



## SUMMARY OF PRODUCT CHARACTERISTICS

### Product Summary

**1. Trade Name of the Medicinal Product**

Paracetamol Infant Drops 100 mg/ml  
Infadrops

**2. Qualitative and Quantitative Composition**

Paracetamol, 100mg per ml

**3. Pharmaceutical Form**

Oral solution

A clear, pink viscous liquid with an odour of raspberry.

### Clinical Particulars

**4.1 Therapeutic Indications**

Paracetamol Infant Drops are indicated in the management of pain and fever associated with such conditions as the common cold, influenza, headache and teething.

Paracetamol Infant Drops are suitable for babies who develop fever following vaccination at 2 months.

**4.2 Posology and Method of Administration**

For oral administration only.

Recommended Doses and Dosage Schedules.

Children

0 to 3 months : 0.6ml

For babies who develop a fever following vaccination at 2 months.

In all other cases the dose is 0.4 ml - on doctors advice only.

3 to 12 months : 0.8ml

12 months to 2 years : 1.2ml

2 to 3 years : 1.6ml

Use the measuring pipette provided. Dose may be given 3-4 times daily, at intervals of not less than 4 hours.

#### 4.3 **Contra-Indications**

Hypersensitivity to paracetamol or any other constituents of the preparation.

#### 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.

Prolonged use except under medical supervision could be harmful.

If symptoms persist for more than 3 days or worsen at any time, consult your doctor.

Do not exceed the stated dose.

**The label shall say: "Do not give with any other paracetamol-containing products" and "Immediate medical advice should be sought in the event of an overdose, even if the child seems well."**

The leaflet shall say: "Immediate medical advice should be sought in the event of an overdose, even if the child seems well, because of the risk of delayed, serious liver damage."

#### 4.5 **Interactions with other Medicaments and other forms of Interaction**

Patients who have taken barbiturates, tricyclic antidepressants and alcohol may show diminished ability to metabolise large doses of paracetamol, the plasma half-life of which can be prolonged.

Alcohol can increase the hepatotoxicity of paracetamol overdosage.

Chronic ingestion of anticonvulsants or oral steroid contraceptives induce liver enzymes and may prevent attainment of therapeutic paracetamol levels by increasing first pass metabolism or clearance.

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

The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.

#### 4.6 **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 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

Not relevant.

#### 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 and agranulocytosis, but these were not necessarily causally related to paracetamol.

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

#### 4.9 Overdosage

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 and any patient who had ingested around 7.5g or more of paracetamol in the preceding 4 hours should undergo gastric lavage. Administration of oral methionine or intravenous N-acetylcysteine which may have a beneficial effect up to at least 48 hours after the overdose, may be required. Measurements of the blood paracetamol level and the time elapsed since ingestion is important in order to determine whether further therapy with N-acetylcysteine is necessary. General supportive measures must be available.

Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, coma and death. Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

Liver damage is possible in adults who have taken 10g or more of paracetamol.

### Pharmacological Properties

#### 5.1 Pharmacodynamic Properties

ATC Classification: N02B E01 Other analgesics and antipyretics; Anilides

The site and mechanism of the analgesic effect of paracetamol is unclear. Paracetamol reduces fever by a direct action on the hypothalamic heat-regulating centres, which increases dissipation of body heat (via vasodilation and sweating). The action of endogenous pyrogen on heat-regulating centres is inhibited.

Paracetamol is almost as potent as aspirin in inhibiting prostaglandin synthetase in the CNS but its peripheral inhibition of prostaglandin synthesis is minimal, which may account for its lack of clinically significant anti rheumatic or anti-inflammatory effects.

Paracetamol does not inhibit platelet aggregation, affect prothrombin response or produce GI ulceration.

#### 5.2 Pharmacokinetic Properties

- Absorption:** Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract. Peak plasma concentrations occur within 0.5 to 2 hours, with slightly faster absorption of liquid preparations.
- Distribution:** Usual analgesic doses produce total serum concentrations of 5 to 20mcg/ml; a good correlation between serum concentration and analgesic effect has not been found. Serum protein binding varies from 20 to 50% at toxic serum concentrations.
- Metabolism:** Paracetamol is extensively metabolised in the liver by glucuronisation and conjugation with sulphates. Approximately 4% is metabolised via cytochrome P-450 to a toxic metabolite which is normally detoxified by preferential conjugation with hepatic glutathione and excreted in the urine as conjugates of cysteine and mercapturic acid. When paracetamol is used chronically or taken acutely in large doses, glutathione stores are depleted and hepatic necroses may occur.
- Elimination:** Paracetamol is excreted in the urine, mostly as metabolites; 2 to 4% is excreted unchanged. The average elimination half-life is 1 to 4 hours; half-life is slightly prolonged in neonates (2.2 to 5 hours) and in cirrhotics.

### 5.3 Preclinical Safety Data

Data in the literature on toxic doses and serum levels of paracetamol in children is limited, but paracetamol is relatively non-toxic in therapeutic doses.

Paracetamol toxicity may result from a single toxic dose or from long term ingestion of the drug. It has been reported in the literature that children may be less susceptible to acute paracetamol poisoning than adults. Hepatic necrosis is dose dependent and is the most serious acute toxic effect associated with overdosage. It is potentially fatal, and nausea, vomiting and abdominal pain usually occur within 2-3 hours after ingestion of toxic doses of the drug.

Acute toxic doses of paracetamol in laboratory animals produce death from liver and renal damage.

## Pharmaceutical Particulars

### 6.1 List of Excipients

Citric acid monohydrate  
 Erythrosine (E127)  
 Glycerol  
 Polyethylene Glycol 400  
 Propylene Glycol  
 Methyl parahydroxybenzoate  
 Propyl parahydroxybenzoate  
 Raspberry flavour No.1  
 Saccharin Sodium  
 Sodium Citrate  
 Purified Water

### 6.2 Incompatibilities

Not relevant.

### 6.3 Shelf Life

Unopened: 24 months.  
 Opened: 3 months.

**6.4 Special Precautions for Storage**

Store below 25°C, in a dry place.  
Protect from light.

**6.5 Nature and Contents of Container**

Amber glass bottles with black closures of LD-polyethylene.  
Enclosed with the bottle is a measuring pipette, made of plastic, with three graduations; 0.4ml, 0.6ml and 0.8ml. The bottle and the pipette are packed in a cardboard carton.

Pack sizes 15ml and 20ml.

**6.6 Instruction for Use/Handling**

No special instructions

**Administrative Data**

**7. Marketing Authorisation Holder**

Goldshield Pharmaceuticals Limited  
NLA Tower  
12-16 Addiscombe Road  
Croydon  
Surrey  
CR0 0XT  
United Kingdom

**8. Marketing Authorisation Number**

PL 12762/0135

**9. Date of First Authorisation/Renewal of Authorisation**

5 August 2002

**10. Date of (Partial) Revision of the Text**

**Legal Category**

**P** – Pharmacy only