Summary of Product Characteristics

1. Name of the medicinal product

V-PADRYL SYRUP

(Chlorpheniramine Maleate 2 mg/5 mL)

2. Qualitative and quantitative composition

Each teaspoonful (5 mL) contains:

- Chlorpheniramine maleate 2 mg

For excipients, see 6.1.

3. Pharmaceutical form

Syrup

Product description

Red clear syrup, raspberry flavor.

4. Clinical particulars

4.1 Therapeutic indications

For symptomatic prevention or alleviation of allergic conditions, including

- runny nose; red, itchy, watery eyes; itchy nose or throat; sneezing; urticaria; itchy skin.
- relief of runny nose caused by common cold.

4.2 Posology and method of administration

Oral administration only.

Do not exceed the stated dose or frequency of dosing.

The minimum interval between the doses should be 4 hours.

Not recommended for children below 2 years.

Children aged 2 - 6 years:

2.5 ml (1 mg) every 4 to 6 hourly.

Maximum daily dose: 15 ml (6 mg) in any 24 hours.

Children aged 6 - 12 years:

5 ml (2 mg) every 4 to 6 hourly.

Maximum daily dose: 30 ml (12 mg) in any 24 hours.

Adults and Children aged 12 years and over:

10 ml (4 mg) every 4 to 6 hourly.

Maximum daily dose: 60 ml (24 mg) in any 24 hours.

4.3 Contraindications

- Known hypersensitivity to active ingredient or to any of the excipients listed in section 6.1.
- Children under 1 year of age because of its increased susceptibility to the antimuscarinic effects.
- Acute asthma.
- Patients on monoamine oxidase inhibitors (MAOIs) within 14 days of stopping such treatment.

4.4 Special warning and precautions

This medicine should be given with caution to patients with epilepsy, severe cardiovascular disorders, liver disorders, glaucoma, urinary retention, prostatic enlargement, pyloroduodenal obstruction, asthma, bronchitis, bronchiectasis, thyrotoxicosis, and severe hypertension.

Special care should be taken when using chlorpheniramine maleate in children and the elderly as they are more prone to developing neurological anticholinergic effects.

The anticholinergic properties of chlorpheniramine may cause drowsiness, dizziness, blurred vision and psychomotor impairment in some patients which may seriously affect ability to drive and use machinery.

If symptoms do not go away within 5 days talk to your pharmacist or doctor.

Although most antihistamines should be avoided by patients with porphyria, chlorpheniramine maleate has been used and is thought to be safe.

Should not be used with other antihistamine containing products, including antihistamine containing cough and cold medicines.

The medicine contains sodium cyclamate or cyclamic acid. Should not be used with other drugs or foods and beverages containing sodium cyclamate or cyclamic acid.

This medicine contains alcohol (ethanol 95%) 0.12% v/v. The amount of alcohol in this medicine is not likely to have an effect in adults and adolescents, and its effects in children are not likely to be noticeable. Avoid alcoholic drinks.

Sweeteners: sucrose, liquid glucose, sucralose, and artificial sweeteners should be used with caution in patients with diabetes.

Methylparaben, propylparaben and ponceau 4R may cause allergic reactions.

Keep all medicines out of the reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

This medicine may enhance the sedative effects of alcohol, hypnotics, anxiolytics, sedatives, opioid analgesics, and neuroleptics.

The antimuscarinic effects of chlorpheniramine are enhanced by other antimuscarinic drugs and both antimuscarinic and sedative effects are enhanced by monoamine oxidase inhibitors (concurrent therapy with which is contraindicated, see 4.3 above) and tricyclic antidepressants.

Metabolism of phenytoin may be inhibited by chlorpheniramine with the possible development of phenytoin toxicity.

4.6 Pregnancy and lactation

There are no adequate controlled studies of chlorpheniramine in pregnant women and this medicine should therefore not be used during pregnancy.

Chlorpheniramine may be secreted in breast milk and its use is not recommended in nursing mothers because of the risk of adverse effects, such as unusual excitement or irritability in infants.

Chlorpheniramine maleate and other antihistamines may inhibit lactation and may be secreted in breast milk. Not to be used during lactation unless considered essential by a physician.

4.7 Effects on ability to drive and use machines

Chlorpheniramine may cause blurred vision, dizziness, drowsiness and interfere with human performance and therefore may seriously influence the ability to drive and operate machinery.

4.8 Undesirable effects

The following convention has been utilised for the classification of the frequency of adverse reactions: very common (>1/10), common (>1/100 to <1/10), uncommon (>1/1000 to <1/100), rare (>1/10,000 to <1/1000) and very rare (<1/10,000), not known (cannot be estimated from available data).

Adverse reactions identified during post-marketing use with chlorpheniramine are listed below. As these reactions are reported voluntarily from a population of uncertain size, the frequency of some reactions is unknown but likely to be rare or very rare:

System Organ Class	Adverse Reaction	Frequency
Nervous system disorders*	Sedation, somnolence	Very common
	Disturbance in attention, abnormal coordination, dizziness headache	Common
Eye disorders	Blurred Vision	Common
Gastrointestinal disorders	Nausea, dry mouth	Common
	Vomiting, abdominal pain, diarrhoea, dyspepsia	Unknown
Immune system disorders	Allergic reaction, angioedema, anaphylactic reactions	Unknown
Metabolism and nutritional disorders	Anorexia	Unknown
Blood and lymphatic system disorders	Haemolytic anaemia, blood dyscrasias	Unknown
Musculoskeletal and connective tissue disorders	Muscle twitching, muscle weakness	Unknown
Psychiatric disorders	Confusion*, excitation*, irritability*, nightmares*, depression	Unknown
Renal and urinary disorders	Urinary retention	Unknown
Skin and subcutaneous disorders	Exfoliative dermatitis, rash, urticaria, photosensitivity	Unknown
Respiratory, thoracic and mediastinal disorders	Thickening of bronchial secretions	Unknown
Vascular disorders	Hypotension	Unknown
Hepatobiliary disorders	Hepatitis, including jaundice	Unknown
Ear and labyrinth disorders	Tinnitus	Unknown
Cardiac disorders	Palpitations, tachycardia, arrythmias	Unknown
General disorders and administration site conditions	Fatigue	Common
	Chest tightness	Unknown
*Children and the elderly are more susceptible to neurological anticholinergic effects and paradoxical excitation (e.g. increased energy, restlessness, nervousness).		

4.9 Overdose

Symptoms and signs

Symptoms and signs include sedation, paradoxical excitation of the CNS, toxic psychosis, convulsions, apnoea, anticholinergic effects, dystonic reactions and cardiovascular collapse including arrhythmias.

Treatment

Management should be as clinically indicated or as recommended by the national poisons centres where available. Symptomatic and supportive measures should be provided with special attention to cardiac, respiratory, renal and hepatic functions and fluid and electrolyte balance. If overdosage is by the oral route, treatment with activated charcoal should be considered provided there are no contraindications for use and the overdose has been taken recently (treatment is most effective if given within an hour of ingestion). Treat hypotension and arrhythmias vigorously. CNS convulsions may be treated with i.v. diazepam. Haemoperfusion may be used in severe cases.

5. Pharmacological properties

5.1 Pharmacodynamic properties

ATC Code R06AB04

Chlorpheniramine is a potent antihistamine (H1-antagonist).

Antihistamines diminish or abolish the actions of histamine in the body by competitive reversible blockade of histamine H1-receptor sites on tissues. Chlorpheniramine also has anticholinergic activity.

Antihistamines act to prevent the release of histamine, prostaglandins and leukotrines and have been shown to prevent the migration of inflammatory mediators. The actions of chlorpheniramine include inhibition of histamine on smooth muscle, capillary permeability and hence reduction of oedema and wheal in hypersensitivity reactions such as allergy and anaphylaxis.

5.2 Pharmacokinetic properties

Chlorpheniramine maleate is almost completely absorbed after administration by mouth, peak plasma concentrations occurring at about 2.5 to 6 hours. The drug is widely distributed including passage into the CNS, with a volume of distribution of between 1 and 10 L/kg. About 70% of chlorpheniramine in the circulation is protein-bound. Chlorpheniramine undergoes some first pass metabolism and enterohepatic recycling.

Chlorpheniramine is extensively metabolised, principally to inactive desmethylated metabolites which are excreted primarily in the urine, together with about 35% unchanged drug. Only trace amounts are excreted in the feces. The mean elimination half-life has been reported to be about 30 hours, with mean values ranging from 2 to 43 hours.

5.3 Preclinical safety data

The antihistaminic potency of chlorpheniramine is confined mainly to its (+)-isomer. The racemate is similarly or slightly more toxic because of the contribution of (-)-isomer. The toxicity may therefore be non- specific, perhaps attributable to local anaesthetic action and the toxic effects (excitation/sedation, coma, convulsions and death) resemble those of other classic H1 antihistamines. Toxic doses may cause hypotension attributable to myocardial depression, an effect which is clearer with the (-)-isomer.

The experimental data on the carcinogenicity and mutagenicity of chlorpheniramine indicate lack of these adverse effects, but the racemate and the (+)-isomer have shown some embryotoxicity in fertility tests.

Effective antihistaminic concentrations of chlorpheniramine in vitro are about 1 -10 µg/L and oral doses of 0.2-1 mg/kg antagonise histamine -induced bronchospasm in guinea pigs.

6. Pharmaceutical particulars

6.1 List of excipients

Sucrose
Methylparaben
Propylparaben
Liquid glucose
Saccharin sodium
Sodium cyclamate
Citric acid monohydrate
Sodium citrate
Levomenthol
Alcohol (Ethanol 95%)
Glycerin
Raspberry essence

Sucralose

Caramel

Ponceau 4R

Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf-life

Storage condition:

Store below 30°C.

Shelf-life:

24 months.

15 days after first opening.

6.4 Special precautions for storage

None

6.5 Nature and contents of container

60 ml amber plastic (PET) bottle with a white aluminium screw cap (under the lid lined with a foam PE sheet).

7. Marketing authorisation holder

V & P Laboratory Co., Ltd.

182 Moo. 14, Petchkasem Road, Raikhing, Sampran, Nakornpathom, 73210 Thailand

8. Marketing authorisation number(s)

1A 66/67

9. Date of first authorisation/renewal of the authorisation

June 4th, 2024.

10. Date of revision of the text

January 2025.