Important Information. Please read carefully.

Progesic®-250

Suspension

Relieves Pain And Fever In Children
Contains No Aspirin

Composition
Each 5 ml contains Paracetamol B.P. 250 mg

Pharmacodynamics
Paracetamol, a para-aminophenol derivative, has analgesic and antipyretic properties and weak anti-inflammatory activity.

Pharmacokinetics
Absorption
Paracetamol is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 10 to 60 minutes after oral doses.

Distribution
Paracetamol is distributed into most body tissues. It crosses the placenta and is present in breast milk. Plasma-protein binding is negligible at usual therapeutic concentrations but increases with increasing concentrations.

Metabolism
Paracetamol is metabolised mainly in the liver. A minor hydroxylated metabolite (N-acetyl-p-benzoquinoneimine), is usually produced in very small amounts by cytochrome P450 isoenzymes (mainly CYP2E1 and CYP3A4) in the liver and kidney. It is usually detoxified by conjugation with glutathione but may accumulate after paracetamol overdosage and cause tissue damage.

Elimination
The elimination half-life of paracetamol varies from about 1 to 3 hours. Paracetamol is excreted in the urine mainly as the glucuronide and sulfate conjugates. Less than 5% is excreted as unchanged paracetamol.

Actions and Uses
Progesic Suspension contains paracetamol - a modern analgesic that relieves pain and fever like aspirin but unlike aspirin may be used with confidence in children.
Progesic Suspension is recommended for the relief of fever and pain such as toothache, and headache in children.

Dosage and Administration

Children	1 – 5 years	2.5 ml - 5 ml every four to six hours
	6 – 12 years	5 ml - 10 ml every four to six hours
Adults	10 ml - 20 ml every four to six hours, up to a maximum of 80ml a day.	

Progesic Suspension may be taken before or after food with a glass of water.
Do not exceed the stated dose. If fever does not subside in 36 hours, a doctor should be consulted.

Contraindications
Like other paracetamol preparations, **Progesic** Suspension should not be used in patients who have shown hypersensitivity to Paracetamol.

Warning & Precautions

WARNING

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

Like other paracetamol preparations, **Progesic** Suspension should be used with caution in patients with kidney or liver disease. There is potential for liver toxicity and severe liver damage. Do not take more than the 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.

Serious skin reactions
Rarely, paracetamol may cause serious skin reactions such as acute generalised exanthematous pustulosis (AGEP), Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. 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.

Drug Interactions
The risk of paracetamol toxicity may be increased in patients receiving other potentially hepatotoxic drugs or drugs that induce liver microsomal enzymes. The absorption of paracetamol may be accelerated by drugs such as metoclopramide. Excretion may be affected and plasma concentrations altered when given with probenecid. Colestyramine reduces the absorption of paracetamol if given within 1 hour of paracetamol.

Side Effects
Progesic Suspension is usually well tolerated. However, if rashes occur, treatment should be discontinued.
Cutaneous hypersensitivity reactions including skin rashes, angioedema, Stevens Johnson Syndrome/Toxic Epidermal Necrolysis have been reported.

Symptoms and Treatment For Overdosage
Overdosage with paracetamol can result in severe liver damage and sometimes acute renal tubular necrosis. Prompt treatment with acetylcysteine or methionine is essential.
Early signs of overdosage (very commonly nausea and vomiting although they may also include lethargy and sweating) usually settle within 24 hours. Abdominal pain may be the first indication of liver damage, which is not usually apparent for 24 to 48 hours and sometimes may be delayed for up to 4 to 6 days after ingestion. Liver damage is generally at a maximum 72 to 96 hours after ingestion. Hepatic failure, encephalopathy, coma, and death may result.
Acute renal failure with acute tubular necrosis may develop, even in the absence of severe liver damage. Other non-hepatic symptoms that have been reported following paracetamol overdosage include myocardial abnormalities and pancreatitis.

Shelf-life
The expiry date is indicated on the packaging.

Presentation
Orange colour suspension with raspberry and cherry flavour in packs of 100ml.

Storage
Store below 30°C. Keep container well closed.

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN
JAUHI DARI KANAK-KANAK

For further information, please consult your pharmacist or physician.

Revision Date: 20-Feb-2020

Manufactured and Marketed by
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