SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Fennings Children's Cooling Powders

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Paracetamol 50mg

For excipients, see 6.1

3 PHARMACEUTICAL FORM

Oral powder

A fine light buff powder

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of pain arising from teething, headache, aches, pains and symptomatic relief of feverish colds, influenza and mild feverish conditions.

4.2 Posology and method of administration

Oral administration according to the following posology:

3 months to under 1 year	1 powder
1 year to under 6 years	2 powders
6 years to under 12 years	4 powders

Do not give more frequently than every 4 – 6 hours. Repeat to a maximum of 4 doses daily. The powder may be given in a little milk or jam.

4.3 Contraindications

Hypersensitivity to paracetamol and/or other constituents.

Not to be given to children under 3 months except on medical advice.

4.4 Special warnings and precautions for use

Use with caution in the presence of severe impaired renal or hepatic function.

Do not give with any other paracetamol-containing products.

Do not exceed the stated dose.

If symptoms persist consult your doctor.
Keep out of the reach and sight of children.
Contains paracetamol.
Patients with rare hereditary problems of galactose intolerance, the LAPP lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been reported in patients with severe illness such as severe renal impairment and sepsis, or in patients with malnutrition or other sources of glutathione deficiency (e.g. chronic alcoholism) who were treated with paracetamol at therapeutic dose for a prolonged period or a combination of paracetamol and flucloxacillin. If HAGMA due to pyroglutamic acidosis is suspected, prompt discontinuation of paracetamol and close monitoring is recommended. The measurement of urinary 5-oxoproline may be useful to identify pyroglutamic acidosis as underlying cause of HAGMA in patients with multiple risk factors.

4.5.1 Interaction with other medicinal products and other forms of interaction

Liver microsomal inducing agents such as barbiturates, tricyclic antidepressants and alcohol may increase paracetamol hepatotoxicity. The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by colestyramine.

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

Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis due to pyroglutamic acidosis, especially in patients with risks factors (see section 4.4).

4.6 Pregnancy and Lactation

A large amount of data on pregnant women indicate neither malformative, nor feto/neonatal toxicity. Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. If clinically needed, paracetamol can be used during pregnancy however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency.

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 applicable

4.8 Undesirable effects

Adverse events of paracetamol from historical clinical trial data are both infrequent and from small patient exposure. Accordingly, events reported from extensive post-marketing experience at therapeutic/labelled dose and considered attributable are tabulated below by system class. Due to limited clinical trial data, the frequency of these adverse events is not known (cannot be estimated from available data), but post-marketing experience indicates that adverse reactions to paracetamol are rare and serious reactions are very rare.

Body System	Undesirable effect	Frequency
Blood and lymphatic system disorders	Thrombocytopenia Agranulocytosis	Very rare
Immune system Disorders	Anaphylaxis Cutaneous hypersensitivity reactions including skin rashes, angiodema and Stevens Johnson syndrome/toxic epidermal necrolysis	Very rare
Respiratory, thoracic and mediastinal disorders	Bronchospasm*	Very rare
Hepatobiliary Disorders	Hepatic dysfunction	Very rare
Skin and subcutaneous tissue disorders	Very rare cases of serious skin reactions have been reported	Very rare
Metabolism and nutrition disorders	High anion gap metabolic acidosis	Not known

* There have been cases of bronchospasm with paracetamol, but these are more likely in asthmatics sensitive to aspirin or other NSAIDs.

Description of selected adverse reactions

High anion gap metabolic acidosis

Cases of high anion gap metabolic acidosis due to pyroglutamic acidosis have been observed in patients with risk factors using paracetamol (see section 4.4). Pyroglutamic acidosis may occur as a consequence of low glutathione levels in these patients.

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 at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Liver damage is possible in adults who have taken 10g or more of paracetamol. Ingestion of 5g or more of paracetamol may lead to liver damage if the patient has risk factors (see below).

Risk factors:

If the patient

- Is on long term treatment with carbamazepine, phenobarbital, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes.
- Regularly consumes ethanol in excess of recommended amounts.
- Is likely to be glutathione deplete e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.

Symptoms

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, haemorrhage, hypoglycaemia, cerebral oedema, and death. Acute renal failure with acute tubular necrosis, strongly suggested by loin pain, haematuria and proteinuria, may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

Management

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. Symptoms may be limited to nausea or vomiting and may not reflect the severity of overdose or the risk

of organ damage. Management should be in accordance with established treatment guidelines, see BNF overdose section.

Treatment with activated charcoal should be considered if the overdose has been taken within 1 hour. Plasma paracetamol concentration should be measured at 4 hours or later after ingestion (earlier concentrations are unreliable). Treatment with N–acetylcysteine may be used up to 24 hours after ingestion of paracetamol, however, the maximum protective effect is obtained up to 8 hours post-ingestion. The effectiveness of the antidote declines sharply after this time. If required the patient should be given intravenous N-acetylcysteine, in line with the established dosage schedule. If vomiting is not a problem, oral methionine may be a suitable alternative for remote areas, outside hospital. Management of patients who present with serious hepatic dysfunction beyond 24 hours from ingestion should be discussed with the NPIS or a liver unit.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

N02B E01 Other analgesics and antipyretics - anilides

Paracetamol is readily absorbed from the gastrointestinal tract.

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

A single or repeated therapeutic doses have no effect on cardiovascular or respiratory systems – acid based changes do not occur.

5.2 Pharmacokinetic properties

Peak plasma concentration:	30 mins to 2 hours after ingestion
Half life:	1 – 4 hours
Metabolism:	Liver
Excretion:	Urine (less than 5% is excreted as unchanged paracetamol). The bulk is excreted after hepatic conjugation with glucuronic acid, or cysteine, although small amounts of unconjugated paracetamol have also been detected.
Plasma protein binding:	Variable increases with increasing concentrations.

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

Liquorice Extract
Lactose
Calcium Phosphate
Heavy Magnesium Carbonate
Heavy Magnesium Oxide

6.2 Incompatibilities

None stated

6.3 Shelf life

36 months

6.4 Special precautions for storage

Keep dry and away from highly scented preparations

6.5 Nature and contents of container

The powder is contained in an unsealed paper sachet and enclosed in a cardboard carton of 10 or 20 powders with tamper evident seals.

6.6 Special precautions for disposal

Customers are advised not to accept the product if the tamper evident seals are broken.

7 MARKETING AUTHORISATION HOLDER

Crescent Pharma Limited
Units 3 and 4, Quidhampton Business Units
Polhampton Lane
Overton
Hampshire
RG25 3ED
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 20416/0208

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18/03/2003

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