Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Panadol Actifast Tablets 500mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains paracetamol 500mg.

Excipients: Contains 173mg (7.5mmol) sodium per tablet.
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-Coated Tablet
Product imported from Greece:
White film-coated capsule shaped tablets with flat edges, debossed with the letter ‘P’.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

A mild analgesic and antipyretic recommended in the short-term management of the symptoms of headaches, musculoskeletal disorders, menstrual pains, toothache and for relieving fever, aches and pains of common colds and flu.

4.2 Posology and method of administration

For oral administration

Adults (including the elderly): 500 to 1000 mg (1-2 tablets) every 4 to 6 hours as required.

Children: Not recommended for children under 12 years of age.

Do not exceed the stated dose.

Should not be used with other paracetamol containing products.

Minimum dosing interval: 4 hours.

Maximum daily dose: 4000 mg (8 tablets).

4.3 Contraindications

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

Use in children under 6 years of age.

4.4 Special warnings and precautions for use

Each PANADOL Actifast tablet contains 173 mg of sodium (346 mg sodium per 2 tablet dose) and should only be used with caution in patients with hypertension, oedema or renal insufficiency because of the sodium content.

If you have been diagnosed with liver or kidney impairment, seek medical advice before taking this medication.

Patients should be advised not to take other paracetamol-containing products concurrently.

If symptoms persist, seek medical advice. Prolonged use except under medical supervision may be harmful.

Keep out of the reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by cholestyramine. 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.

4.6 Fertility, pregnancy and lactation

Human and animal studies with paracetamol have not identified any risk to pregnancy or embryo-foetal development. However as with all drugs, caution should be exercised in its use during the first trimester.

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.

4.7 Effects on ability to drive and use machines

No significant effect.

4.8 Undesirable effects

Panadol Actifast is unlikely to cause significant undesirable effects when used within the dosage recommendations but hypersensitivity (including skin rash/urticaria) and eructation may occur.

4.9 Overdose

Immediate medical attention (in-hospital, if possible) is required in the event of overdose, even if there are no significant early symptoms. There may be no early symptoms following a life-threatening overdose. Ingestion of more than 12 g paracetamol (24 standard 500 mg tablets) or more than 150 mg paracetamol per kg bodyweight (9 g paracetamol in a 60 kg individual), whichever is the smaller, can cause severe liver damage. Liver damage (as demonstrated by a rise in plasma transaminase levels) may be apparent between 8 and 36 hours following overdose. Biochemical evidence of maximal damage, however, may not be attained until 72-96 hours after ingestion of the overdose.

Intravenous N-acetylcysteine (NAC) is effective when initiated within 8 hours of the overdose. Efficacy declines progressively after this time, but NAC may provide some benefit up to and possibly beyond 24 hours. Oral methionine is also effective provided that it is given within 10 to 12 hours of the overdose. Activated charcoal should be considered if the dose of paracetamol ingested exceeds 12 g or 150 mg/kg, whichever is the smaller, and the procedure can be undertaken within 1 hour of the overdose. There is little evidence that undertaking gastric lavage will be of benefit to a patient in whom paracetamol is known to have been the only substance ingested.

Symptoms of paracetamol overdose in the first 24 hours may include pallor, nausea, vomiting, anorexia, and abdominal pain. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, coma and death. Liver damage results when excess quantities of a toxic metabolite (usually

adequately detoxified by glutathione when normal doses of paracetamol are ingested) become irreversibly bound to liver tissue. Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

High doses of sodium bicarbonate may be expected to induce gastrointestinal symptoms including belching and nausea. Gastric rupture has rarely been reported. In addition, high doses of sodium bicarbonate may cause hypernatraemia; hyperosmolarity and metabolic acidosis, particularly in patients with renal disease. Electrolytes should be monitored and if abnormalities occur, the patient should be managed appropriately after seeking expert advice.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Paracetamol is an analgesic and antipyretic. Its mechanism of action is believed to include inhibition of prostaglandin synthesis, primarily within the central nervous system. The lack of peripheral prostaglandin inhibition confers important pharmacological properties such as the maintenance of the protective prostaglandins within the gastrointestinal tract. Paracetamol is, therefore, particularly suitable for patients with a history of disease or on concomitant medication where peripheral prostaglandin inhibition would be undesirable (such as, for example, those with a history of GI bleeding or the elderly).

Sodium bicarbonate has no known analgesic activity.

Clinical data showed PANADOL Actifast to provide faster onset of analgesia than standard PANADOL tablets.

Onset of pain relief for PANADOL Actifast showed no difference in both fasted and fed states in an acute pain study.

5.2 Pharmacokinetic properties

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.

Sodium bicarbonate speeds up tablet dissolution in the stomach and enhances gastric emptying of paracetamol into the small intestine where it is absorbed.

In human volunteer pharmacokinetic studies, mean maximum plasma concentrations were reached at least twice as fast for PANADOL Actifast tablets compared to PANADOL tablets at both a one and two tablet dose and these were statistically significant.

The extent of absorption for PANADOL Actifast tablets is equivalent to that for standard paracetamol tablets as shown by AUC at both a one and two tablet dose.

5.3 Preclinical safety data

Preclinical safety data on paracetamol in the literature have not revealed any pertinent and conclusive findings which are of relevance to the recommended dosage and use of the product and which have not been mentioned elsewhere in this summary.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium bicarbonate
Tricalcium phosphate
Pregelatinised starch
Povidone
Maize starch
Potassium sorbate
Microcrystalline cellulose
Magnesium stearate
Carnauba wax
Opadry II Y-22-7719 which contains:
Titanium dioxide (E171)
Polydextrose
Hypromellose
Triacetin
Macrogol

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

The shelf-life expiry date of this product shall be the date shown on the container and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Opaque PVC/Aluminium foil blister strips packed into cardboard cartons containing 20 tablets.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA 465/158/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 13th July 2007

10 DATE OF REVISION OF THE TEXT

April 2011