National Agency for Food & Drug Administration & Control
(NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)
FIDSON PARACETAMOL SYRUP

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Fidson Paracetamol syrup 125mg/5ml.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains Paracetamol 125mg.

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral Syrup.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the relief of mild to moderate pain including headache, toothache and sore throat.

Symptomatic relief of influenza, feverishness and colds.

4.2 Posology and method of administration

Route of Administration: Oral

Dosage

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

Child's Age	How Much	How often (in 24 hours)*
6 – 8 years	One 5 mL	4 times
8 – 10 years	One 5.0 mL	4 times
10 – 12 years	Two 5 mL	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 • Do not give to children under the age of 6 years		

Children aged 12 – 16 years: Two – three 5mL 4 times a day

Adults and children over 16 years: Two – four 5mL to 4 times a day

However, for children between 3-12 months : 2.5ml -5ml 3 to 4 times a day
Children between 1-5 years: 5ml 3 to 4 times a day

4.3 Contraindications

Hypersensitivity to paracetamol or any of the other constituents.

4.4 Special warnings and precautions for use

The following medical advice should be given:

Should be used with caution in impaired kidney or liver function.
Patients with rare hereditary problems of fructose intolerance should not take this medicine.
If pain or fever persists for more than 3 days, consult your doctor.
Prolonged use without medical supervision may be harmful.
Do not exceed the stated dose.
In case of accidental overdose seek medical attention immediately.

- Contains paracetamol.
- Do not give this medicine with any other paracetamol-containing product.
- For oral use only.
- Never give more medicine than shown in the table.
- Do not overfill the spoon.
- Always use the spoon supplied with the pack.
- 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.
- Keep out of the reach and sight of children.

4.5 Interaction with other medicinal products and other forms of interaction

Alcohol, barbiturates, anti-convulsants and tricyclic anti-depressants may increase the hepatotoxicity of paracetamol particularly after an overdose.

Paracetamol may increase the half-life of chloramphenicol. The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by cholestyramine.

The anti-coagulant effect of warfarin and other coumarins may be enhanced by prolonged regular use of paracetamol with increased risk of bleeding.

4.6 Fertility, pregnancy and lactation

There is epidemiological evidence of the safety of paracetamol in human pregnancy. However, as with all drugs, caution should be exercised in its use during the first trimester.

Paracetamol is excreted in breast milk; however, it may be taken during lactation.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

If given in therapeutic doses side effects are very rare. Haematological reactions have been reported. Skin rashes and

other allergic reactions occur occasionally. Most reports of adverse reactions to paracetamol relate to overdosage with the drug.

4.9 Overdose

An overdose should be treated as soon as possible, (within 12 hours) as liver damage from an overdose does not become apparent for 1 to 6 days after ingestion. Initial symptoms include pallor, nausea, vomiting, anorexia and abdominal pain.

After gastric lavage a suitable antidote such as acetylcysteine or methionine should be given. Acetylcysteine is given by intravenous infusion in an initial dose of 150mg/Kg body weight over 15 minutes. Followed by 50mg/Kg over 4 hours and then by 100mg/Kg over the next 16 hours. Alternatively methionine 2.5g may be given by mouth every four hours to a total of four doses. The blood paracetamol levels should be monitored to determine whether therapy is necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Paracetamol.

ATC CODE: N02BE01.

Fidson Paracetamol Over 6 contains paracetamol which has analgesic and anti-pyretic properties.

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. The elimination half-life varies from about 1 to 4 hours.

5.3 Preclinical safety data

There are no pertinent data not already described elsewhere in this SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium methyl parahydroxybenzoate (E219)
Sodium propyl parahydroxybenzoate (E217)
Sodium saccharin
Sodium cyclamate
Tragacanth
Maltitol solution (E965)
Strawberry flavour PFW 500253E
Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store below 30°C.

6.5 Nature and contents of container

Amber glass sirop bottle, fitted with a tamper evident polypropylene copolymer cap with unfaced closed cell expanded polyethylene wad, containing 70ml, 100ml or 200ml packed into an outer carton.

No all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 APPLICANT/MANUFACTURER

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