Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Optimine Syrup oral solution 500 mcg/5 ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of solution contains azatadine maleate 500 micrograms.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Oral solution.
A clear, colourless, blackcurrant flavoured solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the symptomatic relief of allergic conditions such as hayfever, vasomotor rhinitis, urticaria, pruritus of allergic origin and allergic reactions associated with insect bites and stings.

4.2 Posology and method of adminstration

Adults, the elderly and children over the age of 12 years : - 1mg of azatadine maleate (10ml of syrup) in the morning and evening is recommended. In refractory or more severe cases, 2mg (20ml) may be used.

Children (6-12 years):
0.5 - 1.0mg azatadine maleate (5 - 10ml syrup), twice daily.

Optimine Syrup may be diluted with syrup BP.

Method of administration : Oral.

4.3 Contraindications

Hypersensitivity to the active ingredient or any of the other constituents.

Monoamine oxidase inhibitors, which are known to intensify or prolong the anticholinergic and sedative action of drugs, should not be used concomitantly with azatadine maleate.

Due to the anticholinergic effect of azatadine maleate, the drug should be used with caution in patients with prostatic hypertrophy, urinary retention, glaucoma, stenosing peptic ulcer or pyloroduodenal obstructions.

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

4.4 Special warnings and precautions for use

None known.

4.5 Interaction with other medicinal products and other forms of interaction

Patients taking azatadine maleate should be cautioned against ingestion of alcohol. The drug may potentiate central nervous system depressants.

4.6 Pregnancy and lactation

Until the safety of azatadine maleate concerning adverse effects on human foetal development has been established, the drug is not recommended for use in pregnant or lactating women.

4.7 Effects on ability to drive and use machines

Although drowsiness is infrequent and impairment of psychomotor function is not manifested at the recommended dosage, patients should be cautioned against engaging in mechanical operations requiring mental alertness until individual response to azatadine maleate has been determined.

4.8 Undesirable effects

Azatadine maleate is well tolerated and side effects are generally dose-related and transient. Among these are : weakness, nervousness, dry mouth, increased appetite, anorexia, nausea, headache, drowsiness, dysuria and blurring of vision.

4.9 Overdose

Treatment of the sign and symptoms of overdose is symptomatic and supportive. There is not specific antidote. Consider standard measures to remove any unabsorbed drug in the stomach, such as absorption by activated charcoal administered as a slurry with water. The administration of gastric lavage should be considered. Isotonic and one-half isotonic saline are the lavage solution of choice.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Azatadine maleate is a H_1-receptor antagonist. It inhibits the response of smooth muscle to histamine and strongly antagonises the action of histamine that results in increased capillary permeability and formation of oedema and wheal. Azatadine maleate antagonises the effects of histamine, which when released from the tissues causes allergic reactions.

5.2 Pharmacokinetic properties

Azatadine is readily absorbed from the gastro-intestinal tract and is excreted as active drug and metabolites in the urine. Disposition can best be described as a one compartmental model and the plasma half life is approximately 8-9 hours. Metabolism studies show extensive urinary conjugation.

5.3 Preclinical safety data

None Stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose 70%
Sorbitol solution (non-crystallising) E420
Propylene glycol
Methyl parahydroxybenzoate E218
Propyl parahydroxybenzoate E216
Ethanol (96%)
Purified water
Imitation blackcurrant flavour

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

36 months

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Type III amber glass bottles with metal cap and polyethylene pulp cap liner, containing 120mls syrup.

6.6 Instructions for use and handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Schering Plough Ltd.
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8 MARKETING AUTHORISATION NUMBER

PA 277/1/2

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