Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Panadol 500 mg Film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 500mg paracetamol.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film coated tablet.

Product imported from Greece:
White capsule shaped tablet, imprinted in blue ink with 'panadol' on both faces and scored with a break line on one face.
Or
White capsule shaped film-coated tablet, engraved with 'PANADOL' on one face and scored with a breakline on the other face.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Panadol is a mild analgesic and antipyretic. The tablets are recommended for use in the short-term management of headaches, musculoskeletal disorders, menstrual pains, toothache and for symptoms of common colds and flu. Panadol may also be used in the symptomatic relief of mild to moderate pain associated with osteoarthritis, as diagnosed by a doctor.

4.2 Posology and method of administration

Panadol is for oral administration.
Adults (including the elderly)
2 tablets repeated if necessary 3- 4 times a day to a maximum of 8 tablets in any 24 hour period.

Children 6-12 years:
½ - 1 tablet repeated if necessary 3- 4 times a day to a maximum of 4 tablets in any 24 hour period.

Panadol tablets are not suitable for children under 6 years of age.
These doses should not be repeated more frequently than every 4 hours and not more than 4 doses should be given in any 24 hour period.

4.3 Contraindications

Hypersensitivity to paracetamol or any of the other constituents.
Use in children under 6 years of age.

4.4 Special warnings and precautions for use

Caution is advised in the administration of paracetamol to patients with severe renal or severe hepatic impairment. The hazard of overdose is greater in those with moderate and severe liver disease.
Do not exceed the stated dose.
Patients should be advised not to take other paracetamol-containing products concurrently.
If symptoms persist, consult your doctor. Prolonged use except under medical supervision may be harmful.
This product should only be used when clearly necessary.

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

There is epidemiological evidence of the safety of paracetamol in human pregnancy. Paracetamol is the mild analgesic of choice during pregnancy. However as with all drugs, caution should be exercised in its use during the first trimester. Paracetamol is excreted in breast milk. However the level of paracetamol present is not considered to be harmful.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Adverse effects of paracetamol are rare but hypersensitivity including skin rash 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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Paracetamol has analgesic and antipyretic actions.

5.2 Pharmacokinetic properties

Paracetamol is rapidly and almost completely absorbed from the gastro-intestinal tract. Concentration in plasma reaches a peak in 30 - 60 minutes
Plasma half-life is 1 - 4 hours.
Paracetamol is relatively uniformly distributed throughout most body fluids.
Plasma protein binding is variable.
Excretion is almost exclusively renal, in the form of conjugated metabolites.

5.3 Preclinical safety data

There are no pertinent data not already described elsewhere in this SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch
Povidone
Potassium sorbate
Talc
Stearic acid
Water
Hyprolose
Triacetin
Colour (Only present in tablet with printing ink, not the engraved tablet)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

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

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Blister packs of 20 tablets contained in an outer cardboard carton.

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA 0465/158/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21 October 2005

Date of last renewal: 21 October 2010

10 DATE OF REVISION OF THE TEXT

January 2012