XTPARA 500

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for XTPARA 500 (Paracetamol Tablets I.P. 500mg) [Please refer the complete prescribing information available at <u>www.torrentpharma.com</u>]

PHARMACOLOGICAL PROPERTIES: Paracetamol produces analgesic and antipyretic as main effects and it has been also reported that paracetamol has a weak anti-inflammatory effect. Analgesic action: The central analgesic action of Paracetamol resembles that of aspirin. It produces analgesia by raising pain threshold. Antipyretic effect: The antipyretic effect of Paracetamol is attributed to its ability to inhibit COX in the brain where peroxide tone is low. Recent evidence suggests inhibition of COX-3 (believed to be splice variant product of the COX-1 gene) could represent a primary central mechanism by which Paracetamol decreases pain and possibly fever. Paracetamol is a peripherally acting analgesic with antipyretic activity.

INDICATIONS: Paracetamol are mild analgesic and antipyretic, and are recommended for the treatment of most painful and febrile conditions, for example, headache including migraine and tension headaches, toothache, backache, rheumatic and muscle pains, dysmenorrhoea, sore throat, and for relieving the fever, aches and pains of colds and flu. Also recommended for the symptomatic relief of pain due to non-serious arthritis.

DOSAGE AND ADMINISTRATION: Dose: One tablet 4-6 times a day or as directed by the Physician. Taking more than daily dose of paracetamol may cause serious liver damage. **Method of administration:** Paracetamol 500 mg uncoated tablets should be administered orally.

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients.

WARNINGS & PRECAUTIONS: Underlying liver disease increases the risk or paracetamol related liver damage. Patients who have been diagnosed with liver or kidney impairment must seek medical advice before taking this medication.

DRUG INTERACTIONS: The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.

ADVERSE REACTIONS: Thrombocytopenia, Agranulocytosis, Anaphylaxis, Cutaneous hypersensitivity reactions including, among others, skin rashes and angioedema, Bronchospasm and Hepatic dysfunction.

MARKETED BY:



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(Additional information is available on request)