1. NAME OF THE MEDICINAL PRODUCT

NURAFIVA (Paracetamol Injection 150mg/ml)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Paracetamol BP…….. 150mg

Benzyl Alcohol BP…… 2 %V/V

Water for Injections BP… QS

{For a full list of excipients, see section 6.1}

3. PHARMACEUTICAL FORM

A clear colourless oily solution

4. Clinical particulars

4.1 Therapeutic indications

It is indicated for the relief of mild to moderate pain and the reduction of fever where an intravenous route of administration is considered clinically necessary.

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.

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 Pregnancy and Lactation

Pregnancy

A large amount of data on pregnant women indicate neither malformative, nor feto/neonatal toxicity. Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. If clinically needed, paracetamol can be used during pregnancy however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency.

4.7 Effects on ability to drive and use machines

Not Known.

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 Pharmacodynamics properties

Pharmacotherapeutic group: Analgesics (pain relievers) and Antipyretics (fever reducers)

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

Preclinical studies of Paracetamol injection have been completed. No intolerance has yet been observed.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Paracetamol BP/Ph. Eur

Sodium Metabisulphite BP

Propylene Glycol USP

Polyethylene Glycol 400 BP

Benzyl Alcohol BP

Sodium Acetate BP

Glacial Acetic Acid BP

Water for injection BP

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months from the date of manufacturing.

Use immediately after opening, any unused portion should be discarded.

Special precautions for storage.

Store in a cool & dry place below 30°C. Protect from Light.

Keep all medicines out of the reach of children.

6.4 Nature and contents of container

10 x 2ml, Amber, Blue Dot OPC Glass Ampoule.

6.5 Special precautions for disposal and other handling

Any unused portion should be discarded as per local regulations

7. MANUFACTURER

M/s FARBE FIRMA Pvt Ltd

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