

APOHEALTH Dry Tickly Cough Relief FORTE

Contains the active ingredient Pholcodine

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about APOHEALTH Dry Tickly Cough Relief FORTE. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,

- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

APOHEALTH Dry Tickly Cough Relief FORTE is used to help stop stubborn, dry tickly coughs.

Pholcodine is the active ingredient in APOHEALTH Dry Tickly Cough Relief FORTE, and works on the cough centre in the brain to control and stop coughing.

Your doctor or pharmacist may have prescribed or recommended APOHEALTH Dry Tickly Cough Relief FORTE for another purpose.

Ask your pharmacist or doctor if you have any questions about why this medicine has been prescribed or recommended for you.

This medicine is only available from your pharmacist.

There is no evidence that this medicine is addictive.

Use in Children

This medicine should not be used in children under the age of 12 years.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You have or have had any of the following:**
- severe asthma, bronchitis or other serious respiratory conditions
- **You are hypersensitive to, or have had an allergic reaction to, Pholcodine or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **The expiry date (EXP) printed on the pack has passed.**

- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - asthma or other breathing problems
3. You are currently pregnant or you plan to become pregnant.

Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.

4. You are currently breastfeeding or you plan to breast-feed

It is not known if pholcodine passes into the breast milk. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.

5. You are taking or are planning to take any other medicines. This includes vitamins and supplements that

are available from your pharmacy, supermarket or health food shop.

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

Some medicines may interact with pholcodine. These include:

- sedatives, medicines used to help you relax or sleep
- medicines used to control anxiety
- alcohol

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with pholcodine.

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

How to take this medicine

Follow carefully all directions given to you by your doctor or pharmacist. Their instructions may be different to the information in this leaflet.

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

How much to take

Do not give this medicine to a child under the age of 12 years.

Children over 12 years:

2.5 mL three to four times daily when necessary.

Adults:

3.75 mL three to four times daily when necessary.

How to take it

Shake the bottle well before use and accurately measure the dose with a medicine measure.

Shaking the bottle and using a medicine measure will make sure that you get the correct dose.

How often to take it

Take your medicine every 6-8 hours when necessary.

Do not take it more than 4 times in one day.

It is important to use this medicine exactly as your doctor or pharmacist has advised.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor

or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

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

While you are taking this medicine

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you take this medicine.

If you feel that this medicine is not helping your condition tell your pharmacist or doctor.

Your pharmacist or doctor will assess your condition and decide if you should continue to take the medicine.

Tell your pharmacist or doctor if, for any reason, you have not used this medicine exactly as prescribed.

Otherwise, your pharmacist or doctor may think that it was not effective and change your treatment unnecessarily.

If you become pregnant while taking this medicine, tell your pharmacist or doctor.

Things you must not do

Do not:

- Take more than the recommended dose unless your pharmacist or doctor tells you to.
- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

This medicine may cause drowsiness or dizziness in some people. Drowsiness may continue the following day. If this happens, do not drive, operate machinery or do anything else that could be dangerous.

Avoid alcohol.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking APOHEALTH Dry Tickly Cough Relief FORTE, or if you have any questions or concerns.

This medicine helps most people with stubborn, dry, tickly coughs, but it may have unwanted side effects in a few people.

Do not be alarmed by the following list of possible side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor or pharmacist if you notice any of the following:

- dizziness
- drowsiness
- nausea and vomiting
- stomach pain
- constipation

These are the more common side effects of your medicine. They are usually mild.

Tell your doctor as soon as possible if you notice any of the following:

These may be serious side effects and you may need medical attention:

- lack of coordination and unsteadiness when walking
- unusual mood swings

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and you may need urgent medical attention or hospitalisation:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

These side effects are very rare for low doses of this medicine and when used for a short period of time.

Other side effects not listed above may occur in some patients.

Tell your pharmacist or doctor if you notice anything that is making you feel unwell.

Allergic reactions

If you think you are having an allergic reaction to APOHEALTH Dry Tickly Cough Relief FORTE, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body

- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 30°C.

Do not store your medicine, 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 some medicines.

Do not refrigerate this medicine.

Keep this medicine where children cannot reach it.

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

Disposal

Ask your pharmacist what to do with any medicine that is left over, or if the expiry date has passed.

Product description

What APOHEALTH Dry Tickly Cough Relief FORTE looks like

Clear liquid with a peach flavour.

Each bottle contains either 100mL or 200mL.

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each 1 mL of APOHEALTH Dry Tickly Cough Relief FORTE contains 4mg of Pholcodine as the active ingredient.

It also contains the following inactive ingredients:

- Citric Acid-Anhydrous
- Glycerol
- Propylene Glycol
- Saccharin Sodium
- Sodium Cyclamate

- Water Purified
- Xanthan Gum
- Sodium Benzoate

APOHEALTH Dry Tickly Cough Relief FORTE also contains the following proprietary ingredients:

- Peaches Flavour Natural & Artificial FADUO43

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APOHEALTH Dry Tickly Cough Relief FORTE (Bottle):
AUST R 235308

Sponsor

Apotex Pty Ltd

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