1.3 Product Information
1.3.1 Summary of Product Characteristics (SmPC)

1. Name of the Medicinal Product

(a) Product Name	:	Fexona Paracetamol Injection (Paracetamol Injection)
(b) Strength	:	150 mg/ml
(c) Pharmaceutical Dosage Form	:	Injection

2. Quality and Quantitative Composition
(a) Qualitative Declaration, the active substance should be declared by its recommended INN. Accompanied by its salt or hydrate form if relevant.

Composition:
Each ml contains:
Paracetamol BP 150 mg

(b) Quantitative Declaration, the quantity of the active substance must be expressed per dosage unit

Sr. No.	Name of the Materials	Specification	Label Claim	Quantity (mg/ml)	Active/ Inactive
1	Paracetamol	B.P.	150 mg	150 mg	Active

3. Pharmaceutical Form Visual description of the appearance of the product (colour, markings, etc.) e.g.: Clear colourless solution filled in amber glass vial.

4. Clinical Particulars

4.1 Therapeutic Indications:
Fexona Paracetamol Injection is indicated for the treatment of 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.

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 the active substance, or to any of the excipients. Repeated administration is contraindicated in patients with anemia, cardiac, pulmonary, renal, and hepatic disease.

4.4 Special warning 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.

4.5 Interaction with other medicinal products and other forms of interactions:
Paracetamol may enhance the activity of coumarin anticoagulants, but its effect is not generally of clinical significance.

4.6 Pregnancy and lactation:
Pregnancy:
Pregnancy Category C. There are no studies of intravenous paracetamol in pregnant women; however, epidemiological data on oral paracetamol use in pregnant women show no increased risk of major congenital malformations. Animal reproduction studies have not been conducted with IV paracetamol, and it is not known whether paracetamol can cause fetal harm when administered to a pregnant woman. Paracetamol should be given to a pregnant woman only if clearly needed.

Breastfeeding/lactation:
While studies with paracetamol have not been conducted, paracetamol is secreted in human milk in small quantities after oral administration. Based on data from more than 15 nursing mothers, the calculated infant daily dose of paracetamol is approximately 1 to 2% of the maternal dose. There is one well-documented report of a rash in a breast-fed infant that resolved when the mother stopped paracetamol use and recurred when she resumed paracetamol use. Caution should be exercised when paracetamol is administered to a nursing woman.

4.7 Effects on ability to drive and use machine:
Not relevant

4.8 Undesirable Effects:
Paracetamol has rarely been found to produce any side effects in therapeutic 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: analgesic and antipyretic., ATC code: N02BE01

Mechanism of action:
Paracetamol is a clinically proven analgesic and antipyretic. It produces analgesia 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 the hypothalamus.

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:

Non-clinical 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:

Sr. No.	Name of the Materials	Specification
1	Benzyl Alcohol	B.P.
2	Ethyl alcohol (Inj Grade)	B.P.
3	Propylene Glycol	B.P.
4	PEG 400	B.P.
5	Sodium thio sulphate	B.P.
6	Water for Injection	B.P.

6.2 Incompatibilities:
This medicinal product must not be mixed with other medicinal products except those mentioned in Section 6.6.

6.3 Shelf life:
36 Months

6.4 Special precautions for storage:
Store in a dark and dry place below 25°C. Protect from light and moisture. Do not refrigerate or freeze.

6.5 Nature and contents of container:
15.0 mL vial. Such 10 vials are packed in printed carton along with package insert.

6.6 Instructions for use and handling
Before administration, the product should be visually inspected for any particulate matter and discolouration. For single use only. Any unused product or waste material should be disposed of in accordance with local requirements.

7. Applicant/Manufacturer

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