

Coldrex[®] PE

Phenylephrine

CONGESTION CLEAR

Paracetamol 500 mg and Phenylephrine Hydrochloride 5 mg

Consumer Medicine Information

Please read this information before you start using this medicine.

What is in this leaflet

This leaflet answers some common questions about COLDREX PE PHENYLEPHRINE CONGESTION CLEAR.

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 CONGESTION CLEAR 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 CONGESTION CLEAR is used for

COLDREX PE PHENYLEPHRINE CONGESTION CLEAR is used for the fast, effective temporary relief of sinusitis symptoms including sinus

headache, sinus pain, and nasal congestion. Reduces fever.

COLDREX PE PHENYLEPHRINE CONGESTION CLEAR contain the active ingredients paracetamol and Phenylephrine hydrochloride

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

Phenylephrine hydrochloride 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.

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 from your pharmacist.

Before you take/give COLDREX PE PHENYLEPHRINE CONGESTION CLEAR

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

When you must not take it

Do not take COLDREX PE PHENYLEPHRINE CONGESTION CLEAR if you have an allergy to:

- any medicine containing paracetamol or Phenylephrine hydrochloride
- 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
- have high blood pressure
- have heart disease or problems with your blood vessels
- have kidney disease unless your doctor says you can

- have taken monoamine oxidase inhibitors, medicines used to treat depression, in the last 14 days
- are taking other medicines for the relief of colds & flu, congestion or blocked nose, appetite suppressants or stimulant drugs called amphetamines (sometimes used for attention deficit disorder)

Do not give to children under 12 years of age

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 have had any of the following medical conditions:

- liver disease
- kidney disease
- high blood pressure
- 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
- irregular heart beat
- a rare tumour of the adrenal gland (phaeochromocytoma)

- epilepsy
- bronchitis, asthma or other respiratory problems
- 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 CONGESTION CLEAR 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 CONGESTION CLEAR.

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 CONGESTION CLEAR may interfere with each other. These include:

- medicines to treat depression such as MAOIs or tricyclic antidepressants
- medicines to treat anxiety or help you sleep
- other medicines for the relief of colds & flu, congestion or blocked nose, appetite suppressants or stimulants
- warfarin, a medicine used to prevent blood clots
- metoclopramide, a medicine used to control nausea and vomiting
- medicines used to treat epilepsy or fits
- chloramphenicol, an antibiotic used to treat ear and eye infections
- alcohol
- 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

These medicines may be affected by COLDREX PE PHENYLEPHRINE CONGESTION CLEAR or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist 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 CONGESTION CLEAR

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.

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. Do not take more than 8 caplets in 24 hours.

Do not take more than the recommended dose.

How to take it

Take 2 caplets of COLDREX PE PHENYLEPHRINE CONGESTION CLEAR by mouth with water.

When to take it

Every 6 hours as necessary

Maximum 8 caplets in 24 hours.

How long to take it

Adults:

Only take COLDREX PE PHENYLEPHRINE CONGESTION CLEAR 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 of age.

If you forget to take it

If it is less than 1 hour 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 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 CONGESTION CLEAR. 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.

While you are using COLDREX PE PHENYLEPHRINE CONGESTION CLEAR

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 to 17 years

Do not give COLDREX PE PHENYLEPHRINE

CONGESTION CLEAR 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 give to children under 12 years of age.

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

Do not take COLDREX PE PHENYLEPHRINE CONGESTION CLEAR 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.

Things to be careful of

Avoid drinking alcohol (beer, wine or spirits) while taking COLDREX PE PHENYLEPHRINE CONGESTION CLEAR.

Drinking alcohol while taking COLDREX PE PHENYLEPHRINE CONGESTION CLEAR may increase the risk of liver side effects.

Be careful driving or operating machinery until you know how COLDREX PE PHENYLEPHRINE CONGESTION CLEAR affects you.

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

Side effects

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

This medicine helps most people with the relief of sinusitis symptoms

including sinus headache, sinus pain, and nasal congestion 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.

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
- drowsiness
- difficulty sleeping
- nervousness
- agitation
- restlessness
- dizziness
- fear or anxiety
- rapid heart beat
- tremor
- increased blood pressure
- hallucinations
- trouble urinating (more likely to occur if you have enlarged prostate)

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:

- 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
- unexplained bruising or bleeding
- rapid or irregular heartbeat
- urinary retention
- severe headache

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 CONGESTION CLEAR

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 COLDREX PE PHENYLEPHRINE CONGESTION CLEAR 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 CONGESTION CLEAR is a white, capsule-shaped tablet with flat edges

embossed with the sun graphic within an oval. . A pack contains 20 capsule-shaped tablets.

Ingredients

COLDREX PE PHENYLEPHRINE CONGESTION CLEAR contains 500 mg of Paracetamol and 5 mg of Phenylephrine Hydrochloride as the active ingredients.

It also contains:

- Potassium sorbate
- Talc - purified
- Starch - Maize
- Starch - pregelatinised maize
- Microcrystalline Cellulose
- Povidone
- Sodium laurilsulfate
- Stearic acid

Manufacturer/Supplier

COLDREX PE PHENYLEPHRINE CONGESTION CLEAR is supplied in NEW ZEALAND by:

GlaxoSmithKline Consumer Healthcare

Auckland, New Zealand

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