SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Of

DE-SHALOM PARACETAMOL SYRUP

1. NAME OF THE MEDICINAL PRODUCT

De -Shalom Paracetamol Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains Paracetamol 125 mg

For a full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

A clear syrupy Liquid

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

De -Shalom Paracetamol Syrup is indicated for the treatment of mild to moderate pain and as an antipyretic. It can be used in many conditions including headache, toothache, earache, teething, sore throat, colds & influenza, aches and pains and post-immunisation fever.

4.2 Posology and method of administration

Posology

Age 3 – 12 months: 2.5ml – 5ml three times daily

Age 2 – 5 years: 5ml – 10ml three times daily

Age 6 – 12 years: 10ml – 20ml three times daily

- Do not give more than 4 doses in any 24 hours period
- Leave at least 4 hours between doses
- If symptoms persist after 2 days, consult your doctor.

4.3 Contraindications

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

Patients with liver and kidney impairment.

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 hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease.

4.5 Interaction with other medicinal products and other forms of interaction

The hepatotoxicity of Paracetamol, particularly after overdosage, may be increased by drugs which

induce liver microsomal enzymes such as barbiturates, tricyclic antidepressants, and alcohol.

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

The anticoagulant 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.

4.6 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 drug reactions (ADRs are rare.

4.9 Overdose

Liver damage is possible in adults and adolescents (≥12 years of age) who have taken 7.5g 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.

Ingestion of 5g or more of paracetamol may lead to liver damage if the patient has risk factors.

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 the 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 concentrations 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.

5.0 Pharmacological Properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other Analgesics and Antipyretics
(Anilides) ATC Code: N02BE01

Paracetamol has analgesic and antipyretic effects that do not differ significantly from those of aspirin. However it has only weak anti-inflammatory effects. It is only a weak inhibitor of prostaglandin biosynthesis although there is some evidence to suggest it may be more effective against enzymes in the central nervous system than in the periphery. This may in part account for its activity profile.

The mechanism of analgesic action has not been fully determined. Paracetamol may act predominantly by inhibiting prostaglandin synthesis in the central nervous system (CNS) and, to a lesser extent, through a peripheral action by blocking pain impulse generation. The peripheral action may also be due to inhibition of prostaglandin synthesis or to inhibition of the synthesis or actions of other substances that sensitise pain receptors to mechanical or chemical stimulation.

Paracetamol probably produces antipyresis by acting centrally on the hypothalamic heat regulating centre to produce peripheral vaso-dilation resulting in increased blood flow through the skin, sweating and heat loss. The central action probably involves inhibition of prostaglandin synthesis in the hypothalamus.

5.2 Pharmacokinetic properties

Oral absorption is rapid and almost complete, it may be decreased if Paracetamol is taken following a high carbohydrate meal.

There is no significant protein binding with doses producing plasma concentrations of below 60mcg (µg)/ml, but may reach moderate levels with high or toxic doses.

Approximately 90 - 95% of a dose is metabolised in the liver, primarily by conjugation with

Glucuronic acid, sulphuric acid and cysteine. An intermediate metabolite, which may accumulate in overdosage after primary metabolic pathways become saturated, is hepatotoxic and possibly nephrotoxic.

Half-life is 1 to 4 hours; does not change with renal failure but may be prolonged in acute overdosage, in some forms of hepatic disease, in the elderly, and in the neonate; may be somewhat shortened in children.

Time to peak concentration, 0.5 - 2 hours; peak plasma concentrations, 5 - 20mcg (µg)/ml (with doses up to 650mg); time to peak effect, 1- 3 hours; duration of action, 3- 4 hours.

Elimination is by the renal route, as metabolites, primarily conjugates, 3% of a dose may be excreted unchanged.

Peak concentration of 10 - 15mcg(µg)/ml have been measured in breast milk, 1 - 2 hours following maternal ingestion of a single 650mg dose. Half-life in breast milk is 1.35 - 3.5 hours.

5.3 Preclinical safety data

Preclinical data reveal no special hazard for humans based on conventional studies of single and repeated dose toxicity, genotoxicity, and carcinogenicity.
Conventional studies using the currently accepted standards for the evaluation of toxicity to reproduction and development are not available.

6.0 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Methyl Paraben
- Sucrose
- Propyl Paraben
- C.M.C
- EDTA
- Sodium citrate
- Citric acid (Monohydrate)
- Ethanol
- Raspberry flavor
- Alura Red
- Glycerine

6.2 Incompatibilities

None kmown

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store below 30 °C. Keep away from sunlight.

Keep out of reach of children.

6.5 Nature and contents of container

60ml Amber bottle with aluminum screw cap.

6.6 Special precautions for disposal and other handling

No special requirements apart from NAFDAC guidelines

7.0 APPLICANT/MANUFACTURER

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