

# **SUMMARY OF PRODUCT CHARACTERISTICS**

## **1 NAME OF THE MEDICINAL PRODUCT**

Paracetamol Elixir B.P. 120mg/5ml

## **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each 5ml contains:  
Paracetamol Elixir B.P. 120mg

## **3 PHARMACEUTICAL FORM**

Elixir

## **4 CLINICAL PARTICULARS**

### **4.1 Therapeutic indications**

For the treatment of mild to moderate pain, including headache, migraine, neuralgia, toothache, pain in teething, sore throat, aches and pains  
Symptomatic relief of influenza, feverishness, feverish colds.

### **4.2 Posology and method of administration**

Children 3-12 months: 2.5ml to 5.0ml every four hours.  
Children 1 year – under 6 years: 5.0 ml to 10.0ml every four hours  
Children 6 years – 12 years: 10.0ml to 20.0ml every four hours  
Dosage for children under 3 months is at Physicians discretion.  
Not more than 4 doses should be administered in any 24-hour period.

### **4.3 Contraindications**

Hypersensitivity to Paracetamol.

### **4.4 Special warnings and precautions for use**

Use with caution in patients with Hepatic or Renal Dysfunction or Diabetes. Paracetamol should also be given with care to patients asking other drugs that effect the liver.

Occasionally malnourished patients may be more sensitive to the toxic effects of Paracetamol.

### **4.5 Interaction with other medicinal products and other forms of interaction**

Drugs, which induce hepatic microsomal enzymes such as Alcohol, Barbiturates and Tricyclic Antidepressants, may increase the hepatotoxicity of Paracetamol particularly after overdosage.

Where Paracetamol is taken regularly or in high doses and Oral Anticoagulants such as Warfarin are administered concurrently, potentiation of the oral Anticoagulant may occur.

### **4.6 Fertility, Pregnancy and lactation**

There is an epidemiological evidence of the safety of Paracetamol in pregnancy. Smaller effective doses should be used.

There is no evidence of harm where Paracetamol is or has been taken during breastfeeding. However, in cases where Paracetamol has been taken by nursing mothers, significant amounts have been found in breast milk.

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

Not applicable.

#### **4.8 Undesirable effects**

Side effects from Paracetamol administered in normal dose are rare. There have been isolated reports of Agranulocytosis, Methaemoglobinaemia and Thrombocytopenic Purpura, and after overdosage or prolonged administration isolated cases of Chronic Hepatic Necrosis, Acute Pancreatitis and Hepatotoxicity. Skin rashes and other allergic reactions occur occasionally.

#### **4.9 Overdose**

Overdosage should be treated promptly by gastric lavage followed by I.V.N-Acetylcysteine or oral Methionine since liver Damage following overdosage does not become apparent for 1 to 6 days after ingestion. Initial mild symptoms consist of Nausea, Vomiting and Pallor. Measurements of the blood Paracetamol level and the time lapsed since ingestion is important in order to determine whether further therapy with N-Acetylcysteine is necessary.

The hepatic changes produced by overdosage of Paracetamol result from the accumulation of highly reactive intermediated metabolites and hepatocytes.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Analgesic and Antipyretic

ATC code: N02BE01

Paracetamol has analgesic and antipyretic effects but has only weak anti-inflammatory effects.

These actions are considered to be due to inhibition of the Biosynthesis of Prostaglandins.

#### **5.2 Pharmacokinetic properties**

Paracetamol is readily absorbed from the gastro-intestinal tract with peak plasma concentrations occurring about 30 minutes to 2 hours after ingestion. It is metabolised in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates. Less than 5% is excreted as unchanged Paracetamol. The elimination half-life varies from 1-4 hours. Plasma protein binding is negligible at usual therapeutic concentrations but increase with increasing concentrations. A minor hydroxylated metabolite, which is usually produced in

very small amounts by mixed function, oxidises in the liver and which is usually detoxified by conjugation with liver glutathione may accumulate following Paracetamol overdosage and cause liver damage.

Particularly no Paracetamol is excreted unchanged, and the bulk is excreted after hepatic conjugation with glucuronic acid (about 60%) sulphuric acid (about 35%) or cysteine (about 3%)

Children have less capacity for glucuronidation of the drugs than do adults. When high doses are ingested Paracetamol undergoes N-Hydroxylation to form (for further details see product licence file).

### **5.3 Preclinical safety data**

None stated.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Alcohol 96%, Propylene Glycol, Potassium Sorbate, Sorbital, Glycerol, Saccharin Sodium, Raspberry Flavour (IFF 17.40.0478), Citric Acid Hydrated, Amaranth Ariavit 311801, Purified Water.

### **6.2 Incompatibilities**

None stated.

### **6.3 Shelf life**

36 months.

### **6.4 Special precautions for storage**

Do not store above 25°C. Keep the bottle tightly closed. Store in the original container.

**6.5 Nature and contents of container**

Amber glass bottles with ROPP cap, 60ml, 100ml, and 200ml.

**6.6 Special precautions for disposal**

None stated.

**7 MARKETING AUTHORISATION HOLDER**

Wise Pharmaceuticals Ltd.  
16 Oxford Street, Manchester, M1 5AE  
United Kingdom

**8 MARKETING AUTHORISATION NUMBER(S)**

PL 18374/0059

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

30 September 1996

**10 DATE OF REVISION OF THE TEXT**

05/08/2022