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

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

1. Name of the medicinal product

Paracetamol injection 2ml:300mg

2. Qualitative and quantitative composition

One ml contains 150 mg paracetamol

For a full list of excipients, see section 6.1

3. Pharmaceutical form

Solution for injection.

The solution is clear.

4. Clinical particulars

4.1 Therapeutic indications

Pyrexia of unknown origin, fever and pain, associated with common childhood disorders, tonsilitis, upper respiratory tract infection, postimmunization reactions, post operative fever, after tonsillectomy and other conditions, where patient is unable to take oral medications but where Paracetamol can be administered with advantage for prevention of febrile convulsion, headache, cold, sinusitis, muscle pain, arthritis and toothache.

NOTE: Specific therapy with antibiotics or chemotherapeutic drugs of choice should be carried out whenever indicated.

4.2 Posology and method of administration

Intramuscular route: Adults: 2 - 3 ml every 4 to 6 hours.

Children (2 -12 years / > 33 kg): Up to 2 ml every 4 to 6 hours.

Below 2 years of age: Half to 1 ml every 4 to 6 hours.

Intravenous route: Slow I.V Administration.

4.3 Contraindications

Hypersensitivity to Paracetamol. Repeated administration is contraindicated in patients with anemia, cardiac, pulmonary, renal, and hepatic disease.

4.4 Special warnings and precautions for use

Contains sodium sulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life threatening or less severe asthamatic episodes in certain susceptible persons. Also contains Benzyl Alcohol. This should not be administered to new born or premature infants.

Paracetamol should be given with care to patients with impaired kidney or liver function.

Prescription-only medicine. To be used by or under the supervision of a medical practitioner only.

Do not take any Paracetamol containing medicines concurrently.

4.5 Interaction with other medicinal products and other forms of interaction

Paracetamol may enhance the activity of coumarin anticoagulants, but its effect is not generally of clinical significance.

4.6 Fertility, pregnancy and lactation

Pregnancy:

Clinical experience of the intravenous administration of paracetamol is limited. However, epidemiological data from the use of oral therapeutic doses of paracetamol indicate no undesirable effects in pregnancy or on the health of the foetus / newborn infant.

Prospective data on pregnancies exposed to overdoses did not show any increase in the risk of malformation.

No reproductive studies with the intravenous form of paracetamol have been performed in animals. However, studies with the oral route did not show any malformation or foetotoxic effects.

Nevertheless, Paracetamol 10 mg/ml Solution for Infusion should only be used during pregnancy after a careful benefit-risk assessment. In this case, the recommended posology and duration must be strictly observed.

Lactation

After oral administration, paracetamol is excreted into breast milk in small quantities. No undesirable effects on nursing infants have been reported. Consequently, Paracetamol 10 mg/ml Solution for Infusion may be used in breast-feeding women.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Paracetamol has rarely been found to produce any side effects intherapeutic doses and is usually well tolerated by aspirin sensitive patients.

Toxicity may result from a single toxic dose of the drug or from chronic ingestion. The following adverse reactions have been reported: skin eruption, haematological toxicity.

4.9 Overdose

Symptoms of overdosage may include nausea, vomiting, abdominal pain, diaphoresis, generalized weakness & lethargy. If an overdose of Paracetamol is suspected, blood should be withdrawn immediately for Paracetamol plasma assay, without regard to the presence or absence of symptomatology. The acute hepatotoxicity, nephrotoxicity of paracetamol can be overcome by the administration of sulfinydryl donors, e.g, N-acetyl cysteine which should be given as soon as possible after ingestion.

Treatment after 12 hours is not effective. Paracetamol overdose should be treated with gastric lavage if the patient is seen within 24 hours of ingestion of the drug.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group : other analgesics and antipyretics

ATC Code : N02BE01

Paracetamol is a clinically proven analgesic and antipyretic. It producesanalgesia by elevation of the pain threshold and antipyresis through action on the hypothalamic heat regulating centers. Paracetamol may act predominantly by inhibiting prostaglandin synthesis in the central nervous system 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 inhibition of the synthesis or actions of other substances that sensitize pain receptors to mechanical or chemical stimulation.

Paracetamol produces antipyresis by acting centrally on the hypothalamic heat-regulating center to produce peripheral vasodilation resulting in increased blood flow through the skin, sweating and heat loss. The central action probably involves inhibition of prostaglandin synthesis in thehypothalamus.

5.2 Pharmacokinetic properties

Paracetamol is distributed throughout most body tissues. About 25% of Paracetamol in blood is bound to plasma proteins. The plasma half-life is 1.25 to 3 hours but may be increased by liver damage and following overdose. Paracetamol is metabolized in the liver. About 85% of a dose of Paracetamol is excreted in urine as free and conjugated Paracetamol within 24 hours.

5.3 Preclinical safety data

Preclinical data reveal no special hazard for humans beyond the information included in other sections of the SmPC.

6. Pharmaceutical particulars

6.1 List of excipients

Propylene glycol, polyethylene glycol-400, ethanol, benzyl alcohol, disodium edentate, anhydrous sodium sulfite, water for injections.

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products except for dilution with 0.9% sodium chloride or 5% glucose solution

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 30℃. Protect from light. Store in the original package. Do not refrigerate or freeze.

6.5 Nature and contents of container

Ampoules made of low borosilicate glass.

6.6 Special precautions for disposal and other handling

Before administration, the product should be visually inspected for any particulate matter and discolouration. For single use only. Any unused solution should be discarded.

7.Manufacturer

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