

Coldrex

Syrup & Tablets USP

Coldrex is a brand of medicine containing the active ingredients

- Paracetamol USP.....325mg
- Dextromethorphan hydrobromide USP.....10mg
- Chlorpheniramine Maleate USP..... 1mg

INDICATIONS

Coldrex syrup & tablets 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, Pains and Reduce Fever.

ACTIVE INGREDIENTS:

Paracetamol, Dextromethorphan Hydrobromide and Chlorpheniramine.

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.

CHLORPHENIRAMINE: Chlorpheniramine is an antihistamine used to relieve symptoms of allergy, hay fever, and the common cold. These symptoms include rash, watery eyes, itchy eyes/ nose/ throat/ skin, cough, runny nose, and sneezing.

BEFORE YOU TAKE/GIVE COLDREX SYRUP & TABLET WHEN YOU MUST NOT TAKE IT

Do not take coldrex syrup & tablet if you have an allergy to:

- Any medicine containing paracetamol, dextromethorphan, or chlorpheniramine
- 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 THIS MEDICINE:

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
- 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
- If you are pregnant or breast feeding

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.

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
- Diabetes
- Glaucoma (high pressure in the eyes)
- Pheochromocytoma (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

Ask your pharmacist or doctor about taking Coldrex syrup or tablets if you are pregnant or plan to become pregnant, or breast feeding. Your pharmacist or doctor will discuss the potential benefits and risks of taking the medicine if you are breast feeding.

Some medicines and Coldrex syrup & tablets may interfere with each other. These include:

- Warfarin, a medicine used to prevent blood clots or similar medicines used to thin the blood
- Metoclopramide, a medicine used to control nausea and vomiting
- Phenytoin, a medicine used to treat epilepsy (fits)
- Chloramphenicol, an antibiotic used to treat ear and eye infections
- Medicines used to treat depression (e.g. a selective serotonin reuptake inhibitor (SSRI) such as fluoxetine, or tricyclic antidepressant (such as amitriptyline, clomipramine or imipramine)
- 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
- Opioid analgesics, medicines used to treat pain
- Sedatives
- Alcohol

- Medicines used to treat:
 - Heart conditions
 - High blood pressure
 - Urinary tract infections and bladder problems
 - Behavioural disorders
 - Congestion

- Appetite suppressants

These medicines may be affected by Coldrex syrup & tablet 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.

SIDE EFFECTS

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.

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.

Please see your doctor if your symptoms do not improve, or if you develop a high temperature, skin rash or persistent headache.

DOSAGE

FOR COLDREX SYSUP:

Adults: 2 tablespoons 4 to 6 hourly, but not more than 8 tablespoons within 24 hours.

Children: 6 – 12 years: 1 to 1 - 1/2 teaspoons 4 to 6 hourly, but not more than 9 teaspoons within 24 hours.

2 – 5 years: 1 teaspoons 4 to 6 hourly, but not more than 4 teaspoons within 24 hours or as directed by the physician.

For children under 2 years of age consult your physician.

FOR COLDREX TABLET:

Adults: Two tablets every 4 to 6 hours. Maximum eight tablets within 24 hours

Children: 6-12 years: One tablet every 4 to 6 hours. Maximum 4 tablets within 24 hours or as directed by the physician

STORAGE

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



Manufactured by:
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