1.3 Product Information

1.3.1 SPC, Labeling and Package Leaflet

SPC-Summary of Product Characteristics

Route of Administration: Oral Tablets

SPC-Summary of Product Characteristics

1. Name of the Medicinal Product

Paracetamol Tablets BP 500mg

2. Qualitative and Quantitative Composition

Each uncoated tablet contains:

Paracetamol BP	500 mg
Excipients	q.s

3. Pharmaceutical Form

Uncoated Tablet (For Oral Administration)

White colored, round flat shaped, uncoated tablets having a breakline on one side of each tablet and other side is plain

4. Clinical Particulars

4.1 Therapeutic Indications

Paracetamol has analgesic and antipyretic actions similar to those of aspirin and hence is a suitable alternative for patients sensitive to aspirin.

1) For the relief of mild to moderate pain and febrile conditions, eg headache, toothache, colds, influenza, rheumatic pain and dysmenorrhoea.

4.2 Posology and Method of Administration

Posology

Adults including the elderly and children over 16 years: One to two tablets every 4-6 hours as required, to a maximum of 8 tablets daily in divided doses.

Children 10-15 years: One tablet every 4-6 hours as necessary to a maximum of 4 doses in 24 hours.

Children under 10 years: Not recommended for children under 10 years of age. Alternative presentations of paracetamol are recommended for paediatric usage in order to obtain suitable doses of less than 500mg.

Method of administration

For Oral Administration.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special Warnings and Precautions for use

Where analgesics are used long-term (>3 months) with administration every two days or more frequently, headache may develop or worsen. Headache induced by overuse of analgesics (MOH medication-overuse headache) should not be treated by dose increase. In such cases, the use of analgesics should be discontinued in consultation with the doctor.

Care is advised in the administration of paracetamol to patients with alcohol dependency (see section 4.9), severe renal or severe hepatic impairment. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease.

Label Warnings:

Do not exceed the recommended dose

If symptoms persist consult your doctor

Keep out of the reach and sight of children

Do not take with any other paracetamol-containing products.

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.

or if leaflet present:

Immediate medical advice should be sought in the event of an overdose, even if you feel well.

4.5 Interactions with other medicinal products and other forms of interactions

Anticoagulants - the effect of warfarin and other coumarins may be enhanced by prolonged

regular use of paracetamol with increased risk of bleeding. Occasional doses have no significant effect.

• Metoclopramide – may increase speed of absorption of paracetamol.

• Domperidone – may increase speed of absorption of paracetamol.

• Colestyramine – may reduce absorption if given within one hour of paracetamol.

• Imatinib - restriction or avoidance of concomitant regular paracetamol use should be taken with imatinib.

4.6 Fertility, Pregnancy and Lactation

Pregnancy

A large amount of data on pregnant women indicate neither malformative, nor feto/neonatal toxicity. Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. If clinically needed, paracetamol can be used during pregnancy however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency.

Breast-feeding

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

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable Effects

Adverse effects of Paracetamol are rare but hypersensitivity including skin rash may occur. There have been reports of blood dyscrasias including thrombocytopenia, neutropenia, pancytopenia, leukopenia and agranulocytosis but these were not necessarily causality related to Paracetamol

Very rare cases of serious skin reactions have been reported.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow

Card Scheme; website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Liver damage is possible in adults who have taken 10g or more of Paracetamol. Ingestion of 5g or more of Paracetamol may lead to liver damage if the patient has risk factors (see below).

Risk Factors:

If the patient

a, Is on long term treatment with carbamazepine, phenobarbital, phenytoin, primidone, rifampicin, St John's Wort or other drugs than induce liver enzymes.

Or

B, Regularly consumes ethanol in excess of recommended amounts.

Or

C, Is likely to be glutathione depleted e.g. eating disorders, cystic fibrosis, HIV, starvation, cachexia.

Symptoms

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 poisioning, hepatic failure may progress to encephalopathy, haemorrhage, hypoglycaemia, cerebral oedema, and death. Acute renal failure with acute tubular necrosis, strongly suggested by loin pain, haematuria and proteinuria, may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

Management

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.

Symptoms may be limited to nausea or vomiting and may not reflect the severity of overdose or the risk of organ damage. Management should be in accordance with established treatment guidelines, see BNF overdose section.

Treatment with activated charcoal should be considered if the overdose has been taken within 1 hour. Plasma paracetamol concentration should be measured at 4 hours or later after ingestion (earlier concentrations are unreliable). Treatment with N-acetylcysteine may be used up to 24 hours after ingestion of Paracetamol, however, the maximum protective effect is obtained up to 8 hours post-ingestion. The effectiveness of the antidote decines sharply after this time. If required the patient should be given intravenous N-acetylcysteine, in line with the established dosage schedule. If vomiting is not a problem, oral methionine may be a suitable alternative for remote areas, outside hospital. Management of patients who present with serious hepatic dysfunction beyond 24h from ingestion should be discussed with the NPIS or a liver unit.

5.Pharmacological Properties

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Other analgesics and antipyretics.

ATC code N02B E01

Paracetamol has analgesic and antipyretic properties but it has no useful anti-inflammatory properties.

Paracetamol's effects are thought to be related to inhibition of prostaglandin synthesis.

5.2 Pharmacokinetics

Absorption

Paracetamol is readily absorbed from the gastrointestinal tract.

Distrubution

Peak plasma concentrations occur about 10 to 60 minutes after oral doses. Paracetamol is distributed into most body tissues. It crosses the placenta and is present in breast milk. Plasma-protein binding is negligible at usual therapeutic concentrations but increases with increasing concentrations.

Biotransformation

It is metabolised in the liver. A minor hydroxylated metabolite which is usually produced in very small amounts by mixed-function oxidases in the liver and which is usually detoxified by conjugation with liver glutathione may accumulate following paracetamol overdosage and cause tissue damage.

Elimination

It is excreted in the urine, mainly as the glucuronide and sulfate conjugates. The elimination half-life varies from about 1 to 4 hours.

5.3 Pre Clinical Safety Data

Conventional studies using the currently accepted standards for the evaluation of toxicity to reproduction and development are not available.

5. Pharmaceutical Particulars

6.1 List of Excipients

Maize starch
Microcrystalline Cellulose
Aerosil
Sodium Starch glycolate
Sodium Methyl Paraben
Sodium propyl paraben
PVPK 30
Maize starch
Gelatin
Purified water
Talcum
Sodium Starch glycolate
Magnesium Stearte
Sodium Lauryl Sulphate

6.2 Incompatibilities

None known.

6.3 Shelf Life

Shelf-life

Three years for PE tablet containers.

Five years for blisters and PP tablet containers.

Shelf-life after dilution/reconstitution

Not applicable.

6.4 Special precautions for Storage

Store below 30°C in a dry place. Protect from light.

6.5 Nature and contents of Container

10 x 10 Tablets Alu-PVC

6.6 Special precautions for disposal

Not applicable

7. REGISTRANT

Merit Organics Ltd

Plot No 2104/2/A, G.I.D.C , Sarigam , Bhilad,

Dist- Valsad-396155, Gujarat , INDIA

8. MANUFACTURER

Merit Organics Ltd

Plot No 2104/2/A, G.I.D.C , Sarigam , Bhilad,

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9. DATE OF REVISION OF THE TEXT

Applicable once the registration is obtained.