



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

RONFIT COLD EXTRA

(Paracetamol, Phenylephrine, Caffeine with Chlorphenamine Tablets)

Read all of this leaflet carefully before you start RONFIT COLD EXTRA using

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

In this leaflet:

1. What RONFIT COLD EXTRA is and what it is used for
2. Before you take RONFIT COLD EXTRA
3. How to take RONFIT COLD EXTRA
4. Possible side effects
5. How to store RONFIT COLD EXTRA
6. Further information

1. WHAT RONFIT COLD EXTRA AND WHAT IT IS USED FOR

Mechanism of Action:

Pharmacotherapeutic Group: Other analgesics and antipyretics & Other cold combination preparations

ATC code: N02BE51

PARACETAMOL

Analgesic:

The mechanism of analgesic action has not been fully determined. Paracetamol may act predominantly by inhibiting a prostaglandin synthesis in the central nervous system (CNS) and to a lesser extent through a peripheral action by blocking pain-impulse generation. The peripheral action may also be due to inhibition of prostaglandin synthesis or to inhibition of the synthesis or actions of other substances that sensitise pain receptors to mechanical or chemical stimulation.

Antipyretic:

Paracetamol probably produces antipyresis by acting on the hypothalamic heat-regulating centre to produce peripheral vasodilation resulting in increased blood flow through the skin, sweating and heat loss. The central action probably involves inhibition of prostaglandin synthesis in the hypothalamus.





CAFFEINE

Central nervous system stimulant – Caffeine stimulates all levels of the CNS, although its cortical effects are milder and of shorter duration than those of amfetamines.

Analgesia Adjunct:

Caffeine constricts cerebral vasculature with an accompanying decrease in cerebral blood flow and in the oxygen tension of the brain. It is believed that caffeine helps to relieve headache by providing a more rapid onset of action and/or enhanced pain relief with lower doses of analgesic. Recent studies with ergotamine indicate that the enhancement of effect by the addition of caffeine may also be due to improved gastrointestinal absorption of ergotamine when administered with caffeine.

PHENYLEPHRINE HYDROCHLORIDE

Sympathomimetic amines, such as phenylephrine, act on alpha-adrenergic receptors of the respiratory tract to produce vasoconstriction, which temporarily reduces the swelling associated with inflammation of the mucous membranes lining the nasal and sinus passages. This allows the free drainage of the sinusoidal fluid from the sinuses.

In addition to reducing mucosal lining swelling, decongestants also suppress the production of mucus, therefore preventing a buildup of fluid within the cavities which could otherwise lead to pressure and pain.

Chlorpheniramine in provides prompt relief of itchy watery eyes, runny nose, sneezing, itching of the nose or throat due to respiratory allergies.

2. BEFORE YOU TAKE RONFIT COLD EXTRA

Care is advised in the administration of paracetamol to patients with severe renal or severe hepatic impairment. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease.

Use with caution in patients with Raynaud's phenomenon and diabetes mellitus.

The following warnings will appear on the pack:-

CONTAINS PARACETAMOL

- If symptoms persist consult your doctor.
- Do not exceed the stated dose.
- Keep all medicines out of the reach and sight of children.
- Do not take with any other paracetamol-containing products.

The Label shall say:

Immediate medical advice should be sought in the event of an overdose, even if you feel well.

The Leaflet shall say:

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.

If you are pregnant or being prescribed medicine by your doctor, seek your doctor's advice before taking this product.





3. HOW TO TAKE YOUR MEDICINE

Posology:

Adults and children 12 years of age and over

1 tablet twice or thrice daily. Or as directed by the physician.

Method of Administration:

Oral administration

4. POSSIBLE SIDE EFFECTS

Adverse effects of paracetamol are rare but hypersensitivity including skin rash may occur.

There have been reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these were not necessarily causally related to paracetamol.

Nausea and insomnia have been noted.

Phenylephrine hydrochloride may elevate blood pressure with headache, vomiting and rarely palpitations; tachycardia or reflex bradycardia; tingling and coolness of the skin. There have been rare reports of allergic reactions.

5. HOW TO STORE RONFIT COLD EXTRA

Store in a dry place below 30°C. Protect from light, heat & moisture.

KEEP MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.

6. FURTHER INFORMATION

What RONFIT COLD EXTRA contains:

- The active pharmaceutical ingredient(s) are

Paracetamol

Phenylephrine HCL

Chlorphenamine Maleate

Caffeine

- The other ingredient(s) are

Microcrystalline Cellulose

Maize Starch

Povidone

Sodium Methyl paraben

Sodium Propyl paraben

Purified Water

Magnesium Stearate

Sodium Starch Glycolate





What RONFIT COLD EXTRA looks like and contents of the pack: White colour round shape uncoated tablet, having break line on one side and plain on other side.

1 X 4 Tablets are packed in a blister & such 48 blister are placed in a carton with pack insert.

Manufacturer

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