# SUMMARY OF PRODUCTS CHARACTERISTICS

## 1.NAME OF THE FINISHED PHARMACEUTICAL PRODUCT :

1.1 Brand Name : Kelvin Tablet

1.2 Generic Name : Paracetamol Tablets BP

1.3 Strength : 500mg per tablet

1.4 Pharmaceutical Form: Tablet

## 2. QUALITATIVE & QUANTITATIVE COMPOSITION :

Each Uncoated tablet contains:

Paracetamol BP 500 mg

## 3. PHARMACEUTICAL FORM

Tablet

White coloured, round shaped, flat beveled, uncoated tablet having central break-line on one face of each tablet.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Paracetamol is indicated in the treatment of mild to moderate pain & as an antipyretic. It is also used in the symptomatic relief of headache, migraine, neuralgia, toothache and teething pains, sore throat, rheumatic aches and pains, influenza, feverishness and feverish cold.

**4.2 Posology and method of administration**

- **Adults including the elderly and children over 16 years:** 1 or 2 tablets every 4 to 6 hours as required, to a maximum of 8 tablets in 24 hours.
- **Children 10-15 years:** 1 tablet every 4-6 hours as required, to a maximum of 4 tablets in 24 hours.
- **Children under 10 years:** Not recommended.

**4.3 Contraindications:**

Paracetamol (Kelvin), should be given with care to patients with severe impaired kidney or liver function. Paracetamol should be contraindicated in patients with known hypersensitivity to Paracetamol or any other components of Kelvin.

**4.4 Special warnings and special precautions for use:**

Alcohol dependence, before administering check when paracetamol was last administered and cumulative paracetamol dose over previous 24 hours chronic alcoholism, chronic dehydration, chronic malnutrition and hepatocellular insufficiency. It should be given with care to patients with severe impaired kidney or liver function.

**Potential for Drug Abuse and Dependence:** The most serious adverse effect of acute overdosage of Paracetamol is dose dependant, potentially fatal hepatic necrosis. In adults, hepatotoxicity may occur after ingestion of a single dose of Paracetamol 10-15 gm. A dose more than 25 gm is potentially fatal. Major manifestation of hepatic failure e.g. jaundice, hypoglycemia and metabolic acidosis may take 3 days to develop.

**4.5 Interaction with other FPPs and Other forms of Interaction**

**Anticoagulants:** Prolonged regular use of paracetamol possibly enhances anticoagulant effect of Coumarins.

**Antidiabetics:** Absorption of paracetamol possibly reduced when given 1 to 4 hours after Lixisenatide.

**Antiepileptics:** Metabolism of paracetamol possibly accelerated by Carbamazepine, Fosphenytoin, Phenobarbital, Phenytoin and Primidone (also isolated reports of hepatotoxicity)

**Antifungals:** Avoidance of paracetamol advised by manufacturer of Ketoconazole.

**Cytotoxics:** Paracetamol possibly inhibits metabolism of intravenous Busulfan.

**Lipid-regulating Drugs:** Absorption of paracetamol reduced by Colestyramine.

**Metoclopramide:** Rate of absorption of paracetamol increased by Metoclopramide.

**4.6 Pregnancy and lactation**

**Pregnancy:** Epidemiological studies in human pregnancy have shown no effects due to paracetamol used in the recommended dosage. However, paracetamol should be avoided in pregnancy unless considered essential by the physician.

**Breast feeding:** Paracetamol is excreted in breast milk but not in a clinically significant amount.

### 4.7 Effects on ability to drive and use machines

None known

### 4.8 Undesirable effects

**Rare:** Acute generalized exanthematous pustulosis, malaise, skin reactions, Stevens-Johnson syndrome, toxic epidermal necrolysis.

**Frequency not known:** Blood disorders, leucopenia, neutropenia & thrombocytopenia.

**Adverse 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. Most reports of adverse reactions to paracetamol relate to overdosage with the drug.

### 4.9 Overdose

Pallor, anorexia, nausea & vomiting are frequent early symptoms of Paracetamol overdosage. Hepatic necrosis is a dose related complication of Paracetamol overdosage.

**Treatment:** To protect patient, against delayed hepatotoxicity, should be treated promptly by measures to limit absorption (gastric lavage or activated charcoal) followed by N-acetylcysteine IV or oral methionine.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

**Pharmacotherapeutic group: Analgesic; Antipyretic**

**Mechanism of action:**

Paracetamol is a centrally acting analgesic and antipyretic which increases the pain threshold in the brain. Paracetamol weakly inhibits peripheral prostaglandin, but strongly inhibits brain prostaglandin synthesis. After oral administration, Paracetamol is absorbed rapidly and completely from the small intestine. Peak plasma levels occur within 30-120 minutes after oral administration. Paracetamol is excreted in the urine mainly as the glucuronide and sulphate conjugates.

### 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.

**Metabolism:** It is metabolized in the liver. A minor hydroxylated metabolite which is usually produced in very small amounts by mixed-function oxidizes 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**

None Known

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of Excipients

| SN | Ingredients | Spec. |
|---|---|---|
| 01. | Starch (Maize) | BP |
| 02. | Methyl Hydroxybenzoate | BP |
| 03. | Propyl Hydroxybenzoate | BP |
| 04. | Purified Talc | BP |
| 05. | Magnesium Stearate | BP |
| 06. | Sodium Starch Glycolate | BP |
| 07. | Colloidal Anhydrous Silica (Colloidal Silicon Dioxide) | BP |
| 08. | Povidone | BP |
| 09. | Sodium Lauryl Sulphate | BP |
| 10. | Gelatin | BP |
| 11. | Purified Water | BP |

**6.2 Incompatibilities**

Not Known

**6.3 Shelf life**

36 months

**6.4 Special precautions for storage**

Store at temperature not exceeding $30^0$C. Do not refrigerate. Protect from light. Keep out of reach of children. Keep container tightly closed.

**6.5 Nature and contents of container**

10 blisters of 10 tablets packed in an inner carton (10x10)
100 blisters of 10 tablets packed in an E-flute (10x100)

**6.6 Instructions for use and handling**

Please see the package insert.

**7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS**

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**8. MARKETING AUTHORISATION NUMBER**

**AMD/12/2002 & AMD/6/2002**

**9. DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION**

**AMD/12/2002& AMD/6/2002:**

**a) Date of first authorization: 21/01/1989**

**b) Date of latest renewal: 01/01/2018**

**10. DATE OF REVISION OF THE TEXT**

**01/01/2023**