Summary of Products Characteristics

Summary of Products Characteristics

1.0 Name of the Finished Pharmaceutical Product

PARAMED SYRUP

2.0 Qualitative and Quantitative Composition

Each 5 ml syrup contains:

Paracetamol BP 160mg

Pseudoephedrine hydrochloride BP 15mg

Chlorphenamine maleate BP 1mg

3. Pharmaceutical Form

Oral Liquid

Orange coloured syrupy liquid.

4. Clinical particulars

4.1 Therapeutic Indications

Paramed Syrup is combination of three drugs (Paraceamol, Pseudoephedrine Hydrochloride, Chlorphenamine Maleate). It is indicated for:

1. Relieving nasal congestion due to the common cold, hay fever or other upper respiratory allergies, and nasal congestion associated with sinusitis.
2. Temporarily relieving of sinus congestion and pressure.
3. Symptomatic relief of hay fever, vasomotor rhinitis, runny nose, sneezing, itchy and watery eyes.
4. Relief of Pain, fever associated with cold & flu.

4.2 Posology and Method of administration

Children >12 years and Adults: 20ml every 4-6 hours (Maximum: 120 ml/24 hours) **Do not exceed 120ml /day**

Children between 2-6 years: 5ml every 4-6 hours (**maximum: 30 ml/24 hours)**

Children between 6-12 years: 10ml every 4-6 hours **(maximum: 60ml/24 hours)**

Route of administration: Oral

4.3 Contraindications

An inherited disorder of protein metabolism called phenylketonuria Known sensitivity or allergy to any ingredient.

The anticholinergic properties of Chlorphenamine are intensified by monoamine oxidase inhibitors (MAOIs). PARAMED SYRUP is therefore contra-indicated in patients who have been treated with MAOIs within the last fourteen day.

PARAMED SYRUP is contraindicated in individuals with severe hypertension or coronary artery disease.

4.4 Special warnings and precautions for use

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

Chlorphenamine in common with other drugs having anticholinergic effects, should be used with caution in epilepsy, raised intra-ocular pressure including glaucoma, prostatic hypertrophy; severe hypertension or cardiovascular disease; bronchitis, bronchiectasis and asthma; hepatic impairment and thyrotoxicosis.

The effects of alcohol may be increased and therefore concurrent use should be avoided.

PARAMED SYRUP containing Pseudoephedrine Hydrochloride hence used with caution in patients with hypertension, heart disease, diabetes, hyperthyroidism, elevated intraocular pressure and prostatic enlargement.

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

PARAMED SYRUP is combination of three drugs (Paraceamol, Pseudoephedrine Hydrochloride, Chlorphenamine Maleate). Following interactions can be occur:

- Cholestyramine may reduce the absorption of paracetamol from the gut.
- Metoclopramide and domperidone may increase the absorption of paracetamol from the gut.

- Long-term or regular use of paracetamol may increase the anti-blood-clotting effect of warfarin and other anticoagulant medicines, leading to an increased risk of bleeding.
- Concurrent use of Chlorphenamine and hypnotics or anxiolytics may cause an increase in sedative effects, therefore medical advice should be sought before taking Chlorphenamine concurrently with these medicines.
- Chlorphenamine inhibits phenytoin metabolism and can lead to phenytoin toxicity.
- The anticholinergic effects of Chlorphenamine are intensified by MAOIs.
- Concomitant use of with Tricyclic antidepressants, sympathomimetic agents (such as decongestants, appetite suppressants and amphetamine-like psychostimulants) or with monoamine oxidase inhibitors, which interfere with the catabolism of sympathomimetic amines, may occasionally cause a rise in blood pressure.

4.6 Pregnancy and Lactation

Pregnancy

Paramed Syrup should be avoided in pregnancy unless considered essential by the physician.

It was shown that pseudoephedrine caused reduced average weight, length, and rate of skeletal ossification in the animal fetus.

Use during the third trimester may result in reactions in the newborn or premature neonates.

Lactation

Paracetamol & Pseudoephedine Hydrochloride is excreted in breast milk but not in a clinically significant amount and the effect of this on breast-fed infants is not known. Available published data do not contraindicate breast feeding.

4.7 Effects on ability to drive and use machines

Paracetamol: None Known

Chlorphenamine Maleate: The anticholinergic properties of Chlorphenamine may caused drowsiness, dizziness, blurred vision and psychomotor impairment, which can seriously hamper the patients ability to drive and use machinery.

Pseudoephedrine Hydrochloride: None Known

4.8 Undesirable effects

Blood disorders, skin rashes, arrhythmias, bradycardia, CNS depression, dizziness, constipation, dysphagia, dry throat, respiratory difficulty.

Pseudoephedrine may also cause side effects associated with other stimulant drugs, including:

- Fear
- Anxiety
- Tenseness
- Tremor
- Hallucinations
- Seizures

Other side effects includes mild reactions include dizziness, headache, loss of appetite, nausea or dry mouth.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via EFDA yellow Card Scheme, online at https://primaryreporting.who-umc.org/ET or toll free call 8482 to Ethiopian food and drug authority (EFDA).

4.9 Overdose and Treatment

Symptoms:

Symptoms and signs of overdose of Chlorphenamine includes include sedation, paradoxical stimulation of CNS, toxic psychosis, seizures, apnoea, convulsions, anticholinergic effects, dystonic reactions and cardiovascular collapse including arrhythmias.

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 metabolic acidosis may occur. In severe poisioning, hepatic failure may progress to encephalopathy, hemorrhages, hypoglycaemia, cerebral oedema, and death. Acute renal failure with acute tubular necrosis, strongly suggested by loin pain, haematuria and proteinuria, may develop even in

the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

Paracetamol overdose Symptoms includes irritability, restlessness, tremor, convulsions, palpitations, hypertension and difficulty in micturition.

Treatment

Necessary measures should be taken to maintain and support respiration and control convulsions. Gastric lavage should be performed if indicated. Catheterisation of the bladder may be necessary. If desired, the elimination of pseudoephedrine can be accelerated by acid diuresis or by dialysis.

Treatment with N-acetylcysteine may be used up to 24 hours after ingestion of Paracetamol; however, the maximum protective effect is obtained up to 8 hours post-ingestion.

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

Mechanism of action

Paracetamol acts by reducing production of prostaglandins, which are involved in the pain and fever processes, by inhibiting the cyclooxygenase (COX) enzyme.

Pseudoephedrine acts directly on both alpha- and, to a lesser degree, beta-adrenergic receptors. Through direct action on alpha-adrenergic receptors in the mucosa of the respiratory tract, pseudoephedrine produces vasoconstriction. Pseudoephedrine relaxes bronchial smooth muscle by stimulating beta2-adrenergic receptors. Like ephedrine, pseudoephedrine releasing norepinephrine from its storage sites, an indirect effect. This is its main and direct mechanism of action. The displaced noradrenaline is released into the neuronal synapse where it is free to activate the postsynaptic adrenergic receptors.

Chlorphenamine

The actions of chlorphenmine include inhibition of histamine on smooth muscle, capillary permeability and hence reduction of oedma and wheal in hypersneitivity reactions such as allergy and anaphylaxis.

5.2 Pharmacokinetic Properties

Paracetamol is rapidly and almost completely absorbed from the gastro-intestinal tract. Human pharmacokinetic data demonstrate that early absorption of paracetamol (fraction of dose over the first 60 minutes) is 32% greater from Concentration in plasma reaches a peak in 30 - 60 minutes. Plasma protein binding is variable. Plasma half-life is 1 - 4hours. Paracetamol is relatively uniformly distributed throughout most body fluids. Excretion is almost exclusively renal, in the form of conjugated metabolites.

Pseudoephedrine is a sympathomimetic agent, structurally similar to ephedrine, used to relieve nasal and sinus congestion and reduce air-travel-related otalgia in adults. The salts pseudoephedrine hydrochloride and pseudoephedrine sulfate are found in many over-the-counter preparations either as single-ingredient preparations, or more commonly in combination with antihistamines and/or paracetamol/ibuprofen.

Chlorphenamine is well absorbed from the gastro-intestinal tract, following oral administration. The effects develop within 30 minutes, are maximal within 1 to 2 hours and last 4 to 6 hours. The plasma half-life has been estimated to be 12 to 15 hours.

Chlorphenamine is metabolised to the monodesmethyl and didesmethyl derivatives. About 22% of an oral dose is excreted unchanged in the urine.

5.3 Preclinical Safety Data

Not Applicable

6.0 Pharmaceutical Particulars

6.1 List of Excipients

Sucrose, Sodium Methyl Hydroxybenzoate, Sodium Propyl Hydroxybenzoate, Disodium Edetate, Saccharin Sodium, Citric Acid Monohydrate, Color Sunset Yellow Supra, Propylene Glycol, Mixed Fruit Flavour (Liquid), Purified Water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store at temperature not exceeding 30°C in a dry place. Protect from light. Keep out of reach of children.

6.5 Nature and contents of container

Oral Liquid packed in 100 ml Amber coloured PET Bottle. Further each bottle packed in unit carton along with leaflet.

6.6 Special precautions for disposal

No special requirements

7.0 Marketing Authorization holder

MEDICAMEN Biotech Limited

SP-1192 A&B, Phase - IV,

Industrial area, Bhiwadi - 301 019

Distt. Alwar, Rajasthan

INDIA.

8.0 Marketing Authorization Number

Certificate No: 08563/08261/VAR/2022

9.0 Date of first registration/renewable of registration

Apr 5, 2023

10.0 Date of revision of the text

August 2023