



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

RONFIT EFFER

(Paracetamol, Diclofenac & Caffeine Effervescent Tablets)

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

1. WHAT RONFIT EFFER AND WHAT IT IS USED FOR

2. RONFIT EFFER 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.

3. BEFORE YOU TAKE RONFIT EFFER

- 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
- 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.
- 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.
- Caution is required if administered to patients suffering from, or with a previous history of, bronchial asthma since NSAIDs have been reported to cause bronchospasm in such patients.
- NSAIDs should only be given with care to patients with a history of gastrointestinal disease.





- Undesirable effects may be minimised by using the minimum effective dose for the shortest possible duration.
- Side effects are generally more serious in the elderly and if serious, diclofenac sodium should be withdrawn.
- Patients on long term treatment should be monitored and patients with severe hepatic, cardiac or renal insufficiency should be kept under close surveillance as the use of NSAIDs may result in deterioration of renal function. Patients with impaired cardiac or renal function or recovering from major surgery or being treated with diuretics should be considered because of the importance of prostaglandins in maintaining blood flow. The dose should be kept as low as possible and renal function should be monitored in these patients.
- NSAIDs should be given with care to patients with a history of heart failure or hypertension since oedema has been reported in association with NSAID administration.

4. HOW TO TAKE YOUR MEDICINE

Posology:

Paracetamol, Diclofenac & Caffeine Soluble Tablets should be dissolved in at least half a tumbler of water.

Dosage

Adults

One to two tablets dissolved in water not more frequently than every 4-6 hours when necessary to a maximum of 8 tablets in 24 hours.

Elderly

Same as adult dose. A reduced dose may be required

Paediatric population:

Children aged 16-18 years:

One to two tablets dissolved in water every 4-6 hours when necessary to a maximum of 8 tablets in 24 hours.

Children aged 12-15 years:

One tablet dissolved in water every 6 hours when necessary to a maximum of 4 tablets in 24 hours.

Children aged less than 12 years:

Not recommended for children under 12 years.

Method of Administration:

Oral administration





5. 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.

6. HOW TO STORE RONFIT EFFER

Store below 30°C. Protected from light & moisture.

Keep away from Children.

7. FURTHER INFORMATION

What RONFIT EFFER contains:

- The active pharmaceutical ingredient(s) are Paracetamol BP, Diclofenac sodium BP, Caffeine BP. The other ingredient(s) are Citric acid, Sodium bicarbonate, PVP K-30, Sodium Saccharine, PVP K-30, Purified water, Simethicone, Isopropyl alcohol, Orange flavour, Sucralose, Sodium Carbonate & Sodium benzoate.

What RONFIT EFFER looks like and contents of the pack:

White to off-white colour, round flat faced beveled edge tablets with orange odour.

4 Tablets are packed in a ALU-PVC Strip such a 3 strip is placed in a carton with package insert.

(3 x 4 tablets Alu-Alu strip).

Manufacturer

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