BioWell FASMOL 250MG/5ML SUSPENSION

DESCRIPTION
Pink in colour suspension, opaque and with raspberry flavour.

CONTENT
Each 5 ml contains: Paracetamol.....250 mg
Preservatives: Methyl Paraben 0.1% w/v & Propyl Paraben 0.01% w/v

PHARMACODYNAMICS
Paracetamol is considered to act mainly by inhibiting the biosynthesis of prostaglandins. It is often described as peripherally acting compound. Antipyretic activity is considered to involve the hypothalamus.

PHARMACOKINETICS
Paracetamol is readily absorbed from the gastrointestinal 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 glucoronide and sulphate conjugates. Less than 5% is excreted as unchanged Paracetamol. The elimination half-life varies from about 1 hour to 4 hours. Plasma protein binding is negligible at usual therapeutic concentrations but increases with increasing concentrations. A minor hydroxylated metabolite which is usually produced in very small amounts by mixed-function oxidases in the liver and which is usually detoxified by conjugation with liver glutathione may accumulate following Paracetamol overdose and cause liver damage.

INDICATIONS
For relief of fever and pain (such as headache and toothache) in children.

RECOMMENDED DOSE
Children aged 1 to 5 years : ½ to 1 teaspoonful (2.5 ml to 5 ml).
6 to 12 years : 1 to 2 teaspoonfuls (5 ml to 10 ml).
Doses may be repeated every 4 to 6 hours when necessary (maximum of 4 doses in 24 hours).

ROUTE OF ADMINISTRATION
FOR ORAL USE ONLY

CONTRAINDICATIONS
Hypersensitivity to Paracetamol.

WARNINGS AND PRECAUTIONS
This drug should be used with care in hepatic and renal impairment. Long term usage should be avoided. Do not exceed the recommended dose or use for more than 10 days unless prescribed. Paracetamol should not to be taken concomitantly with a drug that acts on the liver.

THIS PREPARATION CONTAINS PARACETAMOL.
DO NOT TAKE ANY OTHER PARACETAMOL CONTAINING MEDICINES AT THE SAME TIME.

Allergic alert: *Paracetamol may cause severe skin reactions.*
Symptoms may include skin reddening, blisters or rash.
These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.

DRUG INTERACTION
Paracetamol should not to be taken concomitantly with alcohol, cholestyramine (reduces absorption of Paracetamol), Warfarin (prolonged use of Paracetamol enhances Warfarin), and Metoclopramide and Domperidone (accelerate absorption of Paracetamol (enhanced effect)).

PREGNANCY AND LACTATION
There is epidemiological evidence of safety with Paracetamol in human pregnancy.
Paracetamol is excreted in breast milk, but not in clinically significant quantities.

SIDE EFFECTS
Adverse effects are usually mild. Nausea, gastrointestinal upsets, rashes and allergic conditions have occurred. Overdose can cause hepatic damage that is signified by jaundice, gastrointestinal bleeding and hypoglycaemia.
Cutaneous hypersensitivity reactions including skin rashes, angioedema, Stevens Johnson Syndrome/Toxic Epidermal Necrolysis have been reported.

SYMPTOMS AND TREATMENT OF OVERDOSE
The only early features of Paracetamol poisoning are nausea and vomiting, which however, settle within 24 hours. This is usually followed by pain and tenderness in the right subcostal area of the abdomen.
Although the likely toxicity of a Paracetamol overdose can be assessed by examining the changing pattern of Paracetamol blood concentrations, prompt specific treatment is essential. Any patient therefore, who has taken 7.5 g or more of Paracetamol and can be treated within 10 hours of ingestion should be given a specific antidote, even if the blood concentrations are not known. There is a risk that the suphadryl donors used as antidotes may exacerbate any liver damage if given 10 hours after the overdose. Once specific therapy is established then blood concentrations of Paracetamol can be monitored. Generally, treatment is required if the blood concentration is higher than a line (the '200' line) drawn on log/linear paper joining the points 200 mg per litre at 4 hours and 60 mg per litre at 10 hours. There have been suggestions that treatment may be necessary when lower concentrations of Paracetamol are present.
Cysteamine is sometimes used by injection as an antidote but acetylcystein or methionine is now preferred. Acetylcystein is given by intravenous infusion in an initial dose of 150 mg per kg body-weight over 15 minutes followed by 50 mg per kg over 4 hours and then 100 mg per kg over the next 16 hours. Alternatively, methionine 2.5 g may be given by mouth every 4 hours to a total of 4 doses. Haemoperfusion may be worthwhile if too much time has elapsed since the poisoning to allow use of acethlcystein or methionine. Basic measures that may be required include dextrose and blood infusions. Removal of stomach contents by aspiration and lavage forms an early part of treatment and the administration of Activated Charcoal should be considered.

PACKING/PACK SIZE(S):
Plastic bottles of 100 ml.

JAUHI UBAT DARIPADA KANAK-KANAK
KEEP OUT OF REACH OF CHILDREN

SHAKE WELL BEFORE USE

STORAGE CONDITION:
Store below 30°C. Protect from light.

Product Registration Holder: **SSJ PHARMA SDN. BHD.**
658-D, Jalan Bukit Melaka 1/1,
Taman Bukit Melaka, Bukit Beruang,
Bukit Baru, 75450 Melaka Tengah,
Melaka, Malaysia.

Manufactured By: **DYNAPHARM (M) SDN. BHD. 198001011897 (65683-V)**
2497, MK1, Lorong Perusahaan Baru 5,
Kawasan Perushaan Perai 3, 13600 Perai
Pulau Pinang, Malaysia.

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