

Coldrex[®] PE

Phenylephrine Cold & Flu Night & Day Caplets

Day caplet - Paracetamol 500 mg, Dextromethorphan Hydrobromide 15 mg, Phenylephrine Hydrochloride 5 mg;

Night caplet - Paracetamol 500 mg, Dextromethorphan Hydrobromide 15 mg, Phenylephrine Hydrochloride 5 mg and Chlorpheniramine Maleate 2 mg

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about COLDREX PE PHENYLEPHRINE COLD & FLU NIGHT & DAY caplets.

It does not contain all the available information. It does not take the place of talking to your pharmacist or doctor.

All medicines have risks and benefits. Your pharmacist or doctor has weighed the risks of you taking COLDREX PE PHENYLEPHRINE COLD & FLU NIGHT & DAY caplets 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 the medicine.

You may need to read it again.

What COLDREX PE PHENYLEPHRINE COLD & FLU NIGHT & DAY are used for

COLDREX PE PHENYLEPHRINE COLD & FLU NIGHT & DAY CAPLETS are used for the temporary relief of the following symptoms of cold and flu: headache,

runny or blocked nose, sore throat, dry cough, body aches and pains.

Reduces fever. The NIGHT caplet also relieves runny nose, sneezing, itchy and watery eyes and allows rest by providing effective temporary relief from these symptoms.

COLDREX PE PHENYLEPHRINE COLD & FLU DAY caplets contain the active ingredients paracetamol, dextromethorphan hydrobromide and phenylephrine hydrochloride.

COLDREX PE PHENYLEPHRINE COLD & FLU NIGHT caplets contain the active ingredients paracetamol, dextromethorphan hydrobromide, phenylephrine hydrochloride and chlorpheniramine maleate.

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

Dextromethorphan hydrobromide is a cough suppressant that is used to suppress a dry cough.

Phenylephrine HCl works to reduce nasal stuffiness.

Chlorpheniramine maleate 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.

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 not addictive.

It is only available in the pharmacy.

Before you take/give COLDREX PE PHENYLEPHRINE COLD & FLU NIGHT & DAY CAPLETS

Taking too much paracetamol can cause serious harm to your liver.

When you must not take it

Do not take COLDREX PE PHENYLEPHRINE COLD & FLU NIGHT & DAY CAPLETS if you have an allergy to:

- any medicine containing paracetamol, dextromethorphan, phenylephrine, 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, throat or other parts of the body
- rash, peeling, itching or hives on the skin or mouth ulcers

Always read and follow the label.

Do not take this medicine:

- If you are taking any other prescription or non-prescription medicines containing paracetamol to treat pain, fever, symptoms of cold and flu, or to aid sleep
- within several hours of going to bed as it may cause sleeplessness
- if you have very high blood pressure, heart problems or are taking antidepressant medicines unless your doctor has told you to
- if you are taking or have taken in the last 14 days, drugs called monoamine oxidase inhibitors, medicines used to treat depression
- if you are taking other medicines for the relief of colds and flu, congestion or blocked nose, appetite suppressants or stimulants, or other medicines containing antihistamines (sometimes used to treat allergy)
- if you regularly drink large quantities of alcohol
- if you have a chest infection, worsening asthma or severe respiratory problems
- if you are having an asthma attack
- You are pregnant or breastfeeding
- If you have
 - glaucoma (high pressure in the eyes)
 - stomach or duodenal ulcer, or other stomach problems
 - prostate problems
 - bladder problems

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 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 had any of the following medical conditions:

- liver or kidney disease
- overactive thyroid gland
- heart disease, blood vessel disease such as Raynauds phenomenon (which may appear as pain in the fingers or toes in response to cold or stress)
- high blood pressure
- irregular heartbeat
- epilepsy (fits)
- diabetes
- glaucoma (high pressure in the eyes)
- phaeochromocytoma (a tumour near the kidney)
- prostate gland enlargements
- long term or persistent cough
- asthma, bronchitis or a chronic lung disorder or a cough with excessive phlegm
- are underweight or malnourished
- regularly drink alcohol

You may need to avoid using this product altogether or limit the amount of paracetamol that you take.

- a severe infection as this may increase the risk of metabolic acidosis

Sign of metabolic acidosis include:

- deep, rapid, difficult breathing
- feeling sick (nausea), being sick (vomiting)
- loss of appetite

Contact a doctor immediately if you get a combination of these symptoms

Ask your pharmacist or doctor about taking COLDREX PE

PHENYLEPHRINE COLD & FLU NIGHT & DAY CAPLETS if you are pregnant or plan to become pregnant, or breastfeeding. Your pharmacist or doctor will discuss the potential benefits and risks of taking the medicine if you are breastfeeding.

If you have not told your pharmacist or doctor about any of the above, tell him/her before you start taking COLDREX PE PHENYLEPHRINE COLD & FLU NIGHT & DAY CAPLETS.

Taking other medicines

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 COLDREX PE PHENYLEPHRINE COLD & FLU NIGHT & DAY CAPLETS may interfere with each other. These include:

- warfarin, a medicine used to prevent blood clots or similar medicines used to thin the blood
- medicines to treat anxiety or help you sleep or relax (sedatives and hypnotics)
- phenytoin, a medicine used to treat epilepsy (fits)

- medicines to treat depression (e.g. a selective serotonin reuptake inhibitor (SSRI) such as fluoxetine or tricyclic antidepressant (such as clomipramine or imipramine)
- metoclopramide, a medicine used to control nausea and vomiting
- chloramphenicol, an antibiotic used to treat ear and eye infections
- alcohol
- monoamine oxidase inhibitors, a medicine used to treat depression, especially if taken within the last 14 days
- quinidine and amiodarone, medicines used to treat abnormal or irregular heartbeat
- medicines used to treat:
 - heart conditions
 - high blood pressure
 - urinary tract infections and bladder problems
 - behavioural disorders
 - congestion
- appetite suppressants
- opioid analgesics, medicines used to treat pain

These medicines may be affected by COLDREX PE PHENYLEPHRINE COLD & FLU NIGHT & DAY CAPLETS 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 COLDREX PE PHENYLEPHRINE COLD & FLU NIGHT & DAY

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/bottle, ask your pharmacist or doctor for help.

Do not exceed the stated dose or frequency of dosing.

Always use the lowest effective dose to relieve your symptoms

How much to take

Adults and children 12 years and over, take 2 caplets (capsule-shaped tablets). Do not take more than 4 DAY caplets and 2 NIGHT caplets within 24 hours.

Do not take more than the recommended dose.

How to take

Take 2 caplets (capsule-shaped tablets) of COLDREX PE PHENYLEPHRINE COLD & FLU NIGHT & DAY CAPLETS by mouth with fluid as necessary.

When to take it

Adults and children 12 years and over:

DAY:

Take 2 DAY caplets every 6 hours with water as necessary.

Maximum 6 DAY caplets in 24 hours

NIGHT:

At bedtime, take 2 NIGHT caplets with water as necessary.

Maximum 2 NIGHT caplets in 24 hours.

Do not take the NIGHT caplets within 6 hours of the DAY caplets.

How long to take it

Adults and children 12 years and over:

Only take COLDREX PE PHENYLEPHRINE COLD & FLU NIGHT & DAY CAPLETS for a few days at a time except on medical advice.

Children aged 12 to 17 years:

Do not take for more than 48 hours except on medical advice.

Do not use in children below 12 years old.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 0800 764 766) 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 COLDREX PE PHENYLEPHRINE COLD & FLU NIGHT & DAY CAPLETS. Seek medical advice immediately even if there are no signs of discomfort or poisoning because of the risk of liver failure.

You may need urgent medical attention.

Taking too much paracetamol can lead to delayed, serious liver damage.

While you are using COLDREX PE PHENYLEPHRINE COLD & FLU NIGHT & DAY

Things you must do

Talk to your pharmacist or doctor if your symptoms do not improve or if your cough is accompanied by high temperature, skin rash or persistent headache.

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

Things you must not do

Children:

Do not give COLDREX PE PHENYLEPHRINE COLD & FLU NIGHT & DAY CAPLETS to children under the age of 12 years.

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 doctor tells you to.

Do not take COLDREX PE PHENYLEPHRINE COLD & FLU NIGHT & DAY CAPLETS 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.

Keep out of reach of children.

Do not drink alcohol while taking COLDREX PE PHENYLEPHRINE COLD & FLU NIGHT & DAY CAPLETS.

The sedation effects of alcohol may be increased.

Things to be careful of

Avoid drinking alcohol (beer, wine or spirits) while taking COLDREX PE PHENYLEPHRINE COLD & FLU NIGHT & DAY CAPLETS.

Drinking alcohol while taking COLDREX PE PHENYLEPHRINE COLD & FLU NIGHT & DAY CAPLETS may increase the risk of side effects.

Be careful driving or operating machinery until you know how COLDREX PE PHENYLEPHRINE COLD & FLU NIGHT & DAY CAPLETS affects you.

This medicine may cause drowsiness, dizziness or blurred vision in some people. You should not drive or operate machinery until you are sure you are not affected.

Side effects

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are taking COLDREX PE

PHENYLEPHRINE COLD & FLU NIGHT & DAY CAPLETS.

This medicine helps most people with the relief of sinus congestion and pain, nasal congestion, runny nose or dry cough but there 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.

Children and the elderly are more likely to develop side effects with this medicine.

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, dyspepsia or vomiting
- drowsiness or sleepiness
- difficulty sleeping
- nervousness
- fatigue
- headache
- blurred vision
- excitability
- restlessness
- dizziness
- difficulty concentrating
- lack of co-ordination
- rapid heart beat
- increased blood pressure
- dry mouth, nose and throat
- nervousness and irritability

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

- allergic reactions such as
 - skin rash or itching

- skin rash or peeling, or mouth ulcers
- redness sometimes with breathing problems (difficulty breathing)
- swelling of mouth or eyes, lips, tongue, throat or face
- previously experienced breathing problems with aspirin or non-steroidal anti-inflammatories, and experience similar reactions with this product
- difficulty passing water (this is most likely to occur in men with enlarged prostate gland)
- unexplained bruising or bleeding
- severe drowsiness or dizziness
- severe excitability
- unusually fast pulse rate or a sensation of an unusually fast or irregular heartbeat
- tremor
- hallucinations (this is rare but more likely in children)
- twitching or jerking muscles
- severe nausea and vomiting
- experience some or all of the following symptoms:
 - extreme confusion
 - nervousness and anxiety
 - restlessness
 - sweating
 - shaking
 - shivering
 - sudden jerks of the muscles
 - increased blood pressure
- These may be symptoms of a condition called serotonin syndrome, which may be rare.
- loss of vision, which may be due to abnormally high blood pressure in the eye.
 - This is very rare but is more likely to occur in those with glaucoma.

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 COLDREX PE PHENYLEPHRINE COLD & FLU NIGHT & DAY CAPLETS

Storage

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

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

Do not store COLDREX PE PHENYLEPHRINE COLD & FLU NIGHT & DAY CAPLETS 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

COLDREX PE PHENYLEPHRINE COLD & FLU DAY CAPLETS are blue capsule-shaped tablet with flat edges. One face is marked with the sun within an oval.

COLDREX PE PHENYLEPHRINE COLD & FLU NIGHT CAPLETS tablet are white capsule-shaped tablet with flat edges. One face is marked with a crescent within an oval.

A pack contains 24 caplets consisting of 16 DAY (blue) caplets and 8 NIGHT (white) caplets.

Ingredients

COLDREX PE PHENYLEPHRINE COLD & FLU DAY CAPLET contains 500mg paracetamol, 5mg Phenylephrine Hydrochloride and 15mg Dextromethorphan Hydrobromide as the active ingredients.

The DAY caplet also contains:

- Cellulose – microcrystalline
- Potassium sorbate
- Povidone
- Sodium lauryl sulfate
- Starch – maize
- Starch – pregelatinised maize
- Stearic acid
- Talc – purified
- Indigo Carmine

COLDREX PE PHENYLEPHRINE COLD & FLU NIGHT CAPLET contains 500mg Paracetamol, 5mg Phenylephrine Hydrochloride, 15mg Dextromethorphan Hydrobromide and 2mg of Chlorpheniramine Maleate as the active ingredients.

The NIGHT caplet also contains:

- Cellulose - microcrystalline
- Potassium Sorbate
- Povidone
- Sodium Lauryl sulfate
- Starch - Maize
- Starch - pregelatinised maize
- Stearic acid
- Talc - purified
- Water - purified

Manufacturer

COLDREX PE PHENYLEPHRINE COLD & FLU NIGHT & DAY

CAPLETS are supplied in New Zealand by:

GlaxoSmithKline Consumer Healthcare

Auckland, New Zealand

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