms while taking this medication.

You may report any side effect or adverse drug reaction directly to the National Centre for Adverse Drug Reaction Monitoring by calling 03-78835550, or visiting the website <u>portal.bpfk.gov.my</u> (Consumers→Reporting).

#### Storage and disposal of Pholcodyl Syrup

#### - Storage

Store at temperature below 30 °C.

# - 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

Clear, orange syrup with orange flavour.

#### - Ingredient(s)

- Active Ingredient Pholcodine

- Inactive Ingredients
- Liquid Glucose
- Propylene Glycol
- Citric Acid
- Syrup Simplex
- Sweet Orange
- Sodium Benzoate
- Sorbitol
- Sunset Yellow

# <u>- MAL number</u> MAL05072033A

#### Manufacturer

Sunward Pharmaceutical Sdn. Bhd. No. 9,11 & 17, Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

# **Product Registration Holder**

Sunward Pharmaceutical Sdn. Bhd. No. 9,11 & 17, Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

# **Date of revision**

25/11/2015

#### Serial number

BPFK(R4/1)241115/00450