

PHENSEDYL[®] DRY COUGH LINCTUS

Promethazine hydrochloride/Pholcodine/Ephedrine hydrochloride (3.6mg/4mg/7.2mg per 5ml)

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What Phensedyl is used for

Phensedyl is used to aid the suppression of dry irritating coughs day and night.

How Phensedyl works

The name of your medicine is Phensedyl Dry Cough Linctus (called Phensedyl throughout this leaflet). It contains a combination of three active ingredients:

- Promethazine Hydrochloride works by blocking a natural substance (histamine) that your body makes during an allergic reaction in the upper respiratory tract.
- Pholcodine is a cough suppressant which has a central action on the cough centre in the medulla (a part of the brain).
- Ephedrine Hydrochloride unblocks your nose and sinuses helping you to breathe more easily.

Before you use Phensedyl

When you must not use it

Do not take Phensedyl if:

- You are allergic (hypersensitive) to pholcodine, promethazine or ephedrine
- Signs of allergic reaction include: a rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue.
- You are taking monoamine oxidase inhibitors (for depression), or have taken them in the last 14 days
- You have any liver diseases
- You have asthma

Do not use this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist

before taking Phensedyl.

Pregnancy and breastfeeding

Talk to your doctor before taking this medicine if you are pregnant, might become pregnant or think you may be pregnant or breastfeeding. Do not use during pregnancy without medical advice.

Before you start to use it

Check with your doctor before taking Phensedyl if:

- Your child is under 2 years of age
- Use with caution and on doctor's or pharmacist's advice in children 2 to 6 years of age.
- You are allergic (hypersensitive) to sodium metabisulphite (one of the ingredients in Phensedyl)

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Phensedyl.

Taking other medicines

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines as these combinations are inadvisable:

- Alcohol or other central nervous system depressants
- Monoamine oxidase inhibitors- used for depression

How to use Phensedyl

Always take Phensedyl exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Take this medicine by mouth
- Do not mix Phensedyl with any other liquids. Do not dilute it.

How much to use

Children 2 to 5 years

- Usual dose is 2.5ml two to three times a day

Children 5 to 10 years

- Usual dose is 2.5~5ml two to three times a day

Children over 10 years

- Usual dose is 5~10ml two to three times a day

Adults

- Usual dose is 5~10ml two to three times a day

Phensedyl is not recommended for use in children below 2 years of age.

When to use it

Take Phensedyl at about the same time each day unless your doctor tells you otherwise.

How long to use it

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

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 a forgotten dose.
- If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you use too much (overdose)

If you take more Phensedyl than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. The following effects may happen to:

-Children

- Over-excitement
- Lack of voluntary coordination of muscle movements (ataxia)
- Slow, continuous, writhing movements of the limbs (athetosis)
- Hallucination
- Convulsion

-Adults

- Drowsiness
- Coma
- Convulsion
- Fast heartbeats (tachycardia)
- Difficulty in breathing

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

Things you must not do

- Do not give this medicine to anyone

else, even if they have the same condition as you.

- Do not use this medicine to treat any other complaints unless your doctor tells you to.
- Do not stop taking Phensedyl, or change the dosage, without checking with your doctor.

Things to be careful of

Driving and using machines

Phensedyl can make you feel drowsy which may impair your ability to concentrate and react. If you are affected, do not drive or operate any machines.

Side Effect

Like all medicines, Phensedyl can cause side effects, although not everyone gets them.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor immediately if you notice any of the following side effects:

- Drowsiness
- Nausea
- Vomiting
- Constipation
- Sedation
- Blurred vision
- Dryness of mouth
- Dizziness
- Increased or decreased blood pressure
- Rash

Other side effects not listed above may 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 (Consumers → Reporting).

Storage and Disposal of Phensedyl

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

Storage

- Keep this medicine in a safe place where children cannot see or reach it.

- Do not use Phensedyl after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.
- Store below 30°C. Protect from light.

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

Phensedyl is presented as a brown liquid with a banana odour. They are available in 90ml bottle.

Ingredients:

Each 5ml contains:

- 3.6mg of Promethazine Hydrochloride
- 4.0mg of Pholcodine
- 7.2mg of Ephedrine Hydrochloride

MAL number:

Phensedyl Dry Cough Linctus

MAL08091409A

Manufacturer and Product Registration Holder

Manufacturer

Sanofi-Aventis Pakistan Limited,
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Product registration holder

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Date of revision

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