SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

MILPOL SYRUP (Paediatric Paracetamol Oral Solution BP 120mg/5ml)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Label Claim: Each 5ml contains:

Paracetamol BP 120mg

Preservatives: Sodium Benzoate-10.0 mg/tab

Methyl Paraben-9.0 mg/tab

Propyl Paraben-1.0 mg/tab

3. PHARMACEUTICAL FORM: Syrups

Red coloured syrup having pleasant flavour

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of mild to moderate pain and as an anti-pyretic. Used for the relief of pain and feverishness associatedwith teething, toothache, headache, colds, flu and post-immunisation pyrexia

4.2 Posology and method of administration

1- 3 years: ½ teaspoonful 2-3 times a day.

3- 7years:1-2 teaspoonful 2-3 times a day.

7- 12 years: 2 teaspoonful 2-3 times a day or as directed by the Physician.

If necessary the dose can be repeated every 4-6 hours up to a maximum of 4 doses in 24 hours.

4.3 Contraindications:

Hypersensitivity to Paracetamol or any of the other constituents.

4.4 Special warnings and precautions for use:

Care is advised in the administration of Paracetamol to patients with severe renal or severe hepatic impairment. Thehazards of overdose are greater in those with (non-cirrhotic) alcoholic liver disease.

Caution is advised if paracetamol is administered concomitantly with flucloxacillin due to increased risk of high anion gapmetabolic acidosis (HAGMA), particularly in patients with severe renal impairment, sepsis, malnutrition and othersources of glutathione deficiency (e.g. chronic alcoholism), as well as those using maximum daily doses of paracetamol.Close monitoring, including measurement of urinary 5-oxoproline, is recommended.

The label should contain the following statements:

• Contains paracetamol.

• Do not give this medicine with any other paracetamol-containing product.

• For oral use only.

• Never give more medicine than shown in the table.

• Do not overfill the spoon.

• Always use the spoon supplied with the pack.

• Do not give more than 4 doses in any 24 hour period.

• Leave at least 4 hours between doses.

• Do not give this medicine to your child for more than 3 days without speaking to your doctor or pharmacist.

• If your baby still needs this medicine two days after receiving the vaccine talk to you doctor or pharmacist. (leaflet).

• As with all medicines, if your child is currently taking any medicine consult your doctor or pharmacist before taking thisproduct.

• Do not store above 25°C. Store in the original package.

• Keep all medicines out of the sight and reach of children

• Talk to a doctor at once if your child takes too much of this medicine, even if they seem well (label).

• Talk to a doctor at once if your child takes too much of this medicine, even if they seem well. This is because too muchparacetamol can cause delayed, serious liver damage. (leaflet)

Patients with rare hereditary problems of fructose intolerance should not take this medicine

4.5 Interaction with other medicinal products and other forms of interaction:

Drugs which induce hepatic microsomal enzymes such as alcohol. Concomitant barbiturates and tricyclicantidepressants may increase the hepatoxicity of Paracetamol particularly after overdose. Anti-convulsant or oral steroidcontraceptives have the ability to reduce serum levels of Paracetamol by liver enzyme induction. The speed ofabsorption of Paracetamol may be increased by metoclopramide or domperidone and absorption reduced bycolestyramine. The anti-coagulant effect of warfarin and other coumarins may be enhanced by prolonged regular use ofParacetamol with increased risk of bleeding; occasional doses have no significant effect.

Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has beenassociated with high anion gap metabolic acidosis, especially in patients with risks factors (see section 4.4)

4.6 Pregnancy and lactation

Epidemiological studies in human pregnancy have shown no ill effects due to Paracetamol used in the recommendeddosage, but patients should follow the advice of their doctor regarding its use. A large amount of data on pregnantwomen indicate neither malformative, nor feto/neonatal toxicity. Epidemiological studies on neurodevelopment in childrenexposed to paracetamol in utero show inconclusive results. If clinically needed, paracetamol can be used duringpregnancy however it should be used at the lowest effective dose for the shortest possible time and at the lowestpossible frequency.

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

4.7 Undesirable effects

Very rare cases of serious skin reactions have been reported. Adverse effects of Paracetamol are rare buthypersensitivity including skin rash may occur. There have been reports of blood dyscrasias including thrombocytopeniaand agranulocytosis, but these were not necessarily causually related to Paracetamol. With prolonged use oroverdosage, hepatic necrosis, acute pancreatitis and nephrotoxicity have been reported.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continuedmonitoring of the benefit/risk balance of the medicinal product.

4.8 Overdose

Liver damage is possible in adults who have taken 10 g or more of Paracetamol. Ingestion of 5 g or more of Paracetamolmay lead to liver damage if the patient has risk factors.

Risk Factors

If the patient:

a, Is on long term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St. John's Wort orother drugs that induce liver enzymes.

or

b, Regularly consumes ethanol in excess of recommended amounts.

or

c, Is likely to be glutathione deplete e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.

Symptoms

Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain.Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolicacidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, haemorrhage, hypoglycaemia,cerebral oedema and death. Acute renal failure with acute tubular necrosis, strongly suggested by loin pain, haematuriaand proteinuria, may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis havebeen reported.

Management

Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of significant earlysymptoms, patients should be referred to hospital urgently for immediate medical attention. Symptoms may be limited to

nausea or vomiting and may not reflect the severity of overdose or the risk of organ damage. Management should be inaccordance with established treatment guidelines, see BNF overdose section.

Treatment with activated charcoal should be considered if the overdose has been taken within one 1 hour. PlasmaParacetamol concentration should be measured at 4 hours or later after ingestion (earlier concentrations are unreliable).Treatment with N-acetylcysteine may be used up to 24 hours after ingestion of Paracetamol, however, the maximumprotective effect is obtained up to 8 hours post-ingestion. The effectiveness of the antidote declines sharply after thistime. If required the patient should be given intravenous N-acetylcysteine, in line with the

established dosage schedule. Ifvomiting is not a problem, oral methionine may be a suitable alternative for remote areas, outside hospital. Managementof patients who present with serious hepatic dysfunction beyond 24 h from ingestion should be discussed with the NPISor a liver unit.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics Properties

Paracetamol is an antipyretic analgesic. The mechanism of action is probably similar to that of aspirin and dependent onthe inhibition of prostaglandin synthesis. This inhibition appears, however, to be on a selective basis.

5.2 Pharmacokinetic properties

Paracetamol is rapidly and almost completely absorbed from the gastro-intestinal tract. The concentration in plasmareaches a peak in 30 to 60 minutes and the half-life in plasma is 1 to 4 hours after therapeutic doses. Paracetamol isrelatively uniformly distributed throughout most body fluids. Binding of the drug to plasma proteins is variable; 20 to 50%may be bound at the concentrations encountered during acute intoxication. Following therapeutic doses 90 to 100% ofthe drug may be recovered in the urine within the first day. However, practically no Paracetamol is excreted unchanged,and the bulk is excreted after hepatic conjugation.

5.3 PRECLINICAL SAFETY DATA

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in othersections of the SPC. Conventional studies using the currently accepted standards for the evaluation of toxicity toreproduction and development are not available..

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose, Methyl paraben, Propyl paraben, Citric acid Monohydrate, Propylene glycol, Sodium benzoate, Saccharin sodium, ColourCarmosine Supra, ESS Paramol 10077.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 30°C in a dry & dark place. Do not Refrigerate

6.5 Nature and contents of container

100ml amber coloured glass bottle packed in a carton along with pack insert.

6.6 Instructions for use and handling

Store below 30°C in a dry & dark place. Do not refrigerate

For Handling: Keep all medicines out of reach of children.

7. MARKETING AUTHORISATION HOLDER

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Road No. 9, Opposite MIDC Office,

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8. NUMBER(S) IN THE NATIONAL REGISTER OF FINISHED PHARMACEUTICAL PRODUCTS

07027/09320/NMR/2021

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

15.01.2022

10. DATE OF REVISION OF THE TEXT

07.07.2023