SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

MILZOR TABLETS (Paracetamol Tablets BP 500 mg)

Strength

Paracetamol BP 500 mg

Pharmaceutical Form

Uncoated Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Uncoated Tablet contains:

Paracetamol BP…500 mg

3. PHARMACEUTICAL FORM

Uncoated Tablet

Description

White coloured, round, uncoated tablet having ‘P/500’ mark and breakline on one side and other side plain of each tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Milzor tablets are used for the relief of headache, rheumatic pains, neuralgia and relief of symptoms of colds and influenza.

4.2 Posology and method of administration

Adults and children over 12 years

One to two 500mg tablets every four to six hours, not exceeding eight tablets in any 24 hour period.

Children 6 to 12 years

Half to one tablet to be taken three or four times daily at intervals of not less than four hours, up to a maximum of four tablets in 24 hours.

4.3 Contraindications

Hypersensitivity to any of the ingredients of Milzor tablet. It may also cause severe liver disease.

4.4 Special warnings and special precautions for use

Milzor tablets should be taken with caution in patients with impaired liver and kidney function. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease. Patient should not exceed the stated dose. Milzor tablet should not to be given to children under 6 years, without medical advice. Dosage should not be continued for more than three days without consulting your doctor.

4.5 Interaction with other medicinal products and other forms of interaction

The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by cholestyramine. The anticoagulant effect of warfarin and other coumarin may be enhanced by prolonged regular use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.

4.6 Pregnancy and lactation

Epidemiological studies in human pregnancy have shown no ill effects due to paracetamol when used in the recommended dosage but patients should follow the advice of their doctor regarding its use.

Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data do not contraindicate breast feeding.

4.7 Effects on ability to drive and use machines

No adverse effects known.

4.8 Undesirable effects

Side-effects are usually mild and may include skin rashes and other allergic reactions occasionally. Very rarely there have been reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these were not necessarily causally related to paracetamol.

4.9 Overdose

Symptoms of paracetamol overdosage in the first 24 hours include pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion as liver function tests become abnormal. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe cases liver failure may lead to encephalopathy, coma and death. Acute renal failure with acute tubular necrosis may develop with or without severe liver damage. Cardiac arrhythmias and pancreatitis have been reported. Liver damage is likely in adults who have taken 10g or more of paracetamol. It is considered that excess quantities of a toxic metabolite (usually

adequately detoxified by glutathione when normal doses of paracetamol are ingested), become irreversibly bound to liver tissue.

Immediate treatment is essential in the management of paracetamol overdosage. Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention and any patient who has ingested around 7.5g or more of paracetamol in the preceding 4 hours should undergo gastric lavage. Administration of oral methionine or intravenous N-acetylcysteine which may have a beneficial effect up to at least 48 hours after the overdose, may be required. General supportive measures must be available.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Paracetamol is a peripherally acting analgesic with antipyretic activity.

5.2 Pharmacokinetic properties

Paracetamol is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 30 minutes to 2 hours after ingestion. Paracetamol is metabolised in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates, with about 10% as glutathione conjugates. Less than 5% is excreted as unchanged paracetamol. The elimination half-life varies from about 1-4 hours. Plasma protein binding is negligible at usual therapeutic concentrations, although this is dose-dependent.

5.3 Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium starch glycolate, Starch, Micro crystalline cellulose, Gelatin, Sodium lauryl sulphate, Polyvinylpyrolidone, Talcum powder, Magnesium Stearate.

Preservative: Methyl paraben, Propyl paraben

6.2 Incompatibilities

None known

6.3 Shelf life

36 months

6.4 Special precaution for storage

Protect from light.

6.5 Nature and contents of container

Aluminium -PVC Blister pack

Pack size: Blister pack of 10X10 T

Bulk pack of 1000's T

6.6 Special precautions for disposal

Not applicable

7. REGISTRANT

Milan Laboratories (India) Pvt. Ltd.
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opp.MIDC Office, Wagle Estate,
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8. MANUFACTURER

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Plot No. 35, 36, 63, 64, 65, 67 & 87.
J.C.I.E. LTD., Kamothe,
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9. MARKET AUTHORIZATION NUMBER

04615/4991/NMR/2017

10. DATE AUTHORIZATION
Sep 4, 2019