



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

RONFIT COLD-D

(Dextromethorphan Hydrobromide, Phenylephrine Hydrochloride, Cetirizine Hydrochloride & Racementhol Syrup)

Read all of this leaflet carefully before you start RONFIT COLD-D 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-D is and what it is used for
2. Before you take RONFIT COLD-D
3. How to take RONFIT COLD-D
4. Possible side effects
5. How to store RONFIT COLD-D
6. Further information

1. WHAT RONFIT COLD-D AND WHAT IT IS USED FOR

RONFIT COLD-D is a medicine which is used to help relieve dry, irritating coughs. The liquid contains dextromethorphan hydrobromide which is an antitussive to help stop persistent coughing. The medicine is for use in adults and children aged 12 years and over.

2. BEFORE YOU TAKE RONFIT COLD-D

This medicine is suitable for most people but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist. Taking this medicine regularly, particularly for a long time, can lead to addiction. Only use this medicine as described in the leaflet.

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Speak to your doctor if you experience withdrawal symptoms.

Do not use this medicine...

- If you have ever had a bad reaction to dextromethorphan or any of the other ingredients of this medicine (listed in section 6).
- If you suffer from lung disease.





- If you are taking, or have taken in the last two weeks, drugs for depression known as Monoamine Oxidase Inhibitors (MAOIs).

- If you are taking selective serotonin re-uptake inhibitors (used to treat depression and anxiety such as fluoxetine, paroxetine and sertraline).

- For children under 12 years old.

If any of these apply to you, get advice from a doctor or pharmacist without using RONFIT COLD-D.

Talk to your doctor or pharmacist...

- If you suffer from liver problems.

- If you have chronic bronchitis, emphysema or asthma or have had a cough for a few weeks or a cough with a lot of mucus (phlegm).

- If you are taking any other cough and cold medicines.

- If your child is prone to developing certain allergic reactions (e.g. atopic reactions). If you are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.

- If you have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.

- If you have been told by your doctor that you are a slow metabolizer of CYP2D6.

- If you are taking medicines such as certain antidepressants or antipsychotics this medicine may interact with these medicines and you may experience mental status changes (e.g. agitation, hallucinations, coma), and other effects such as body temperature above 38°C, increase in heart rate, unstable blood pressure, and exaggeration of reflexes, muscular rigidity, lack of coordination and/or gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea).

- If you are taking any other medicines, including:

- Certain drugs for depression such as norepinephrine-dopamine reuptake inhibitors (NDRI), which include bupropion.

- Antipsychotics (drugs used to treat mood disorders such as haloperidol, thioridazine, perphenazine).

- Anti-arrhythmic agents (drugs used to treat irregular heart beats such as amiodarone, propafenone, quinidine and flecainide).

- Calcimimetic agents (drugs used to treat secondary hyperparathyroidism, elevated parathyroid hormone levels such as cinacalcet).

- Anti fungals (terbinafine).

- Opioid analgesics (drugs used to relieve pain e.g. codeine, tramadol, morphine, methadone).

3. HOW TO TAKE YOUR MEDICINE

Check the table that follows to see how much medicine to take.

- For oral use only.

- Do not take more medicine than the label tells you to. i Children under 12 years Do not give to children under 12 years old. i Adults and children aged 12 years and over

Age Dose Adults and children aged 12 years and over Take two 5 ml spoonfuls four times a day

DEXTROMETHORPHAN HYDROBROMIDE, PHENYLEPHRINE HYDROCHLORIDE, CETIRIZINE HYDROCHLORIDE & RACEMENTHOL SYRUP





- Do not take more than 4 doses in 24 hours.
- If symptoms persist or worsen, talk to your doctor or pharmacist.

If anyone has too much

If anyone has too much contact a doctor or your nearest Accident and Emergency Department (Casualty) taking this leaflet and pack with you. If you take more of this medicine than you should, you may experience the following symptoms: nausea and vomiting, involuntary muscle contractions, agitation, confusion, somnolence, disturbances in consciousness, involuntary and rapid eye movements, cardiac disorders (rapid heart beating), coordination disorders, psychosis with visual hallucinations, and hyperexcitability. Other symptoms in case of massive overdose may be: coma, severe breathing problems, and convulsions. Contact your doctor or hospital straight away if you experience any of the above symptoms.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side-effects, although not everybody gets them. If you experience any of the following stop using this medicine and seek immediate medical help:

- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.
- Fits If you experience any of the following stop using the medicine and talk to your doctor:
- Itching, rash, hives. Other effects which may occur but it is not known how often, include:
- Dependence and addiction (see section “How do I know if I am addicted?”)
- Dizziness or drowsiness.
- Nausea, vomiting or diarrhoea.
- Upset stomach or stomach pain.
- Difficulty sleeping or feeling agitated, jittery, restless or confused.
- Shallow breathing.

5. HOW TO STORE RONFIT COLD-D

Do not store above 30°C.

Keep this medicine out of the sight and reach of children.

6. FURTHER INFORMATION

What RONFIT COLD-D contains:

The active pharmaceutical ingredient(s) are Dextromethorphan Hydrobromide, Phenylephrine Hydrochloride, Cetirizine Hydrochloride & Racementhol.

- The other ingredient(s) are
 - Sodium Methyl Paraben
 - Sodium Propyl Paraben
 - Sorbic acid
 - Enisweet EP Powder
 - Sucrose





Propylene glycol
Sodium Saccharin
Sodium Citrate
Citric acid
Colour Ponceau 4R
Pineapple M-452 Flavour
Purified Water

What RONFIT COLD-D looks like and contents of the pack: Red coloured, clear syrupy liquid with characteristic flavour.

100 ml Amber colour round pet bottle in a mono carton with pack Insert.

Manufacturer

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