PAROL®

paracetamol

THE ALL-ROUNDER FOR PAIN AND FEVER

THERAPEUTIC INDICATIONS adults and children	
As analgesic	**As antipyretic and analgesic**
Headache Toothache / Outbreak of the teeth Dysmenorrhea Migraine Myalgia Neuralgia Musculoskeletal pain Posttraumatic pain Postoperative pain	Coryza Influenza Colds Acute pharyngitis Sinusitis Otitis Other acute febrile illnesses

POSOLOGY		
Children 1 - 5 years old	**Children 6 - 12 years old**	**Adults**
125 - 250 mg every 4 to 6 hours	250 - 500 mg every 4 to 6 hours	500 - 1000 mg every 4 to 6 hours
max 1g / 24 h		max 4g/ 24 h

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3FIPARE 2022

Dafra PHARMA

Setting the Standard
www.dafrapharma.com

PAROL®

paracetamol

EUROPEAN GMP

THE ALL-ROUNDER FOR PAIN AND FEVER

Adults: 30 tablets 500 mg
Children: Syrup 250 mg / 5 ml

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paracetamol

ADVANTAGES AND KEY POINTS

- **PAROL®** is an effective analgesic and antipyretic substance.
- **PAROL®** is at your disposal:
  - In two oral galenic formulations: tablets and paediatric syrup
  - In packs of 30 tablets or bottles of 100ml
- The paediatric syrup of **PAROL®** has a very appealing strawberry taste, specifically developed in order to increase therapy compliance.
- **PAROL®** has an excellent tolerability profile at therapeutic dosages*.
- **PAROL®**, in contrast to the NSAID's, presents the advantage of not being associated with gastric bleeding*.
- **PAROL®**: the all-rounder for pain and fever with the inherent quality of Dafra: European fabrication according to European GMP standards.

(*) Prescribing information **PAROL®** - Dafra Pharma (2008)

CONTRAINDICATIONS

PAROL® is contraindicated in patients with a known hypersensitivity to paracetamol, advanced liver disease (Child-Pugh class C) and severe chronic alcoholism.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

when not to take **PAROL®**:

Conditions affecting its use, especially: allergies to paracetamol or acetyl salicylic acid, liver or kidney disorders, chronic disorders related to liver, lungs, heart or kidneys, hematologic disorder caused by the deficiency of Glucose-6-phos-phate dehydrogenise (G6PD), alcohol dependency, the usage of any medicine including paracetamol.

If the patient has had any allergic reaction to any of active or inactive ingredients of **PAROL®**.

INTERACTIONS WITH OTHER MEDICINAL PRODUCTS

Please inform your doctor or pharmacist if you are taking or have recently taken other medicines, even those not prescribed. Also inform your physician about the currently used medicines before giving blood or urine samples and any surgery or dental treatment which requires anesthesia. In patients receiving coumarin or indandione type oral anticoagulants, chronic high-dose administration of paracetamol may result bleeding problems. Adjustment of anticoagulant dosage based on prothrombin time determinations may be necessary. Risk of totixicity related to liver may be increased in alcohol dependent patients and in patients receiving hepatoxic mediciation. Hepatic enzyme inducers (barbiturates, primidone) may decrease clinical effeciency of paracetamol by increasing its metabolism.

FERTILITY, PREGNANCY AND LACTATION

If you are pregnant or likely to become pregnant, ask your doctor or pharmacist for advice before taking any medicine. **Pregnancy**: there has not been reported any harmful effect related to the usage of **PAROL®** during pregnancy. **Lactation**: Paracetamol passes into human milk. Please consult your doctor before use this medication. A decision should be taken by your doctor whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

EFFECTS ON ABILITY TO DRIVE AND USE OTHER MACHINES

PAROL® at the recommended dose levels is not expected to affect skill and alertness required for driving and operating machinery.

UNDESIRABLE EFFECTS

The following rare side effects are reported while the usage of **PAROL®**: Allergic reactions: Itching, skin rashes and eruptions. If you are allergic to acetylsalicylic acid, you might be allergic to paracetamol too. Excessive sensitivity: swellings on face, tongue or throat, anaphylactic reactions. Nausea, disgorgement, diarrhea, pains in stomach, perspiration, exhaustion (these symptoms point out the high amounts of paracetamol usage). Pain in kidneys, reduction

on the amount of urine, cloudy urine, urine containing blood or protein, the increase of urea levels in blood (these symptoms are seen in the patients having acetylsalicylic acid or paracetamol for a long time in high doses). Reduction of white blood cells (leucopenia, agranulocytosis) and trombocytes, bleeding problems.

OVERDOSE

The consequences of overdose can be extremely serious. Symptoms of paracetamol overdose in the first 24 hours are pallor, nausea, vomiting, anorexia, and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Cardiac arrhythmias have been reported. Symptoms during the first 2 days of acute poisoning do not reflect the potential seriousness of the overdose. Nausea, vomiting, anorexia and abdominal pain may persist for a week or more. Abdominal pain may be the first indication of liver damage. Liver injury may become manifest on the second day (or later), initially by elevation of serum transaminase and lactic dehydrogenase activity, increased serum bilirubin concentration and prolongation of prothrombin time. The liver damage may progress to encephalopathy, coma and death. Cerebral oedema and nonspecific myocardial depression have also occurred. In the event of overdose consult a doctor or take the patient to the nearest hospital immediately. Specialised treatment is essential as soon as possible. Prompt treatment is essential. Any patient who has ingested about 7,5 g or more of paracetamol in the preceding 4 hours should undergo gastric lavage or emesis This is followed by the administration of activated charcoal slurry which should be removed prior to the administration of acetylcystein solution. Specific therapy with an antidote such as acetylcysteine or methionine may be necessary. If decided upon, acetylcysteine should be administered IV as soon as possible, preferably within 8 hours of overdose.

Acetylcysteine treatment should be started immediately without waiting for the results of the determination of paracetamol concentrations in blood. Acetylcysteine is administered at an initial dose of 140 mg/kg followed by 70 mg/kg every 4 hours for a total 17 doses. Each dose should be diluted to 5 % concentration with a suitable drink. Plasma paracetamol concentrations should be determined starting from the 4th hour after ingestion of the drug. If determinations are done earlier than 4th hour they are not useful for the prediction of hepatotoxicity. Concentrations above the values presented below indicate potential hepatotoxicity and call for the completion of the whole course of acetylcystein treatment.

4th hour	6th hour	10th hour
150mcg/ml	70 mcg/ml	50 mcg/ml
15th hour	**20th hour**	**24th hour**
20 mcg/ml	8 mcg/ml	3.5 mcg/ml

If acetylcysteine treatment could not be started within 24 hours or if paracetamol is ingested in excessive amounts, removal of the drug from the blood by hemodialysis or hemoperfusion should be considered.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Paracetamol is an effective analgesic and antipyretic substance without significant anti-inflammatory activity. Its analgesic action is considered to be due to the inhibition of prostaglandin synthesis in the central and peripheral nervous system. Paracetamol decreases sensitivity of nerve endings involved in pain reception by elevating pain threshold. Antipyretic action results from the inhibition of prostaglandin E2 synthesis and preventing the stimulation of thermoregulatory center in the anterior hypothalamus by the PGE2.

Pharmacokinetic properties

Following oral administration paracetamol is absorbed rapidly and almost completely. Absorption is reduced after a high- carbohydrate meal. Its analgesic action starts in 30 minutes following oral administration, reaches a maximum in 1 to 3 hours and lasts 3 to 4 hours. Paracetamol distributes extensively into body tissues and fluids. About 90 % to 95 % of the drug is converted to conjugated metabolites in the liver and excreted in the urine. The half-life of paracetamol is 1 to 4 hours (average 2.7 hours) It passes into human milk and through placenta into fetus. Paracetamol can be removed from the blood by hemodialysis.

STORAGE

Shelf life: 3 years.

Store below 30°C, in the original package. Keep out of reach and sight of children. Shake well before use. Do not use after the expiry date, stated on the packaging (Exp.). The expiry date refers to the last day of that month.

For the complete SMPC, please visit www.dafrapharma.com