Panadol® Actifast™

For relief of pain and fever

(ANALGESIC / ANTIPYRETIC)

DESCRIPTION

Each tablet contains Paracetamol Ph. Eur. 500mg.

PHARMACEUTICAL FORM

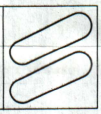
Film coated tablet. White, capsule shaped tablets with flat edges, debossed with the letter "P".

INDICATIONS

PANADOL ACTIFAST is an analgesic and antipyretic. It is effective for the relief of fever and the treatment of mild to moderate pain including: headache, migraine, backache, rheumatic and muscle pain, period pain, pain of osteoarthritis, toothache, pain following dental procedures/tooth extraction, pain after vaccination, sore throat and the discomfort from colds and influenza.

DOSAGE AND ADMINISTRATION

For oral administration.

ADULTS (INCLUDING THE ELDERLY) AND CHILDREN OVER 12 YEARS:	
Two tablet (1g) every 4 to 6 hours as required. Minimum dosing interval: 4 hours. Do not take more than 8 tablets (4g) in 24 hours.	

Not recommended for children under 12 years of age.

CONTRAINDICATIONS

PANADOL ACTIFAST is contraindicated in patients with a previous history of hypersensitivity to paracetamol or to any of the other ingredients in the tablets.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Keep out of the reach of children.

Do not exceed the stated dose. If symptoms persist, seek medical advice.

This product should not be used with other paracetamol containing products.

Do not take this product for pain for more than 10 days or for fever for more than 3 days unless directed by a doctor.

If you have been diagnosed with liver or kidney impairment, seek medical advice before taking this medication. Each PANADOL ACTIFAST tablet contains 173mg of sodium (346mg sodium per 2 tablet dose) and should not be taken by patients on a low sodium diet.

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.

PREGNANCY AND LACTATION

Human and animal studies with paracetamol have not identified any risk to pregnancy or embryo-foetal development. Human studies with paracetamol have not identified any risk to lactation or the breast fed offspring. Paracetamol crosses the placental barrier and is excreted in breast milk but not in a clinically significant amount. As with any medication, medical advice should be sought before using this product in pregnancy.

SIDE-EFFECTS

Adverse effects of paracetamol are rare but hypersensitivity including skin rashes may occur.

OVERDOSE

Immediate medical management is required in the event of overdose, even if symptoms of overdose are not present. Paracetamol overdose may cause liver failure.

Administration of N-acetylcysteine or methionine may be required (follow standard procedure for paracetamol). General supportive measures must be available.

High doses of sodium bicarbonate may be expected to induce gastrointestinal symptoms including belching and nausea. In addition, high doses of socium bicarbonate may cause hypernatraemia; electrolytes should be monitored and patients managed accordingly.

PHARMACODYNAMIC PROPERTIES

Paracetamol has analgesic and antipyretic actions based on the inhibition of prostaglandin biosynthesis. Sodium bicarbonate has a role in increasing the rate of gastric emptying and therefore the speed of absorption of paracetamol.It has no known analgesic activity.

PHARMACOKINETIC PROPERTIES

Paracetamol is rapidly and almost completely absorbed from the gastro-intestinal tract. Paracetamol is relatively uniformly distributed throughout most body fluids. Paracetamol is metabolised in the liver and excreted in the urine mainly as glucuronide and sulphate conjugates - less than 5% is excreted as unmodified paracetamol. Binding to the plasma proteins is minimal at therapeutic concentrations. In a human volunteer pharmacokinetic study, mean maximum plasma concentrations were reached at least twice as fast for PANADOL ACTIFAST tablets compared to PANADOL tablets in both fed and fasted states (p=0.0002). The extent of absorption for PANADOL ACTIFAST tablets is equivalent to that for PANADOL tablets as shown by AUC.

SHELF LIFE

The expiry date is indicated on the packaging.

STORAGE CONDITIONS

Store below 25°C.

GlaxoSmithKline

Manufactured by GlaxoSmithKline, Dungarvan Ltd., Ireland.

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THIS IS A MEDICINE

- Medicines are products that affect your health, and failure to follow the instructions may be dangerous for you.
- Follow your doctor's advice carefully, the method of use, and the instructions of the pharmacist who sold you the medicine.
- Your doctor and pharmacist are expert in the use of medicines, and their benefits and risks.
- Do not stop your course of treatment early unless advised to do so by your doctor or pharmacist.
- Do not repeat your prescription without consulting your doctor.

KEEP MEDICINES OUT OF REACH OF CHILDREN

Council of Arab Health Ministers
Union of Arab Pharmacists