

Information for the User COLDREX TABLETS

What should you know about Coldrex Tablets

Please read this leaflet carefully before you take Colrex Tablets, especially the section headed “check before you take this medicine”. This leaflet provides information available on your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

What is in the pack

This pack contains 12 or 24 tablets in a blister strip enclosed in an outer box.

What is in Coldrex Tablets?

Each tablet contains Paracetamol 500mg, Caffeine 25mg, Phenylephrine Hydrochloride 5mg, Terpin Hydrate 20mg and Vitamin C (ascorbic Acid) as the active ingredients.

The tablets also contain soluble starch, maize starch, talc, stearic acid, polyvinyl pyrrolidone, potassium sorbate, sodium lauryl sulphate and colour sunset yellow (E110).

Who makes Coldrex Tablets

The product licence holder is Omega Pharma Ltd, 32 Vauxhall Bridge Road, London, SW1V 2SA, UK and all enquiries should be sent to this address.

The manufacturer is GlaxoSmithKline Dungarvan Ltd., Knockbrack, Co. Waterford, Ireland.

How do Coldrex Tablets work?

Coldrex tablets contain paracetamol is an analgesic (a pain killer) and antipyretic (it reduces body temperature when you have a fever). Phenylephrine hydrochloride is a decongestant which unblocks your nose and sinuses helping you breathe more easily without causing drowsiness. Caffeine is present as a mild stimulant and terpin hydrate as an expectorant. Ascorbic acid (Vitamin C) is a common ingredient of flu and cold products and is included to help replace the vitamin C which may be lost in the initial stages of flu and colds.

What are Coldrex Tablets for?

Coldrex Tablets are recommended for the relief of the symptoms of influenza (flu) and colds.

Check before you take this medicine

IMPORTANT:

- **Do not take with any other Paracetamol-containing products. Do not take with any other flu, cold or decongestant products.**
- **Avoid drinking too much coffee or tea when taking these tablets.**
- **Do not take more than the recommended dose.**

Do not take Coldrex Tablets if:

- you are allergic to paracetamol, phenylephrine hydrochloride, caffeine, terpin hydrate, vitamin C or any of the other ingredients listed above. Colour E110 can cause allergic reactions including asthma: reactions are more common in people who are allergic to aspirin. Potassium sorbate (E202) can cause irritation, including dermatitis.
- you suffer from severe kidney or liver problems, overactive thyroid, diabetes or are under the care of your doctor for high blood pressure or heart disease, angle closure glaucoma or phaeochromocytoma.
- you are taking tricyclic antidepressants (e.g. imipramine or amitriptyline) or drugs for heart problems (including beta-blockers) or you are taking (or have taken within the last two weeks) drugs called monoamine oxidase inhibitors (MAOIs) prescribed by your doctor or hospital for depression.

Take special Care with Coldrex Tablets:

- This product may cause dizziness. If affected, do not drive or operate machinery.

Ask your doctor before you take this medicine:

- if you have blood vessel disease (such as Raynaud's Phenomenon).
- if you have an enlarged prostate.

If you are taking other medicines:

Talk to your doctor or pharmacist before taking Coldrex Tablets if you are taking any prescribed medicines particularly metoclopramide or domperidone (for nausea [feeling sick] or vomiting [being sick] or colestyramine (to lower blood cholesterol) or drugs to lower blood pressure; appetite suppressants or stimulants; ergot alkaloids (e.g. ergotamine or methylsergide); drugs to treat depression such as tricyclic antidepressants (e.g. amitriptyline) or heart disease (e.g. digoxin); if you take blood thinning drugs (anticoagulants e.g. warfarin) and you need to take a pain reliever on a daily basis talk to your doctor because of the risk of bleeding. But you can still take occasional doses of Coldrex Tablets at the same time as anticoagulants.

If you are pregnant or breast feeding:

Do not take Coldrex Tablets if you are pregnant.

This product should not be used while breast-feeding unless advised by a doctor.

How should you take Coldrex Tablets?***Adults and children aged 12 years and over:***

1-2 tablets can be taken up to 4 times a day.

Do not exceed 8 tablets in 24 hours.

These doses should not be repeated more frequently than every four hours.

Do not take continuously for more than 7 days without medical advice.

Do not give to children under 12 years.

If symptoms persist consult your doctor.**What should you do if you take too much?**

Taking Coldrex Tablets than recommended on the pack or in this leaflet may be harmful. Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.

What side effects can Coldrex Tablets have?

Like all medicines, Coldrex Tablets can have side effects but not everybody gets them.

Stop taking this medicine and tell your doctor immediately if you experience:

- Allergic reactions which may be severe such as skin rash and itching sometimes with swelling of the mouth or face or shortness of breath.
- Skin rash or peeling or mouth ulcers.
- Breathing problems. These are more likely if you have experienced them before when taking other painkillers such as ibuprofen and aspirin.
- Unexplained bruising or bleeding.
- Nausea, sudden weight loss, loss of appetite and yellowing of the eyes and skin.
- Nervousness, irritability, restlessness and excitability.
- Headache, dizziness or insomnia.
- Raised blood pressure or an usually fast pulse rate or a sensation of an unusually fast or irregular heartbeat.
- Nausea, diarrhoea or sickness.
- Unexplained bruising or bleeding.

These reactions are rare. If you do get any side effects, even those not mentioned in this leaflet, tell your doctor or pharmacist.

Further information

Store in a dry place.

Do not use this medicine after the “Use by” date shown on the pack.

Keep out of the reach and sight of children.

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Omega Pharma (Logo)

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Coldrex is a registered trade mark.