

PACKAGE LEAFLET: INFORMATION FOR THE USER

Coldrex MaxGrip Lemon

Powder for oral solution

PARACETAMOL, PHENYLEPHRINE, ASCORBIC ACID

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

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1. WHAT COLDREX MAXGRIP LEMON IS AND WHAT IT IS USED FOR

Coldrex MaxGrip Lemon is for the short term relief of the symptoms of influenza (flu), colds and chills. These symptoms include headache, feverishness, aches and pains, congested or blocked nose, painful sinuses and sore throat pain.

Coldrex Max Grip Lemon contains a combination of three active substances: paracetamol, phenylephrine hydrochloride and ascorbate acid (vitamin C):

- Paracetamol is an analgesic (a pain killer) and antipyretic (it reduces body temperature when you have a fever).
- Phenylephrine hydrochloride is a sympathomimetic decongestant which unblocks your nose and sinuses helping you breathe more easily.
- Ascorbic acid (vitamin C), which is a usual part of the preparations against flu. It supplements C vitamin, which the body often misses at the early stage of flu and cold.

2. BEFORE YOU TAKE COLDREX MAXGRIP LEMON

Do not take COLDREX MAXGRIP LEMON if

- you are allergic to paracetamol, ascorbic acid, phenylephrine hydrochloride or any of the other ingredients listed above. The lemon flavors contain trace amounts of soya oil, which may rarely cause severe allergic reactions
- you have kidney or liver disease including alcoholic liver disease, overactive thyroid, diabetes or are under the care of your doctor for high blood pressure or heart disease
- you are taking tricyclic antidepressants (eg. imipramine or amitriptyline) or medicines for heart problems (including beta-blockers) or you are taking (or have taken within the last two weeks) medicines called monoamine oxidase inhibitors (MAOIs) prescribed by your doctor or hospital for depression
- you have glaucoma or phaeochromocytoma
- if you are under 12 years of age
- if you are in the last trimester of pregnancy

Take special care with COLDREX MAXGRIP LEMON, so you must tell the doctor if you

- If you have problems with your liver or kidneys
- if you suffer from heart disease or vascular disease such as Raynaud's phenomenon (which may be manifested by pain in the fingers and toes in response to cold or stress, if you suffer from the problem of enlarged prostate or difficulty urinating)
- If you are pregnant, trying to become pregnant or breast-feeding
- If you are on a diet impoverished in sodium; one sachet contains 0.12 g of sodium,
- If you have diabetes. Each dose contains 4 g of sucrose.
- If you are taking other medicines (see Other medicines and Coldrex MaxGrip Lemon)

Children

It should not be given to children under 12 years of age, except upon the recommendation of a doctor.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Do not take Coldrex MaxGrip Lemon:

- With any other medicines contain paracetamol, a decongestant, or a combination of active ingredients for the suppression of cough and colds
- If you are taking or have within the last two weeks taken medicines called monoamine oxidase inhibitors (MAOIs), and the doctor has prescribed them for the treatment of depression.
- medicines to control blood pressure such as beta-blockers
- medicines to treat depression such as tricyclic antidepressants, eg. Amitriptyline

Contact your doctor or pharmacist for advice before taking this medicine if you are taking any of the following:

- A blood thinner such as warfarin. If every day you need to take medication to ease the pain, consult your doctor because there is a risk of bleeding.
- Digoxin or similar medicines for heart disease
- medicines to decrease or increase the appetite
- Ergot alkaloids such as ergotamine or metilsergid (used to treat migraine)
- medicines to treat depression such as tricyclic antidepressants (eg, amitriptyline)
- Metoclopramide and domperidone (used against nausea and vomiting)
- Cholestyramine (used to lower blood cholesterol)
- Zidovudine (a medicine used for the treatment of AIDS and HIV infection)

- medicines to treat epilepsy (eg, carbamazepine, phenytoin, phenobarbital)
- Probenecid (for gout)

Taking food and drink with COLDREX MAXGRIP LEMON tablets

While using COLDREX MAXGRIP LEMON tablets do not drink alcohol. Concomitant consumption of alcohol can lead to liver damage.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Do not take COLDREX MAXGRIP LEMON if you are pregnant or breast feeding unless advised by a doctor.

Driving and using machines

This medicine may cause dizziness. If that happens, do not drive or use machines.

Other warnings

- Coldrex MaxGrip Lemon contains 4 g of sucrose per dose. If you have been told by your doctor that you have a disease called intolerance to some sugars, before you start taking this medicine, consult your doctor.
- It contains 117 mg of sodium per dose. That should be taken into account in patients on controlled sodium diet.

3. HOW TO TAKE COLDREX MAXGRIP LEMON

Take COLDREX MAXGRIP LEMON tablets exactly as directed in this leaflet. Please check with your doctor or pharmacist if you are not sure.

For oral administration.

Empty contents of one sachet into a mug. Half fill with very hot water. Stir well. Add cold water as necessary and sugar if desired.

Adults (including the elderly) and children aged 12 years and over:

The contents of one sachet to be taken every four to six hours as necessary. Do not take more than 4 sachets in any 24 hours.

Do not give to children under 12 years of age unless your doctor tells you to.

Do not take for more than 7 days (adults) and 3 days (children) without asking your doctor. If symptoms persist consult your doctor.

Patients with impaired liver or kidney function

Seek medical advice because of dose adjustments before taking this medicine. Once you assessed your medical condition, your doctor may recommend taking a lower dose of the medicine or increasing the spaces between the administrations of the medicine.

The recommended dose should not be exceeded.

If you take more COLDREX MAXGRIP LEMON than you should

It will be harmful to take more than the doses stated on the pack and in this leaflet. 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.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, COLDREX MAXGRIP LEMON can cause side effects, although 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.
- Visual disturbances. This is rare but is more likely in those with glaucoma.
- Usually fast pulse rate or a sensation of an unusually fast or irregular heartbeat
- Difficulty passing water. This is more likely to occur in men with an enlarged prostate gland.

These reactions are rare.

The following side effects may occur. Tell your doctor if you get them:

- Raised blood pressure, headache, dizziness, difficulty sleeping, nervousness, diarrhea or sickness.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE COLDREX MAXGRIP LEMON

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use COLDREX MAXGRIP LEMON after the expiry date which is stated on the label.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What COLDREX MAXGRIP LEMON contains

1 bag with 6.4 g of powder for oral solution containing 1000 mg of paracetamol, 10 mg of phenylephrine hydrochloride and 40 mg of ascorbate acid

- The other ingredients are sucrose; sodium citrate; Citric acid, anhydrous; corn starch; sodium cyclamate; saharinnatrij; silica, colloidal anhydrous; lemon flavor and curcumin, color (E100).

What COLDREX MAXGRIP LEMON looks like and contents of the pack

Coldrex Max Grip Lemon 5 or 10 bags with 6.4 g of powder in a box.

Regime of dispensing

The medicine is issued without a doctor's prescription.

Manufacturer

SmithKline Beecham SA
Avda. de Alvira Km 2500

28806 Alcala de Henares
Madrid, Spain