

APOHEALTH Cold & Flu Relief Day/Night Tablets

Contains the active ingredients Paracetamol, Pseudoephedrine hydrochloride, Codeine phosphate and Chlorpheniramine maleate

Consumer Medicine Information

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

What is in this leaflet

This leaflet answers some common questions about APOHEALTH Cold & Flu Relief Day/Night tablets. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your pharmacist or doctor has weighed the risks of you taking APOHEALTH Cold & Flu Relief Day/Night tablets against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your pharmacist or doctor.

Keep this leaflet with your medicine.

You may want to read it again.

What APOHEALTH Cold & Flu Relief Day/Night tablets is used for

This product is used for temporary relief of cold and flu symptoms.

Paracetamol works to stop the pain messages from getting through to the brain. It also acts in the brain to reduce fever.

Pseudoephedrine belongs to a group of medicines called sympathomimetic decongestants. It works by reducing congestion in the upper respiratory tract, including the nose, nasal passages and sinuses, and making it easier to breathe.

Chlorpheniramine belongs to a group of medicines called 'antihistamines'. Antihistamines help reduce allergic symptoms by preventing the effects of a substance called histamine. Histamine is produced by the body in response to foreign substances that the body is allergic to.

Codeine phosphate belongs to a group of medicines called analgesics. It is an opioid analgesic and it acts by blocking pain and your emotional response to pain.

Ask your pharmacist or doctor if you have any questions about this medicine.

Your pharmacist or doctor may have given it for another reason.

This medicine is only available from a pharmacist.

Before you take/give APOHEALTH Cold & Flu Relief Day/Night tablets

When you must not take it

Do not take APOHEALTH Cold & Flu Relief Day/Night tablets if you have an allergy to:

- any medicine containing codeine, paracetamol, pseudoephedrine, or chlorpheniramine, or other antihistamines
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- 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

Do not take APOHEALTH Cold & Flu Relief Day/Night tablets if you have:

- very high blood pressure

- severe coronary artery disease (heart disease caused by poor blood flow or narrowing of the blood vessels of the heart)
- taken monoamine oxidase inhibitors, medicines used to treat depression, in the last 14 days

Do not take this medicine if you have or have had any of the following medical conditions:

- glaucoma (high pressure in the eyes)
- stomach or duodenal ulcer, or other stomach problems
- prostate problems
- bladder problems
- acute breathing difficulties such as bronchitis, unstable asthma or emphysema
- chronic constipation
- diarrhoea caused by antibiotics or poisoning

Do not take this medicine if you have alcohol dependence.

Do not take this medicine if you are pregnant or plan to become pregnant.

It may affect your developing baby if you take it during pregnancy. Your pharmacist or doctor will discuss the benefits and possible risks of taking the medicine during pregnancy.

Do not take this medicine during labour, especially if the baby is premature.

The medicine may produce withdrawal effects in the newborn baby.

Do not take this medicine if you are breastfeeding or plan to breastfeed.

It passes into the breast milk and there is a possibility that the baby may be affected.

Do not give this medicine to newborn or premature babies.

Do not give to children under 12 years.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your pharmacist or doctor.

Before you start to take it

Tell your pharmacist or doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your pharmacist or doctor if you have or have had any of the following medical conditions:

- high blood pressure
- low blood pressure
- underactive thyroid
- overactive thyroid gland
- diabetes
- heart disease and poor blood flow in the blood vessels of the heart
- glaucoma (high pressure in the eyes)
- prostate problems
- liver or kidney disease
- epilepsy
- difficulty breathing, wheezing, chronic cough, asthma or other chronic breathing conditions

- a history of drug dependence, including alcohol dependence
- recent surgery on the stomach or intestines
- head injury

Tell your pharmacist or doctor if you take sedatives (medicines used to help you relax or sleep).

If you have not told your pharmacist or doctor about any of the above, tell him/her before you start taking APOHEALTH Cold & Flu Relief Day/Night tablets.

Taking other medicines

Do not take with other medicines containing paracetamol. It is important to check the labels of all other medicines you are taking to make sure they do not contain paracetamol. Taking too much paracetamol may cause serious liver damage.

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

Some medicines and APOHEALTH Cold & Flu Relief Day/Night tablets may interfere with each other. These include:

- warfarin, a medicine used to prevent blood clots
- metoclopramide, a medicine used to control nausea and vomiting
- medicines such as phenytoin used to treat epilepsy or fits
- chloramphenicol, an antibiotic used to treat ear and eye infections
- medicines used to treat depression, especially monoamine oxidase inhibitors and tricyclic antidepressants, taken within the last 14 days
- medicines used to treat heart conditions
- medicines used to treat high blood pressure
- medicines used to treat urinary tract infections and bladder problems
- medicines used to treat behavioural disorders
- phenylephrine, a medicine used to treat congestion
- appetite suppressants
- medicines used to help you relax, sleep or relieve anxiety, such as barbiturates, sedatives and hypnotics
- medicines used to relieve stomach cramps or spasms, to prevent travel sickness and to treat Parkinson's disease
- medicines for diarrhoea, such as kaolin, pectin and loperamide
- other opioid analgesics and medicines used to treat pain
- quinidine, a medicine used to treat abnormal or irregular heart beat
- phenothiazines and antipsychotic agents, medicines used to treat mental disorders
- alcohol

These medicines may be affected by APOHEALTH Cold & Flu Relief Day/Night tablets, or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

How to take APOHEALTH Cold & Flu Relief Day/Night tablets

Follow all directions given to you by your pharmacist or doctor carefully.

They may differ from the information contained in this leaflet.

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

How much to take

DAY MEDICATION DOSAGE (White tablets)

Adults & Children 12 years and over: Take 2 white Day tablets in the morning and two in the afternoon when necessary with water.

NIGHT MEDICATION DOSAGE (Pink tablets)

Adults & Children 12 years and over: Take 2 pink Night tablets at bedtime if required.

Dosage may be repeated after 4 to 6 hours if required.

Do not take the Night tablet within 4 hours of taking the Day tablet.

Do not exceed 4 doses (8 Day & Night tablets) in 24 hours.

Do not take more than the recommended dose.

Do not give to children under 12 years.

May cause sleeplessness if it is taken up to several hours before going to bed in people sensitive to pseudoephedrine.

Talk to your doctor about pain control if the medicine is not helping.

About 8% of people are poor metabolisers of codeine. If your body cannot metabolise codeine properly, you may be getting reduced benefit from the medicine.

If you are over 65 years of age, talk to your pharmacist or doctor about how much to take.

Elderly patients are more likely to have side effects such as less effective kidney function from taking these medicines due to age. This may increase the risk of side effects.

How to take it

Take tablet or tablets as required with water.

When to take it

Take tablet or tablets every 4 to 6 hours as required.

How long to take it for

Do not take this medicine for longer than a few days at a time (Adults) or 48 hours at a time (Children over 12 years) unless advised to by a doctor.

If you forget to take it

If it is less than 4 hours before your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your pharmacist or doctor.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and

Emergency at the nearest hospital, if you think that you or anyone else may have taken too much APOHEALTH Cold & Flu Relief Day/Night tablets. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking APOHEALTH Cold & Flu Relief Day/Night tablets

Things you must do

Talk to your pharmacist or doctor if your symptoms do not improve.

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

Things you must not do

Children 12 years and over:

Do not give this medicine for more than 48 hours unless a doctor has told you to.

Adults:

Do not take for more than a few days at a time unless your doctor tells you to.

Do not take more than the recommended dose unless your pharmacist or doctor tells you to.

Do not take APOHEALTH Cold & Flu Relief Day/Night tablets to treat any other complaints unless your pharmacist or doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not drink alcohol while taking APOHEALTH Cold & Flu Relief Day/Night tablets.

The sedation effects of alcohol may be increased. Drinking large quantities of alcohol while taking paracetamol may increase the risk of liver side effects.

Things to be careful of

Be careful driving or operating machinery until you know how APOHEALTH Cold & Flu Relief Day/Night tablets affects you.

This medicine may cause dizziness or sleepiness in some people. If this happens, do not drive, use or operate machinery.

Do not take high doses of the medicine for long periods of time unless your doctor tells you to.

Codeine may be habit forming.

Possible side effects

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are taking APOHEALTH Cold & Flu Relief Day/Night tablets.

This medicine helps most people with the symptoms of Cold and Flu, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your pharmacist or doctor to answer any questions you may have

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

- nausea or dyspepsia
- vomiting
- difficulty sleeping
- nervousness and irritability
- excitability
- restlessness

- dizziness
- fear or anxiety
- fast or rapid heart beat
- tremor
- hallucinations
- drowsiness or sleepiness
- dry mouth, nose and throat
- constipation
- anxiety
- twitching or jerking muscles

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Children and people over 65 years of age may have an increased chance of getting side effects.

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

- difficult or painful urination
- seizures (fits)
- shallow breathing
- unusual or extreme mood swings
- dizziness, light-headedness
- flushing of the face
- fast heart beat

The above list includes serious side effects that may require medical attention. These side effects are rare.

If any of the following happen, tell your pharmacist or doctor immediately or go to Accident and Emergency at your nearest hospital:

- urine retention
- 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

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare for low doses of this medicine and when used for a short period of time.

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

Other side effects not listed above may also occur in some people.

After using APOHEALTH Cold & Flu Relief Day/Night tablets

Storage

Keep your medicine in the original pack until it is time to take it.

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

Do not store APOHEALTH Cold & Flu Relief Day/Night tablets 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.

Keep it 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 it looks like

This medicine is sold in a carton containing 24 tablets in blister packs.

16 tablets are white in colour and are for Day time use.

8 tablets are pink in colour and are for Night time use.

Ingredients

APOHEALTH Cold & Flu Relief Day/Night tablets contains 500 mg of Paracetamol, 30 mg of Pseudoephedrine hydrochloride, 6 mg of Codeine phosphate (Day tablets only) and 2 mg of Chlorpheniramine maleate (Night tablets only) as the active ingredients.

It also contains:

- Cellulose - microcrystalline
- Crospovidone
- Magnesium stearate
- Povidone
- Stearic acid
- Starch - pregelatinised maize
- Erythrosine (Night tablets only)

Sponsor and Supplier

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