SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICALS PRODUCT

Hoemal Oral Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains paracetamol 250mg with methyl paraben 0.1% w/v and propyl paraben 0.01% w/v as preservatives in red blackcurrant flavoured suspension.

3. PHARMACEUTICAL FORM

Liquid suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Indicated for the relief of most mild to moderate pain including teething pain and for the symptomatic relief of fever in influenza and feverish colds. It is also a substitute for aspirin for its analgesic or antipyretic uses in patients who are allergic to aspirin or when aspirin is contra-indicated as in children and patients with peptic ulcer.

4.2 Posology and method of administration

Oral administration. For 1-6 years, it requires ½ -1 teaspoon meanwhile for 7-12 years about 1-2 teaspoon and it can be given undiluted 3 to 4 times daily as required.

4.3 Contraindications

Hypersensitivity to paracetamol or any of the ingredients in the formulation.

4.4 Special warning and precautions for use

Medications containing paracetamol should be given with care to patients with impaired kidney or liver function, and patients taking other drugs that effect the liver. Patients on anticoagulant therapy may require reduction in dosage if on daily paracetamol medication.
Do not exceed the stated dosage more frequently than 4 hourly. If symptoms persist, please consult your doctor or pharmacist. This preparation contains PARACETAMOL. Do not use any other paracetamol containing medicines at the same time.

Allergy alert: Paracetamol may cause severe skin reactions. Symptoms may include skin reddening, blisters or rash. These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.

4.5 Interaction with other medicinal products and other forms of interactions

Unknown.

4.6 Pregnancy and lactation

Unknown.

4.7 Effects on ability to drive and use machine

Unknown.

4.8 Undesirable effects

Side effects are usually mild. Cutaneous hypersensitivity reactions including skin rashes, angioderma, Steven Johnson Syndrome/Toxic Epidermal Necrolysis have been reported.

4.9 Overdose

Vomiting, hypertension, sweating, gastrointestinal haemorrhage, liver damage, cerebral oedema and renal tubular necrosis.

Treatment of overdosage: Gastric emptying (unless drowsy or unconscious) and/or lavage is recommended as soon as possible after ingestion. Diazepam may be given to control central nervous system stimulation and convulsions. A beta adrenoreceptor blocking agent may be required to control cardiac arrhythmia due to phenylpropanolamine hydrochloride. Ingestion of over 140mg/kg or 10g (for adults) requires prompt hospital treatment.

Antidote: To prevent or reduce liver damage, oral methionine (2.5g) should be given after emesis and/or lavage. Additional therapy (3 further doses of 2.5g methionine at four hourly intervals or IV-cysteamine) is normally considered in the light of blood paracetamol content and the time elapsed since ingestion.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Paracetamol acts as an analgesic and antipyretic.

5.2 Pharmacokinetic Properties

The mode of action of paracetamol is not known. It is thought to act as a prostaglandin synthetase inhibitor in the central nervous system but not in the peripheral tissues. This would account for its antipyretic and analgesic effect and for the possible lack of anti-inflammatory action.

Paracetamol is readily absorbed from the gastro-intestinal tract with peak plasma concentration about 30 minutes to 2 hours after ingestion. It is metabolized in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates. The

elimination half-life varies from about 1 to 4 hours. Plasma protein binding is negligible at usual therapeutic concentrations.

5.3 Preclinical Safety Data

Not available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carmosine, Propylparaben, Methylparaben, Flavor Blackcurrant, Saccharin Sodium, Xanthan Gum (Rhodigel-23), Tragacanth, Purified Water, Sorbitol 70% Solution and Sucrose.

6.2 Incompatibilities
None

6.3 Shelf life
3 years

6.4 Special precautions for storage
Keep container well closed after opening. Store below 30ºC and protect from strong light. Keep out of reach of children.

6.5 Nature and contents of container
PET amber bottle

7. MARKETING AUTHORIZATION HOLDER

HOE Pharmaceuticals Sdn. Bhd.,
Lot 10, Jalan Sultan Mohamed 6, Bandar Sultan Suleiman, 42000 Port Klang, Selangor, MALAYSIA

8. NUMBER(S) IN THE NATIONAL REGISTER OF FINISHED PHARMACEUTICAL PRODUCTS

05160/07224/REN/2020

9. DATE OF FIRST AUTHORIZATION/ RENEWAL OF THE AUTHORIZATION

Date of first authorization : 24/07/2007
Date of last renewal : 01/03/2016

10. DATE OF REVISION OF THE TEXT

26th September 2019