1 NAME OF THE MEDICINAL PRODUCT

Fennings Paracetamol 120mg/5ml Oral Suspension

Well Pharmaceuticals Paracetamol 120mg/5ml Oral Suspension

Paracetamol 120mg/5ml Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml of the oral suspension contains Paracetamol 120mg

Excipients with known effect:

Maltitol liquid (E965) 1 ml

Sodium methyl parahydroxybenzoate (E219) 9 mg

Sodium propyl parahydroxybenzoate (E217) 1 mg

Strawberry flavour contains propylene glycol which amounts to 8mg of propylene glycol in 5ml. See section 4.4.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral Suspension

White to off-white uniform suspension.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Paracetamol 120mg/5ml Oral Suspension is indicated for the treatment of mild to moderate pain and as an antipyretic. It can be used in many conditions

including headache, toothache, earache, teething, sore throat, colds & influenza, aches and pains and post-immunisation fever.

4.2 Posology and method of administration

For the relief of fever after vaccinations at 2, 3 and 4 months:

One 2.5ml spoonful (small end). This dose may be given up to 4 times a day starting at the time of vaccination. Do not give more than 4 doses in any 24 hour period. Leave at least 4 hours between doses. If your baby still needs this medicine two days after receiving the vaccine talk to your doctor or pharmacist.

Age: 2 – 3 months	**Dose**
Pain and other causes of fever – if your baby weighs over 4kg and was born after 37 weeks (not premature)	One 2.5 mL spoonful (small end). If necessary, after 4-6 hours, give a second 2.5 mL dose
• Do not give to babies less than 2 months of age • Leave at least 4 hours between doses • Do not give more than 2 doses. This is to ensure that fever that may be due to a serious infection is quickly diagnosed. If your child is still feverish after two doses, talk to your doctor or pharmacist.	

Child's Age	**How Much**	**How often (in 24 hours)**
3 – 6 months	**One 2.5 mL spoonful (small end)**	**4 times**
6 – 24 months	**One 5 mL spoonful (large end)**	**4 times**
2 – 4 years	**One 5.0 mL spoonful (large end) and one 2.5 mL spoonful (small end)**	**4 times**
4 – 6 years	**Two 5 mL spoonfuls (large end)**	**4 times**
• **Do not give more than 4 doses in any 24 hour period** • **Leave at least 4 hours between doses** • **Do not give this medicine to your child for more than 3 days without**		

speaking to your doctor or pharmacist

It is important to **shake the bottle** for at least 10 seconds before use.

The Elderly:

In the elderly, the rate and extent of paracetamol absorption is normal but plasma half-life is longer and paracetamol clearance is lower than in young adults.

4.3 Contraindications

Paracetamol Oral Suspension is contra-indicated in patients with known hypersensitivity to paracetamol, or any of the other constituents listed in section 6.1.

4.4 Special warnings and precautions for use

Do not exceed the recommended dose. Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help straight away. Quick medical attention is critical for adults as well as children even if signs or symptoms are not noticed.

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. Chronic alcohol user should consult a doctor before use.

Concomitant use of other paracetamol-containing products should be avoided as this could lead to overdose and should therefore be avoided.

Patients should be informed about the signs of serious skin reactions and use of the drug should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.

This product contains sodium methyl parahydroxybenzoate (E219) and sodium propyl parahydroxybenzoate (E217). These may cause allergic reactions (possibly delayed).

It also contains maltitol liquid (E965). Patients with rare hereditary problems of fructose intolerance should not take this medicine.

The strawberry flavour contains propylene glycol in very small amounts of 8mg of propylene glycol in 5ml. This may be of significance when using the product for neonates.

The labelcontains the following statements:

- Contains paracetamol.
- Do not give anything else containing paracetamol while giving this medicine.
- For oral use only.
- Do not give more medicine than the label tells you to. If your child does not get better, talk to your doctor.
- Do not overfill the spoon.
- Always use the spoon supplied with the pack.
- Do not give to babies less than 2 months of age
- For infants 2-3 months no more than 2 doses should be given
- Do not give more than 4 doses in any 24 hour period.
- Leave at least 4 hours between doses.
- Do not give this medicine to your child for more than 3 days without speaking to your doctor or pharmacist
- As with all medicines, if your child is currently taking any medicine consult your doctor or pharmacist before taking this product.
- Do not store above 25°C. Store in the original package.
- Keep out of the sight and reach of children.
- Talk to a doctor at once if your child take too much of this medicine, even if they seem well

Shake the bottle for atleast 10 seconds before use. The leaflet contains the following statements:

- Talk to a doctor at once if your child takes too much of this medicine even if they seem well. This is because too much paracetamol can cause delayed, serious liver damage.
- Very rare cases of serious skin reactions have been reported. Symptoms may include:
  - Skin reddening
  - Blisters
  - Rash

If skin reactions occur or existing skin symptoms worsen, stop use and seek medical help right away.

Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been reported in patients with severe illness such as renal impairment and sepsis or 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 Interaction with other medicinal products and other forms of interaction

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 regular use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.

Chronic alcohol intake can increase the hepatotoxicity of paracetamol overdose and may have contributed to the acute pancreatitis reported in one patient who had taken an overdose of paracetamol. Acute alcohol intake may diminish an individual's ability to metabolise large doses of paracetamol, the plasma half-life of which can be prolonged.

The use of drugs that induce hepatic microsomal enzymes, such as anticonvulsants and oral contraceptives, may increase the extent of metabolism of paracetamol, resulting in reduced plasma concentrations of the drug and a faster elimination rate. Metabolism of paracetamol possibly accelerated by carbamazepine, fosphenytoin, phenytoin, phenobarbital, primidone (also isolated reports of hepatotoxicity).

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 Fertility, Pregnancy and lactation

Fertility

There is no information relating to the effects of Paracetamol Oral Suspension on fertility (see section 5.3).

Pregnancy

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. When given to the mother in therapeutic doses (1 g single dose), paracetamol crosses the placenta into foetal circulation as early as 30 minutes after ingestion and is metabolised in the foetus by conjugation with sulfate and increasingly with glutathione.

Breast-feeding

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

No adverse effects known.

4.8 Undesirable effects

Adverse drug reactions (ADRs) identified during clinical trials and post marketing experience with paracetamol are listed below by System Organ Class (SOC).

The frequencies are defined according to the following convention:

Very common ≥1/10
Common ≥1/100 to <1/10
Uncommon ≥1/1,000 to <1/100)
Rare ≥1/10,000 to <1/1,000
Very rare <1/10,000
Not known (cannot be estimated from the available data).

ADRs are presented by frequency category based on 1) incidence in adequately designed clinical trials or epidemiology studies, if available or 2) when incidence is unavailable, frequency category is listed as Not known.

System Organ Class (SOC)	**Frequency**	**Adverse Drug Reaction (Preferred Term)**
Blood and lymphatic system disorders	Not known	Blood disorder (including thrombocytopenia and agranulocytosis)[1]
Immune System Disorders	Very rare	Anaphylactic reaction
	Very rare	Hypersensitivity
Hepatobiliary disorders	Not known	Liver injury[2]

Skin and Subcutaneous Tissue disorders	Very rare	Rash
	Not known	Fixed eruption
	Not known	Rash pruritic
	Not known	Urticaria
Renal and urinary disorders	Uncommon	Nephropathy toxic
	Not known	Renal papillary necrosis[3]
Investigations	Not known	Transaminases increased[4]
Metabolism and Nutrition disorders	Not Known	High anion gap metabolic acidosis

[1] Reported following paracetamol use, but not necessarily causally related to the drug

[2]Chronic hepatic necrosis has been reported in a patient who took daily therapeutic doses of paracetamol for about a year

[3]Reported after prolonged administration

[4]Low level transaminase elevations may occur in some patients taking therapeutic doses of paracetamol; these elevations are not accompanied with liver failure and usually resolve with continued therapy or discontinuation of paracetamol.

Very rare cases of serious skin reactions have been reported.

Chronic hepatic necrosis has been reported in a patient who took daily therapeutic doses of paracetamol for about a year and liver damage has been reported after daily ingestion of excessive amounts for shorter periods. A review of a group of patients with chronic active hepatitis failed to reveal differences in the abnormalities of liver function in those who were long-term users of paracetamol nor was the control of the disease improved after paracetamol withdrawal.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Children who have ingested 75mg/kg or more of paracetamol in less than 1 hour should be referred to hospital. Administration of activated charcoal should be considered if paracetamol in excess of 150mg/kg is thought to have been ingested within the previous hour.

Liver damage is possible in adults and adolescents (≥12 years of age) who have taken 7.5g or more of paracetamol. It is considered that excess quantities of a toxic metabolite (usually adequately detoxified by glutathione when normal doses of paracetamol are ingested) become irreversibly bound to liver tissue. 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

a) Is on long term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes.

Or

b) Regularly consumes ethanol in excess of recommended amounts.

Or

c) 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, hyperhidrosis, malaise, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. This may include hepatomegaly, liver tenderness, jaundice, acute hepatic failure and hepatic necrosis. Abnormalities of glucose metabolism and metabolic acidosis may occur. Blood bilirubin, hepatic enzymes INR, prothrombin time, blood phosphate and blood lactate may be increased. 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.

Haemolytic anaemia (in patients with glucose-6-phosphate dehydrogenase [G6PD] deficiency): Haemolysis has been reported in patients with G6PD deficiency, with use of paracetamol in overdose.

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 24h from ingestion should be discussed with the NPIS or a liver unit.

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Non-Opioid Analgesic, Antipyretics (Anilides)

ATC code: N02B E01

Paracetamol has analgesic and antipyretic effects similar to those of aspirin and is useful in the treatment of mild to moderate pain. It has weak anti-inflammatory effects.

5.2 Pharmacokinetic properties

Absorption
Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract. Peak plasma concentrations are reached 30-90 minutes post dose and the plasma half-life is in the range of 1 to 3 hours after therapeutic doses.

Distribution
Drug is widely distributed throughout most body fluids.

Biotransformation
Metabolism occurs almost entirely via hepatic conjugation with glucuronic acid (about 60%), sulphuric acid (about 35%) or cysteine (about 3%). Small amounts of hydroxylated and deacetylated metabolites have also been detected.

Children have less capacity for glucuronidation of the drug than do adults.

In overdosage there is increased N-hydroxylation followed by glutathione conjugation. When the latter is exhausted, reaction with hepatic proteins is increased leading to necrosis.

Elimination
Following therapeutic doses 90-100% of the drug is recovered in the urine within 24 hours.

5.3 Preclinical safety data

Mutagenicity

There are no studies relating to the mutagenic potential of Paracetamol Oral Suspension.

In vivo mutagenicity tests of paracetamol in mammals are limited and show conflicting results. Therefore, there is insufficient information to determine whether paracetamol poses a mutagenic risk to man.

Paracetamol has been found to be non-mutagenic in bacterial mutagenicity assays, although a clear clastogenic effect has been observed in mammalian cells in vitro following exposure to paracetamol (3 and 10mM for 2h).

Carcinogenicity

There are no studies to the carcinogenic potential of Paracetamol Oral Suspension.

There is inadequate evidence to determine the carcinogenic potential of paracetamol in humans. A positive association between the use of paracetamol and cancer of the ureter (but not of other sites in the urinary tract) was observed in a case-control study in which approximate lifetime consumption of paracetamol (whether acute or chronic) was estimated. However, other similar studies have failed to demonstrate a statistically significant association between paracetamol and cancer of the urinary tract or paracetamol and renal cell carcinoma.

There is limited evidence for the carcinogenicity of paracetamol in experimental animals. Liver cell tumours can be detected in rats following chronic feeding of 500mg/kg/day paracetamol.

Teratogenicity

There is no information relating to the teratogenic potential of Paracetamol Oral Suspension. In humans, paracetamol crosses the placenta and attains concentrations in the foetal circulation similar to those in the maternal circulation. Intermittent maternal ingestion of therapeutic doses of paracetamol are not associated with teratogenic effects in humans.

Paracetamol has been found to be foetotoxic to cultured rate embryo.

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

Fertility

There is no information relating to the effects of Paracetamol oral suspension on fertility. A significant decrease in testicular weight was observed when male Sprague-Dawley rats were given daily high doses of paracetamol (500 mg/kg/body weight/day) orally for 70 days.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Polysorbate 80
Xanthan gum
Maltitol liquid
Saccharin sodium
Citric acid monohydrate
Sodium methyl parahydroxybenzoate
Sodium propyl parahydroxybenzoate
Strawberry flavour (containing propylene glycol)
Purified water

6.2 Incompatibilities

None Known

6.3 Shelf life

4 years

6.4 Special precautions for storage

Do not store above 25ºC. Store the container in the outer carton. Discard after 2 months of first opening.

6.5 Nature and contents of container

Amber Type III Glass

Child Resistant Tamper Evident Cap- High density polypropylene cap with a polyethylene lining

A spoon with a 2.5 ml and 5 ml measure is supplied with all packs of this product

Pack size: 100ml

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Crescent Pharma Limited
3&4 Quidhampton Business Units
Polhampton Lane
Overton
Hampshire
RG25 3ED
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 20416/0523 Legal status - GSL

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

22/11/2024

10 DATE OF REVISION OF THE TEXT

12/08/2025