תרכיש מהימן ל 대해 ו מצורף להודעה זו וכן נשלח לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות.

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בברכה,

אלנה שוויגמן-
רוקחת ממונה
מדיק-תרים בריאות בע"מ
1. NAME OF THE MEDICINAL PRODUCT

Paracetamol - Fresenius 10 mg/ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 50 ml vial contains 500 mg paracetamol.

3. PHARMACEUTICAL FORM

Each 50 ml vial contains 500 mg paracetamol. As for all solutions for infusion presented in glass vials, the vials are not sterile.

4. PSD (Protein Sorting Domain) of the Medicated Product

The user should be referred to the product information section 4.2.

5. ADMINISTRATION

A 5 or 10 ml syringe should be used to measure the dose of paracetamol. A 50 ml vial of paracetamol should be undiluted (from one to nine volumes diluent) in a 0.9% sodium chloride 9 mg/ml (0.9 %) solution or 50 mg/ml glucose (5 %) solution up to one tenth (one volume Paracetamol – Fresenius 10 mg/ml). In order to avoid the risk of overdose, check that other medicinal products (see section 4.9).

Method of administration:

The dose must not exceed 40 mg/kg body weight.

Preparation of drug solution:

The solution should be prepared in a separate area, away from other forms of interaction.

Once the solution is prepared, it must be used within 4 hours.

B. Paracetamol hydrochloride (prodrug of paracetamol)

Paracetamol hydrochloride is a prodrug of paracetamol. Propacetamol has been administered in a single dose of 500 mg/kg in rats and rabbits. The dose, when given IP, was 15 mg/kg.

C. Administration with other medicinal products and administration in patients with severe renal insufficiency

Concomitant use of paracetamol and oral anticoagulants may lead to decreased anticoagulant activity. This effect is most frequently observed at the first appearance of skin rash or any other sign of hypersensitivity. There is a risk of liver injury (including fulminant hepatitis, necrosis) and some antiepileptics (carbamazepine, phenytoin, phenobarbital), and some antiepileptics (carbamazepine, phenytoin, phenobarbital). There is a risk of liver injury (including fulminant hepatitis, necrosis).

The following adverse events have been noted with propacetamol in patients with severe renal insufficiency (creatinine clearance ≤ 30 mL/min) and some antiepileptics (carbamazepine, phenytoin, phenobarbital). There is a risk of liver injury (including fulminant hepatitis, necrosis) and some antiepileptics (carbamazepine, phenytoin, phenobarbital). There is a risk of liver injury (including fulminant hepatitis, necrosis).

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5. Pharmacodynamic properties

Paracetamol 10 mg/ml reduces fever within 30 minutes after the start of administration. Paracetamol 10 mg/ml provides onset of pain relief within 5 to 10 minutes after the start of administration.

The antipyretic effect of at least 6 hours after the start of administration with a duration of the effect needed in patients with fever.

The analgesic properties of paracetamol has yet to be established; it is known that paracetamol possesses antipyretic, anilides, ATC code: N02BE01.

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5.1 Pharmacodynamic properties

Paracetamol is metabolised mainly in the liver following conjugation with glucuronic acid and sulphate. The glucuronide and sulphate conjugates are excreted in the urine. 90% of the dose administered is excreted in the urine. The volume of distribution of paracetamol is 10⁻³⁰ mL/min, the elimination half-life ranging from 2 to 5.3 hours. For the glucuronide and sulphate conjugates, the elimination rate is 3 times slower in subjects with severe renal impairment (see section 4.2), to increase elimination rate is 3 times slower in subjects with severe renal impairment (see section 4.2), to increase elimination rate is 3 times slower in subjects with severe renal impairment (see section 4.2).

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The elimination of paracetamol is age-related. Paracetamol concentrations were determined in the serum of neonates, children and adults. The elimination half-life is 2.5 hours shorter in children than in adults (1.5 to 2 h) and is significantly prolonged in adults with severe renal impairment (see section 4.2). Paracetamol concentrations were determined in the serum of neonates, children and adults. The elimination half-life is 2.5 hours shorter in children than in adults (1.5 to 2 h) and is significantly prolonged in adults with severe renal impairment (see section 4.2).

5.2 Pharmacokinetic properties

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The treatment includes administration of the antidote, N-acetyl cysteine (NAC), and charcoal. The treatment is particularly effective if given before the 4-hour window, and it can still be useful for up to 10 hours after ingestion. NAC can be given as a single dose (500 mg/kg) or in divided doses (100 mg/kg every 4 hours for 24 hours) to patients with paracetamol overdose. NAC can be given as a single dose (500 mg/kg) or in divided doses (100 mg/kg every 4 hours for 24 hours) to patients with paracetamol overdose.

6. Preclinical pharmacology

Paracetamol is metabolised mainly in the liver following conjugation with glucuronic acid and sulphate. The glucuronide and sulphate conjugates are excreted in the urine. 90% of the dose administered is excreted in the urine. The volume of distribution of paracetamol is 10⁻³⁰ mL/min, the elimination half-life ranging from 2 to 5.3 hours. For the glucuronide and sulphate conjugates, the elimination rate is 3 times slower in subjects with severe renal impairment (see section 4.2), to increase elimination rate is 3 times slower in subjects with severe renal impairment (see section 4.2).

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