PARASAM ‘Y’ CAPLETS

PARACETAMOL 500mg

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Document type: Summary of Product Characteristics

Document status: Final

Release date: 7th January 2020

Number of pages: 7 pages

1. NAME OF THE MEDICINAL PRODUCT

PARACETAMOL 500mg B.P

2. QUALITATIVE AND QUANTITATIVE COMPOSITIONS

Each tablet contains Paracetamol Powder 500mg.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORMS

Yellow flat capsule shaped beveled caplet with 'PARASAM' marked on one side and breakline on the other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indication.

Paracetamol has analgesic and antipyretic actions. Paracetamol is indicated for pains, feverish conditions, cold symptoms and headache.

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

Paracetamol should be given with care to patient with impaired kidney or liver function. Paracetamol should be given with care to patients taking other drugs that affect the liver.

4.4 Special warnings and precaution 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.

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

4.5 Interaction with other medicinal product and other forms of interaction.

- 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.

4.6 Pregnancy and Lactation.

Pregnancy

A large amount of data on pregnant women indicates 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 Effect on the ability to drive and use machine.

It has unknown effect on an individual's ability to drive or operate machinery.

4.8 Undesirable effect.

Adverse effects of Paracetamol are rare but hypersensitivity including skin rash may occur.

Very rare cases of serious skin reactions have been reported

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 regularly consumes ethanol in excess of recommended amounts or is likely to be glutathione depleted.

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.

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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties.

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 Pharmacokinetic properties.

Absorption

Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract.

Distrubution

Peak plasma concentrations occur about 30 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.

Excretion

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 Preclinical safety data.

Product is not a new chemical entity therefore this section is not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch

Purified Talc.

Magnesium Stearate

Tartrazine

Sunset yellow

Methyl Paraben

Propyl Paraben

Gelatine

6.2 Incompatibilities

Unknown

6.3 Shelf-life

30Months from the date of manufacture

6.4 Special precautions for storage

Protect from heat and light, and store in a cool dry place below 30^0C

6.5 Nature and composition of immediate packaging

1000 tablets packed into a polythene seal bag and put into a1000cc plastic secured-container.

7. MARKETING AUTHORISATION HOLDER

SAM PHARMACEUTICALS LIMITED.
2, WESTERN RESERVOIR ROAD,
ILORIN,
KWARA STATE, NIGERIA.
08057075266
sampharmaceuticalltd@gmail.com

8. MARKETING AUTHORISATION NUMBER(S)

04 – 5770

9. AUTHORISATION/RENEWAL OF THE AUTHORISATION

Renewal date: 26th February 2020

10. DATE OF REVISION OF THE TEXT

6th January, 2024