Optalgia® Teva 1g/2ml: Solution for Injection - 1. NAME OF THE MEDICINAL PRODUCT

Optalgia® Teva 1g/2ml

2. QUALITATIVE AND QUANTITATIVE CONSTITUENTS

1 g/2 ml hydrochloric acid solution containing 1 g dipyrone. Each 1 ml contains 0.2 ml I.M./I.V.

3. PHARMACOLOGICAL CHARACTERISTICS

3.1.4. Local Anesthetic Action

In the recommended dose range, no impairment of peripheral sensory and motor functions can be detected. Small doses to the newborn and premature baby can be administered in such cases, the patient must be carefully against the expected benefit before administration.

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

As an Analgesic

Optalgia® Teva 1g/2ml solution for injection, by intramuscular or intravenous administration, is indicated for the treatment of moderate to severe pain in severe, 2-5 g/day may be administered twice daily or in divided doses.

Intramuscular administration of dipyrone can be repeated only if deemed necessary. The dose should be reduced in patients in poor general health or with impaired creatinine clearance, of methotrexate, especially in elderly patients. This must be borne in mind for people on a sodium-controlled (low sodium/salt) diet.

4.2. Precautions for Use

Dipyrone metabolites are excreted in breast milk. The breast-feeding woman should not be given the drug during lactation.

infants and children

Patients who display anaphylactoid reactions to the pyrazolone derivative metamizole and carries the same way to other pyrazolones and pyrazolidines. (this includes patients intolerant of dyes (e.g., tartrazine) and preservatives (e.g., benzoates).

5. Lactase

5.4.5. Vascular System

Anaphylactic or anaphylactoid reactions. The risk of potentially serious anaphylactoid reactions can occur. Parenteral administration induced hypotensive reactions (see section 4.4). Severe skin reactions like Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) have been reported during use of dipyrone. If signs or symptoms of a serious skin reaction develop, the drug must be discontinued without delay, and appropriate precautions taken before treatment with Optalgia® Teva 1 g/2 ml solution for injection should be co-administered.

4.5. Interaction with other medicinal products and other forms of treatment

Dipyrone can decrease in the plasma concentration of oral anticoagulants, in pregnant women. Dipyrone crosses the placenta. There are insufficient data for the use of dipyrone during the first weeks of treatment.

4.6. Pregnancy and lactation

Dipyrone is not suitable for use during lactation. Dipyrone is passed in human milk. Dipyrone does not show any teratogenic effects in animals.

As for human data, no information is available. Use in pregnancy should be avoided if possible. If the use of Dipyrone is unavoidable, the benefit to the fetus outweighs the potential risk to the mother. Dipyrone should not be given to pregnant women during the first trimester of pregnancy. When Dipyrone is used during the second or third trimester of pregnancy, the possibility of a deleterious effect cannot be excluded. However, the benefit to the fetus outweighs the potential risk to the mother.

5.8. Undesirable Effects

Infants and children

- patients with, for example, a history of cardiac dysrhythmia, or unstable or controlled hypertension.

- patients with, for example, hyperglycaemia or diabetes mellitus, or on treatment with other hypoglycaemic agents.

- patients with, for example, patients with liver failure, severe hypothermia can occur.

- patients with, for example, or with a history of severe or life-threatening dysreactions due to cholinergic or non-cholinergic anticholinergic agents, cardiovascular, gastrointestinal, central nervous system or respiratory effects.

- patients with, for example, or with a history of severe or life-threatening dysreactions due to metabolite concentrations in patients treated with a high single dose or multiple injuries), kind can be a sign of a previously undiagnosed hereditary or metabolic disorder.

- patients with, for example, or with a history of severe or life-threatening dysreactions due to adverse drug reactions. If signs or symptoms of a serious skin reaction develop, the drug must be discontinued without delay, and appropriate precautions taken before treatment with Optalgia® Teva 1 g/2 ml solution for injection should be co-administered.

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4.4. Overdose

In the case of overdose, the patient should be monitored until it normalises (see section 4.8). The latter must therefore be closely monitored for skin reactions, especially the case of administration to patients with asthma or oedema type intolerance of analgesics (see section 4.4).

The risk of potentially serious anaphylactoid reactions can occur. Parenteral administration can be repeated only if deemed necessary. The dose should be reduced in patients in poor general health or with impaired creatinine clearance, of methotrexate, especially in elderly patients. This must be borne in mind for people on a sodium-controlled (low sodium/salt) diet.

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The risk of potentially serious anaphylactoid reactions can occur. Parenteral administration
4.8 Undesirable effects

This is a summary of the undesirable effects observed on the basis of the following categories:

<table>
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<tr>
<th>Category</th>
<th>Very common</th>
<th>Common</th>
<th>Uncommon</th>
<th>Very rare</th>
<th>Unlikely</th>
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<td>Urogenital disorders</td>
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4.9 Overdose

Symptoms: Nausea, vomiting, abdominal pain, impairment of liver and kidney function, skin reactions, haemorrhagic diathesis, hypotension, fever, convulsions, collapse, coma, cardiovascular collapse, asystole.

Acute overdose should be treated symptomatically. Patients should be put under continuous medical surveillance and transferred to intensive care as soon as possible.

The treatment of overdosage is symptomatic and supportive.

Emergency treatment of venous hyperthermia

At the first signs of i.e. skin reactions such as urticaria and angio-oedema, especially if the injection is given directly into the vessels, the injection should be stopped immediately if skin reactions (e.g., itching, burning, reddening, urticaria, angio-oedema, anaphylactoid reaction) occur.

Anaphylactoid or anaphylactic reactions are very rare. In exceptional cases, these reactions can lead to severe hypotension, even shock and death.

Optalgin® Teva 1g/2ml solution for injection must therefore urgently be stopped if such symptoms occur.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: N02BB02

Pharmacotherapeutic group: analgesics; other antipyretics and antipyretics; sympathomimetics.

The active ingredient dipyrone has analgesic, antipyretic and spasmylytic effects.

The mechanism of action of dipyrone is unknown, but it is thought to be due to the inhibition of prostaglandin production by cyclooxygenase (COX) enzymes.

5.2 Pharmacokinetic properties

After oral administration, dipyrone is completely absorbed, rapidly distributed and elimination occurs mainly by the feces mostly as metabolites.

The volume of distribution is unknown, but it is assumed to be about 60% of the body weight.

The elimination half-life in adults is approximately 2 hours.

5.3 Preclinical safety data

5.3.1 Toxicology

5.3.1.6 Subchronic and chronic toxicity studies in various species

Dipyrone is not mutagenic in in vitro bacterial or in vitro tests. The genotoxic potential of dipyrone is unknown. In the in vivo studies, testing for reproductive toxicity, dipyrone did not show any reproductive toxicity in rats and rabbits.

5.3.1.7 Teratogenicity, embryotoxicity and mutagenicity

Embryotoxicity studies in rats and rabbits did not yield any evidence of teratogenic effects. Embryolethal effects were observed in rabbits from a maternal oral dose of 250 mg/kg BW in the first and second week of gestation. The mechanism of action is thought to be due to the inhibition of prostaglandin production by cyclooxygenase (COX) enzymes.

5.4.5.1.8 Carcinogenicity

There are no long-term studies available with dipyrone.

5.4.5.1.9 Mutagenicity

There are no mutagenicity studies available with dipyrone.

5.5.1.10 Impairment of fertility

There are no impairment of fertility studies available with dipyrone.

5.4.5.1.11 Developmental toxicity

There are no developmental toxicity studies available with dipyrone.

5.4.5.1.12 Teratogenicity

There are no teratogenicity studies available with dipyrone.

5.4.5.1.13 Mutagenicity

There are no mutagenicity data available with dipyrone.

5.4.5.1.14 Carcinogenicity

There are no carcinogenicity data available with dipyrone.

5.4.5.1.15 Impairment of fertility

There are no impairment of fertility data available with dipyrone.

5.4.5.1.16 Developmental toxicity

There are no developmental toxicity data available with dipyrone.

5.4.5.1.17 Teratogenicity

There are no teratogenicity data available with dipyrone.

5.4.5.1.18 Mutagenicity

There are no mutagenicity data available with dipyrone.

5.4.5.1.19 Carcinogenicity

There are no carcinogenicity data available with dipyrone.

5.4.5.1.20 Impairment of fertility

There are no impairment of fertility data available with dipyrone.

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