Summary Product Characteristics

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

Karemol tablets

2. Qualitative and quantitative composition

Each tablet contains 500mg Paracetamol PhEur.

For the full list of excipients, see section 6.1

3. Pharmaceutical form

Tablet.

4. Clinical particulars

4.1 Therapeutic indications

Paracetamol has an analgesic and antipyretic properties and weak anti-inflammatory activity. Paracetamol is recommended for Treatment of painful and febrile conditions, for example headache, toothache, sore throat, colds, influenza and rheumatic pain.

4.2 Posology and method of administration

Posology

Adults and children over age 12: - 325 to 650 mg orally to be taken every four to six hours.

Maximum dose should not exceed 4g daily

Dosage for long-term therapy should not exceed 2.6g daily.

Children under age 12: 1.5g/m2 body weight daily in divided doses or as shown below.

Children age 9 to 12 years: 1 tablet or 2 tablets junior every 4 to 6 hours. Children age 5 to 8 years: 7.5 ml of the syrup,

1½ tablets Junior every 4 to 6 hours.

Children age 1 to 4 years: 1 tablet Junior every 4 to 6 hours or as directed by a Physician.

Method of Administration

For oral administration.

4.3 Contraindications

Paracetamol is contraindicated in-patients with known hypersensitivity to this compound. Administer the drug cautiously to patients with anaemia, hepatic or renal disease because it has been known to induce these disorders; and to patients with a history of gastrointestinal disease, increased risk of gastrointestinal bleeding, or decreased renal function. Paracetamol may mask the signs and symptoms of acute infection (fever, myalgia, and erythema); patients with high infection risk (such as those with diabetes) should be carefully evaluated.

4.4 Special warnings and precautions for use

Has no significant anti-inflammatory effect. In spite of this, studies have shown substantial benefit in-patients with osteoarthritis of the knee. Therapeutic benefits may stem from the drug's analgesic effects. Many nonprescription products contain paracetamol. Be aware of this when calculating total daily dose. Patients unable to tolerate aspirin may be able to tolerate paracetamol tablet. Use this medication cautiously in the presence of alcoholism, hepatic disease, viral infection, renal function impairment, or cardiovascular disease. Monitor vital signs, especially temperature, to evaluate drug's effectiveness. Assess patient's level of pain and response before and after administration.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant use of Paracetamol may potentiate the effects of anticoagulants and thrombolytic drugs, but this effect appears to be clinically insignificant. Combined caffeine and Paracetamol may enhance the therapeutic effect of Paracetamol. Concomitant use of phenothiazines and Paracetamol in large doses may result in hypothermia.

4.6 Fertility, 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

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

In acute overdose, plasma levels of 300 mcg/ml 4 hours post-administration are associated with hepatotoxicity, clinical manifestations of overdose include cyanosis, anemia, jaundice, skin eruptions, fever, emesis, central Nervous system stimulation, delirium, methemoglobinemia progressing to depression, coma, vascular collapse, convulsions, and death. Paracetamol poisoning develops in stages. Stage 1 (12 to 24 hours after ingestion): nausea, vomiting, diaphoresis, anorexia.

Stage 2 (24 to 48 hours after ingestion): clinically improved but elevated liver function tests. Stage 3 (72 to 96 hours after ingestion): peak hepatotoxicity.

Stage 4 (7 to 8 days after ingestion): recovery to treat overdose of paracetamol tablet, hemodialysis may be helpful to remove from the body.

Monitor laboratory parameters and vital signs closely. Cimetidine has been used investigationally to block metabolism to toxic intermediates.

Provide symptomatic and supportive measures (respiratory support, correction of fluid and electrolyte imbalances).

Determine plasma levels atleast 4 hours after overdose. If plasma levels indicate hepatotoxicity, perform liver function tests every 24 hours for a tleast 96 hours.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other analgesics and antipyretics,

Anilides 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 Pharmacokinetic properties

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 Preclinical safety data

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

6. Pharmaceutical particulars

6.1 List of excipients

Maize Starch
Sodium Starch Glycolate
Low-substituted Hydroxypropyl
cellulose Magnesium stearate
Purified water

6.2 Incompatibilities

None known.

6.3 Shelf life

Three years after manufacturing date

6.4 Special precautions for storage

Store in cool dry place below

30°C Keep medicine out of

direct sunlight.

Keep all medicines out of reach of children.

6.5 Nature and contents of container

10 tablets are packed in one Alu/PVC blister such 10Alu/PVC blisters are packed in carton along with pack insert and 1000 tablets packed in HDPE bottles along with pack insert in a carton.

6.6 Special precautions for disposal and other handling

Not applicable.

7. Marketing authorisation holder

KAREMAX INDUSTRIAL LIMITED

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China

Email; admin@karemax.net

8. Manufactured by

Hebei Jiheng (Group) Pharmaceutical Co., Ltd

No. 368 Jianshe Street, Hengshui City, Hebei, China

9. Legal category:

Over the counter (OTC)

1.6.2 Container Labeling and Packaging