



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

RONADREX

(Paracetamol, Diclofenac Sodium and Caffeine Tablets)

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

1. WHAT RONADREX IS AND WHAT IT IS USED FOR

Paracetamol, Diclofenac Sodium & Caffeine tablets combination medicine which helps in the treatment of painful rheumatic disorders such as rheumatoid arthritis, osteoarthritis, ankylosing spondylitis and acute gout.

RONADREX is indicated for:

RONADREX is indicated in the treatment of painful rheumatic disorders such as rheumatoid arthritis, osteoarthritis, ankylosing spondylitis and acute gout. Acute musculoskeletal disorders and soft tissue inflammation such as peri-arthritis, sprains, strains, tenosynovitis, bursitis, pain in fractures and dislocation. Relief of pain and inflammation associated with orthopedic, dental, gynecological and other minor surgical procedures.

2. BEFORE YOU TAKE RONADREX

Do not take RONADREX

If you are having hypersensitivity to Paracetamol, Diclofenac sodium, Caffeine or any allergic reaction to excipients used in manufacturing of RONADREX Tablets.

Take special care with RONADREX

This medicine should not be used by people who have been diagnosed with hypertension or who are receiving antihypertensive medication, or who have a history of cardiac arrhythmia.



This medicine should not be used by patients recovering from chronic alcoholism who are taking disulfiram.

Taking other medicines

This medicine should not be used if antidepressants (including lithium carbonate), anxiolytics (including clozapine) and sedatives are being used, or by persons with anxiety disorders.

This medicine should not be used by any persons who are also taking ephedrine.

NSAID's should not be administered to patients with a history of, or active peptic ulceration. NSAIDs are contraindicated in patients who have previously shown hypersensitivity reactions (e.g., asthma, rhinitis or urticaria) in response to ibuprofen, aspirin or other non-steroidal anti-inflammatory drugs.

Pregnancy and breast-feeding

Epidemiological studies in human pregnancy have shown no ill effects due to paracetamol used in the recommended dosage, but patients should follow the advice of their doctor regarding its use.

Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data do not contraindicate breast feeding.

Diclofenac sodium should be used in pregnancy only if the benefits outweigh the risk, when the lowest effective dose should be employed. Use of prostaglandin synthetase inhibitors may result in premature closure of the foetal ductus arteriosus or uterine inertia and therefore are not recommended during the last trimester of pregnancy.

Congenital abnormalities have been reported in association with NSAID administration in man; however, these are low in frequency and do not appear to follow any discernible pattern.

Traces have been detected in breast milk but the level is so low as to be thought not to affect the infant.

Caffeine appears in breast milk. Irritability and poor sleeping pattern in the infant have been reported.

Driving and using machines

Must not drive vehicles when taken RONADREX.

3. HOW TO TAKE RONADREX

Always take RONADREX exactly as your health care provider has told you. You should check with your health care provider if you are not sure. The usual dose is as per follows:

Adults, the elderly and children over 12 years of age:

1 Tablet two or three times daily.



Not recommended for children under 12 years of age.

Method of Administration:

Oral administration

If you forget to take RONADREX

Pls do not take a double dose to make up for a forgotten tablet

If you stop taking RONADREX

If you have any further questions on the use of this product, ask your health care provider.

4. POSSIBLE SIDE EFFECTS

Adverse effects of Diclofenac are Gastro-intestinal disorders (rarely with bleeding) and lower intestinal disorders, in some cases with exacerbation of existing conditions such as ulcerative colitis, may occur. These include nausea, vomiting, diarrhoea, dyspepsia, abdominal pain, melaena, haematemesis and gastrointestinal haemorrhage. Less frequently, gastritis, duodenal ulcer, gastric ulcer and gastrointestinal perforation have been observed. Pancreatitis, aphthous stomatitis, glossitis and constipation may occur.

Occasionally there are effects on the CNS such as headaches, dizziness, vertigo, drowsiness, disturbance of taste, vision, hearing and sensation. There may be malaise, fatigue, insomnia, confusion, anxiety or depression, tremor or psychotic reactions.

Skin reactions, including loss of hair and photosensitivity reactions occur occasionally.

5. HOW TO STORE RONADREX

Keep out of the reach and sight of children.

Do not store above 30°C, Store in the original carton. Protect from light, heat and moisture.

Do not use RONADREX after the expiry date which is stated on the blister & carton.

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 RONADREX contains:

- The active pharmaceutical ingredient(s) are Paracetamol., Doclofenac Sodium & Caffeine.
- The other ingredient(s) are Maize starch, Dibasic calcium phosphate, Gelatin, Sodium methyl paraben, Purified water, Magnesium stearate, Purified talc, Sodium starch glycollate, Aerosil, PVP K-30, Colour Ponceau 4R.

What RONADREX looks like and contents of the pack: White and red colored round shaped uncoated Bi-layer tablets, on one side and plain and break line on other side.

10 Tablets are packed in a ALU-PVC blister such 2 blisters are placed in a carton with package insert. And Such 10 monocarton are placed in outer carton 10 x 02 x 10 Tablets.



Manufacturer

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