Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Paracetamol 500mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 500 mg of Paracetamol.

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet
A white flat circular bevel edged tablet embossed "S" and "1" on either side of the breakline on one side and an ankh symbol on the reverse.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a mild analgesic and antipyretic in the management of the symptoms of headache, toothache, common cold, influenza, menstrual pain, Musculoskeletal disorders.

4.2 Posology and method of administration

Paracetamol tablets should be taken with a glass of water if required.

Adults:
The recommended dose is 1-2 tablets 3-4 times daily. A maximum dose of 8 tablets daily should not be exceeded.

Children 6-12 years:
½-1 tablet 3-4 times daily. A maximum dose of 4 tablets (2000 mg) daily should not be exceeded.

Children under 6 years:
Tablets form not recommended.

4.3 Contraindications

Hypersensitivity to paracetamol or any of the other constituents.

4.4 Special warnings and precautions for use

Care 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 non-cirrhotic alcoholic liver disease. Do not exceed the recommended dose.

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

Keep out of 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 effects 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 Pregnancy and lactation

Epidemiological studies in human pregnancy have shown no ill effects due to paracetamol used in the recommended dosage, but patients should follow the advice of their doctor regarding its use.

Paracetamol is excreted in breast milk not in clinically significant amount. Available published data do not contraindicate breast feeding.

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. There have been a few reports of blood dyscrasias including thrombocytopenia and agranulocytosis but these were not necessarily causally related to paracetamol**.**

4.9 Overdose

Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to Encephalopathy, coma and death. Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported. Liver damage is possible in adults who have taken 10g or more of paracetamol. It is considered that excess quantities of a toxic metabolite (usually adequately detoxified by glutathione when normal doses of paracetamol are ingested), become irreversibly bound to liver tissue.

Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention and any patient who has ingested around 7.5g or more of paracetamol or intravenous N-acetylcysteine which may have a beneficial effect up to at least 48 hours after the overdose may be required. General supportive measures must be available.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Analgesics, N02B E01.

Para aminophenol derivative well absorbed from the gut, metabolised in the liver and excreted in urine as glucuronide and sulphate conjugates.

5.2 Pharmacokinetic properties

Half life is 1-4 hours.

5.3 Preclinical safety data

There are no Preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potassium sorbate (E202)
Purified talc
Stearic acid
Povidone
Soluble starch
Maize starch

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

5 years.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original container.

6.5 Nature and contents of container

Paracetamol tablets will be supplied in polypropylene containers of 50, 100 or 500 tablets.
Not all pack sizes may be marketed.

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 MARKETING AUTHORISATION HOLDER

Winthrop Pharmaceuticals UK Limited
One Onslow Street
Guildford
Surrey GU1 4YS
U.K

T/A:

Winthrop Pharmaceuticals (UK) Limited
PO Box 611
Guildford
Surrey GU1 4YS
U.K

8 MARKETING AUTHORISATION NUMBER

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10 DATE OF REVISION OF THE TEXT

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