

PRYTUNE® SYRUP

(Chlorpheniramine Maleate BP 2mg/5ml)

SUBMITTED BY: NALIS PHARMACEUTICALS LTD

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SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC).

1 NAME OF THE MEDICINAL PRODUCT:

Prytune Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

A red-coloured syrup with strawberry flavour.

Each 5 ml contains:

Chlorpheniramine Maleate BP.....2 mg

Excipients.....qs

3. PHARMACEUTICAL FORM

Oral Syrup

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Prytune® syrup is used for the relief of cough and other accompanying symptoms of common cold and allergy in children such as running nose; sneezing, watery/itchy eyes, nose, throat and nasal congestion. Also for fast relief from the symptoms of hay fever; skin, food, pet and house mite dust allergies; insect bites; and mould spore allergies. Also relieves the itchy rash of chickenpox.

4.2 Posology and method of administration

For oral administration.

Dosage:

1 to 2 years - Half teaspoonful (2.5ml) twice daily

2 to 6 years - Half teaspoonful (2.5ml) thrice daily

4.3 Contraindications

Prytune is contraindicated if any of the following conditions is present.

- Hypersensitivity to any of the components
- Impaired renal function with Oliguria
- Angle-closure glaucoma
- Severe myocardial damage
- Premature or full-term neonates
- Prostatic hypertrophy with obstructive uropathy

4.4 Special warnings and precautions for use

When using this product marked drowsiness may occur, avoid alcoholic drinks. Alcohol, sedatives and tranquilizers may increase drowsiness, be careful when driving a motor vehicle or operating machinery. Because of their antimuscarinic actions the sedating antihistamines should be used with care in conditions such as angle-closure glaucoma, urinary retention and prostatic hyperplasia, or pyloroduodenal obstruction; antimuscarinic. Occasional reports of convulsions in patients taking antihistamines suggest a need for caution in patients with epilepsy.

4.5 Interaction with other medicinal products

Sedating antihistamines may enhance the sedative effects of CNS depressants including alcohol, barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives and antipsychotics. Sedative interactions apply to a lesser extent with the non-sedating antihistamines; they do not appear to potentiate the effects of alcohol, but it should be avoided in excess. Sedating antihistamines have an additive antimuscarinic action with other antimuscarinic drugs, such as atropine and some antidepressants (both tricyclics and MAOIs). Potentially hazardous ventricular arrhythmias have occurred when the non-sedating antihistamines astemizole and terfenadine have been given with drugs liable to interfere with their hepatic metabolism, with other potentially arrhythmogenic drugs including those that prolong the QT interval, or with those likely to cause electrolyte imbalance. It has been suggested that some sedating antihistamines could mask the warning signs of damage caused by ototoxic drugs such as aminoglycoside antibacterials. Antihistamines may suppress the cutaneous histamine response to allergen extracts and should be stopped several days before skin testing.

4.6 Pregnancy and lactation

There is no clear risk of harm when used during pregnancy. However, care should be taken in administration during pregnancy.

4.7 Effects on ability to drive and use machines

This product may cause drowsiness and patients receiving it should not drive or operate machinery.

4.8 Undesirable effects

The following is a list of possible side effects that may occur from the use of prytune® syrup. These side effects are possible, but do not always occur. Some of the side effects may be rare but serious.

Consult your doctor if you observe any of the following side-effects, especially if they do not go away.

The most common adverse effect of the sedating antihistamines is CNS depression, with effects varying from slight drowsiness to deep sleep, and including lassitude, dizziness and in coordination.

Other adverse effects that are more common with the sedating antihistamines include headache, npsychomotor impairment and antimuscarinic effects, such as dry mouth, thickened respiratory-tract secretions, blurred vision, urinary difficulty or retention, constipation and increased gastric reflux.

Occasional gastrointestinal adverse effects of antihistamines include nausea, vomiting, diarrhea, or epigastric pain. Palpitations and arrhythmias have been reported occasionally with most antihistamines. Antihistamines sometimes cause rashes and hypersensitivity reactions including bronchospasm, angioedema and anaphylaxis and cross-sensitivity to related drugs may occur.

4.9 Overdose

Sedating antihistamines like Chlorpheniramine Maleate which is the component of Prytune® syrup become toxic when taking in Overdosage form. Overdosage sedating antihistamines is associated with antimuscarinic, extrapyramidal and CNS effects, when CNS stimulation predominates over CNS depression, which is more likely in children or the elderly, it causes ataxia, excitement, tremors, psychoses, hallucinations and convulsions; hyperpyrexia may also occur, deepening coma and cardiorespiratory collapse may follow. In adults, CNS depression is more common with drowsiness, coma and convulsions, progressing to respiratory failure and cardiovascular collapse. In the case of the non-sedating antihistamines, antimuscarinic effects are less marked, but hazardous ventricular arrhythmias (below) have been a particular problem with astemizole and terfenadine, even in modest overdoses and led to restrictions on their use.

Treatment is symptomatic, including gastric lavage, supportive therapy, treatment of convulsions, sedation for restlessness and supportive treatment of hypokalaemia.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Chlorphenamine Maleate

Chlorphenamine Maleate is absorbed relatively slowly from the gastrointestinal tract and peak plasma concentrations occur about 2.5 to 6 hours after oral doses. Bioavailability is low, values of 25 to 50% having been reported. Chlorphenamine appears to undergo considerable first-pass metabolism. About 70% of chlorphenamine in the circulation is bound to plasma proteins.

5.2 Pharmacokinetic properties

Chlorpheniramine Maleate

There is wide inter-individual variation in the pharmacokinetics of chlorpheniramine; values ranging from 2 to 43 hours have been reported for the half-life. Chlorpheniramine is widely distributed in the body and enters the CNS. Chlorpheniramine Maleate is extensively metabolized. Metabolites include desmethyl and didesmethylchlorpheniramine. Unchanged drug and metabolites are excreted mainly in the urine; excretion is dependent on urinary pH and flow rate. Only trace amounts have been found in the faeces. Duration of action of 4 to 6 hours has been reported; this is shorter than may be predicted from pharmacokinetic parameters.

5.3 Preclinical safety data

None.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium CMC, Ethanol, Propylene Glycol, Methyl Paraben, Propyl Paraben, Glycerine, Citric Acid, Xanthan Gum, Sugar, Strawberry Flavour, Carmoisine Red, Sodium Benzoate, Treated Water

6.2 Incompatibilities

None stated except as in 'Interactions with other medicaments'.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not store above 30°C.

Keep away from light

6.5 Nature and contents of container

100ml Pet bottles with ROPP caps and measuring device (dispensing cups).

6.6 Special precautions for disposal and other handling

None

7. APPLICANT/HOLDER OF CERTIFICATE OF PRODUCT REGISTRATION

Nalis Pharmaceuticals Ltd

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8. DRUG PRODUCT MANUFACTURER

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9. NAFDAC REGISTRATION NUMBER(S)

A11-0823