



Renova®

Paracetamol BP

Description: Paracetamol (Renova®) is a potent and fast acting antipyretic & mild analgesic together with some anti-inflammatory effects. Paracetamol is the most widely used popular domestic analgesic and antipyretic for adults and children with significantly less side effects at the recommended dose.

Mode of action: Analgesic effects are thought to be related to the inhibition of prostaglandin synthesis and antipyresis through action on the hypothalamic heat-regulating center.

Pharmacokinetics: Paracetamol is rapidly and completely absorbed after oral administration with peak plasma concentration occurring between 15 mins and 2 hrs after ingestion depending on the formulation. Paracetamol is well absorbed following rectal administration but the rate of absorption is slow. The mean half-life is about 2.3 hrs, with a range of 1.5-3.0 hrs. Paracetamol is extensively metabolized in the liver. Some 2-5% of a therapeutic dose of Paracetamol is excreted unchanged in the urine.

Composition: **Renova® 500 mg Tablet:** Each tablet contains 500 mg Paracetamol BP. **Renova® XR Tablet:** Each extended release tablet contains 665 mg Paracetamol BP. **Renova® Syrup:** Each 5 ml contains 120 mg Paracetamol BP. **Renova® Suspension:** Each 5 ml contains 120 mg Paracetamol BP. **Renova® Paediatric drops:** Each ml contains 80 mg Paracetamol BP. **Renova® 60 mg Suppository:** Each suppository contains 60 mg Paracetamol BP. **Renova® 125 mg Suppository:** Each suppository contains 125 mg Paracetamol BP. **Renova® 250 mg Suppository:** Each suppository contains 250 mg Paracetamol BP. **Renova® 500 mg Suppository:** Each suppository contains 500 mg Paracetamol BP.

Indications: Fever, common cold and influenza, headache, toothache, earache, myalgia, dysmenorrhea, neuralgia and sprains, back pain, post-operative pain, post-partum pain, post-vaccination pain and fever of children, rheumatism and osteoarthritic pain.

Dosage & administration:

Dosage form	Age	Dosing
Tablet	Adults	1-2 tablets, every 4-6 hrs to a maximum of 4 gm daily
	Children (6-12 yrs)	1/2 to 1 tablet; dose may be repeated every 4-6 hrs when necessary
XR Tablet	Adults and children over 12 years	2 tablets, swallowed whole, every 8 hours
Suspension & Syrup	Up to 3 months	10 mg/kg body weight (reduce to 5 mg/kg if jaundiced); dose may be repeated every 4-6 hrs when necessary
	3 months to 1 yr	1/2 to 1 teaspoonful; dose may be repeated every 4-6 hrs when necessary
	1 to 5 yrs	1 to 2 teaspoonful; dose may be repeated every 4-6 hrs when necessary
	6 to 12 yrs	2 to 4 teaspoonful; dose may be repeated every 4-6 hrs when necessary
	Adults	4 to 8 teaspoonful; dose may be repeated every 4-6 hrs when necessary
	Do not exceed 4 doses in 24 hrs	
Suppository	Children up to 1 yrs	60 mg as a single dose, repeated once after 6 hrs when necessary
	Children 1 to 5 yrs	125 to 250 mg; dose may be repeated every 6 hrs when necessary
	Children 6 to 12 yrs	250 to 500 mg; dose may be repeated every 6 hrs when necessary
	Adults	500 mg to 1 gm; dose may be repeated every 6 hrs when necessary

Dosage form	Age	Dosing
Paediatric drops	Up to 3 months	40 mg (0.5 ml); dose may be repeated every 4 hrs when necessary
	4 to 11 months	80 mg (1 ml); dose may be repeated every 4 hrs when necessary
	1 to <2 yrs	120 mg (1.5 ml); dose may be repeated every 4 hrs when necessary
	2 to 3 yrs	160 mg (2 ml); dose may be repeated every 4 hrs when necessary
	4 to 5 yrs	240 mg (3 ml); dose may be repeated every 4 hrs when necessary
Do not exceed 4 doses in 24 hrs		

Contraindications: Known sensitivity to Paracetamol.

Side effects: Side effects are rare with nausea, vomiting, anorexia & abdominal pain; but skin rashes and acute pancreatitis are reported after prolonged use; hepatic damage and less frequently renal damage on acute overdose.

Use in pregnancy & lactation: Paracetamol crosses the placenta and appears in the breast milk, but this is widely used in pregnancy and lactation and no foetal adverse effects have been recorded at the recommended doses.

Precautions: Paracetamol should be given with care in patients with impaired renal & hepatic functions and alcohol dependence.

Drug Interactions: Alcohol, barbiturates, anticonvulsants and tricyclic antidepressants may increase hepatotoxicity of Paracetamol, particularly after an overdose. The speed of absorption of Paracetamol may be increased by metoclopramide or domperidone. The anticoagulant effect of warfarine and other coumarins may be enhanced by prolonged regular use of Paracetamol with increased risk of bleeding.

Storage: Store in a cool (Below 25° C temperature) and dry place protected from light. Keep out of reach of children.

Packaging

Renova® 500 mg Tablet: Each carton contains 10X25 tablets in blister pack.

Renova® XR Tablet: Each carton contains 30X8 tablets in blister pack.

Renova® 60 ml Syrup: Each carton contains a amber pet bottle having 60 ml syrup.

Renova® 100 ml Syrup: Each carton contains a amber pet bottle having 100 ml syrup.

Renova® 60 ml Suspension: Each carton contains a amber pet bottle having 60 ml suspension.

Renova® 100 ml Suspension: Each carton contains a amber pet bottle having 100 ml suspension.

Renova® 15 ml Paediatric drops: Each carton contains a bottle having 15 ml Paediatric drops.

Renova® 30 ml Paediatric drops: Each carton contains a bottle having 30 ml Paediatric drops.

Renova® 60 mg Suppository: Each carton contains 5X2 suppositories in blister pack.

Renova® 125 mg Suppository: Each carton contains 5X2 suppositories in blister pack.

Renova® 250 mg Suppository: Each carton contains 5X2 suppositories in blister pack.

Renova® 500 mg Suppository: Each carton contains 5X2 suppositories in blister pack.


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