Package Insert

Jardin

Jardin Panadinol Syrup (Paracetamol 120mg/5ml)

Product Description
A clear red coloured syrup with strawberry flavour, containing;
- Paracetamol 120mg/5ml.

Pharmacodynamics
Paracetamol is a centrally acting analgesic and antipyretic with minimal anti-inflammatory properties.

Analgesic
The mechanism of analgesic action has not been fully determined. Paracetamol may act predominantly by inhibiting prostaglandin synthesis in the central nervous system (CNS) and, to a lesser extent, through a peripheral action by blocking pain-impulse generation. The peripheral action may also be due to inhibition of prostaglandin synthesis or to inhibition of the synthesis or actions of other substances that sensitize pain receptors to mechanical or chemical stimulation

Antipyretic
Paracetamol act centrally on the hypothalamic heat-regulating centre to produce peripheral vasodilatation, resulting in increased blood flow through the skin, sweating and heat loss. The central action probably involves inhibition of prostaglandin synthesis in the hypothalamus.

Pharmacokinetics
Following oral administration paracetamol is rapidly absorbed.

Absorption:
Paracetamol absorption takes place mainly in the small intestine and therefore the rate of absorption is depending on the rate of gastric emptying. It has been shown that drugs which delay gastric emptying also delay the absorption of paracetamol. The presence of food in the stomach has also been reported to reduce the rate of absorption of paracetamol. Alterations in gastric pH have no appreciable effect on paracetamol absorption. During absorption, the amount of paracetamol which is inactivated is negligible and it has been shown that paracetamol does not affect gastric mucosal permeability and does not produce mucosal bleeding. Peak plasma concentrations are reached 1 hour after absorption. The plasma half life is 1 to 3 hours.

Distribution:
Distributed into most body tissues; crosses the placenta and enters breast milk. Plasma protein binding: Approx 25%.

Metabolism:
Paracetamol is metabolized by the microsomal enzyme system of the liver. This metabolism is mainly to the glucuronide and sulphate conjugates, accounting for approximately 49% and 26% of the ingested dose respectively. About 4% is excreted as free paracetamol. Other minor pathways include the production of catechol derivatives and cysteine conjugates (via glutathione).

Excretion:
Paracetamol excretion is rapid and occurs via the urine. Elimination half-life: Approx 1-3 hr.

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Indications
Indicated for the relief of fever, headache and symptoms of cold and flu, toothache, discomfort of teething and fever after vaccination.

Recommended Dosage
For an accurate dosing, weight your child and work out the dosage to be given based on a 15mg of Paracetamol for every kg body weight given every 4 or 6 hours. e.g: If your child weighs 20 kg:

20 kg x 15 mg = 300 mg

300 mg / 120mg x 5ml = 12.5 ml

Maximum daily dose: 60mg/kg presented in divided doses of 10 - 15mg/kg throughout the 24 hour period.

The table below provides an illustrative guide for dosing based on the child's weight. Please note that this is just an example, and it is recommended to consult with a healthcare professional for precise dosing information.

Child's Age	Child's Weight (kg)	How much	How often (in 24 hours)
3 - 6 months	4	2.5 ml	4 times
6 - 24 months	8	5 ml	4 times
2 - 4 years	12	7.5 ml	4 times
4 - 8 years	16	10 ml	4 times
8- 10 years	24	15 ml	4 times
10 - 12 years	32	20 ml	4 times

- Below 3 months: 5 to 10mg/kg (on doctor's advise only).
- If the fever persists for more than 24 hours (4 doses), seek medical advice. This precaution ensures prompt diagnosis of any fever that might be indicative of a serious infection.
- 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.

Mode Of Administration
Oral.

Contraindications
Hypersensitivity to paracetamol or any of the other ingredients/components of the product. Severe and active hepatic impairment.

Warnings and Precautions
WARNING

This preparation contains Paracetamol.
Do not take any other paracetamol containing medicines at the same time.

- Do not take if allergic to paracetamol.
- Patients should contact their health care provider if symptoms persist (if the pain lasts for more than 10 days, if there is redness or fever lasts more than 3 days).
- Paracetamol should be given with care to patients with impaired kidney or liver function.
- Large doses should be avoided in patients with hepatic impairment. Paracetamol overdose may harm the liver.
- Do not exceed recommended dose.
- Allergy 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.

Interactions With Other Medications
The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.
The hepatotoxicity of Paracetamol, particularly after overdosage, may be increased by drugs which induce liver microsomal enzymes such as barbiturates, tricyclic antidepressants, and alcohol. The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and
absorption reduced by colestyramine.
Antivirals: Regular use of Paracetamol possibly reduces metabolism of Zidovudine (increased risk of neutropenia). 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.

Pregancy and Lactation
This product is intended to be used in children.

Side Effects
Adverse effects of paracetamol are rare and usually mild, although haematological reactions have been reported. Cutaneous hypersensitivity reactions including skin rashes, angioedema, Stevens Johnson Syndrome/ Toxic Epidermal Necrolysis have been reported.

Symptoms and Treatment of Overdose
Symptoms:
Toxic symptoms include vomiting, abdominal pain, hypotension and sweating. The most serious adverse effect of acute overdose of paracetamol is a dose-dependent, potentially fatal hepatic necrosis. Clinical and laboratory evidence of hepatoxicity may be delayed for up to one week. Major
manifestations of liver failure such as jaundice, hypoglycemia and metabolic acidosis may take at least 3 days to develop.

Treatment:
In cases of overdose, methods of reducing the absorption of ingested drug are important. Gastric lavage is essential even if several hours have elapsed. Prompt administration of 50g activated charcoal and 500ml iced mannitol 20% by mouth, may reduce absorption. If the history suggests that 15g Paracetamol or more has been ingested, administer one of the following antidotes:
Acetylcysteine 20% i.v.: Administer intravenously, 20% acetlcysteine (Parvolex, Glaxo) immediately without waiting for positive urine test or plasma level results: initial dose of 150mg/kg over 15 minutes, followed by continuous infusion of 50mg/kg in 500ml 5% glucose/dextrose over 4 hours and 100mg/kg in 1L 5% glucose/dextrose over 16 hours;
OR
Oral Methionine: 2.5g immediately followed by three further doses of 2.5g at four hourly intervals.
For a 3 year old child, 1g methionine every four hours for four doses has been used;
OR
Oral Acetylcysteine 5%: 140mg/kg as a loading dose, then 70mg/kg every 4 hours for a total of 17 maintenance doses. If more than ten hours have elapsed since the overdosage was taken, the antidote may be in ineffective

Effects on Ability to Drive and Use Machine
It is unlikely to impair a patient's ability to drive or use machinery.

Instruction for Use
Shake well before use.

Storage Conditions
Store below 30 °C.
Protect from light.
Keep bottle tightly closed.
Keep out of reach of children.

Dosage Forms And Packaging Available
Syrup. 60ml, 100ml and 120ml in HDPE bottle.

Shelf Life
24 months.

This insert contains basic prescribing information only. For further information, please consult your physician or pharmacist.

Product Registration Holder
Jardin Manufacturing Sdn. Bhd,
No. 12-1, Jalan Delta U6/19,
Sunway Subang Business Park,
Jalan TUDM, 40150 Shah Alam,
Selangor,Malaysia.

Manufacturer
Jardin Manufacturing Sdn. Bhd,
Lot 1, 2, 3 & 4,
Kawasan Industri Batu 7,
23000 Dungun,
Terengganu,Malaysia.

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