

Summary of Product Characteristics

1 TRADE NAME OF THE MEDICINAL PRODUCT

Agelan 2.5mg coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains indapamide hemihydrate 2.5mg

3 PHARMACEUTICAL FORM

Sugar-coated tablets

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Treatment of essential hypertension.

4.2 Posology and method of administration

Agelan tablets are for oral administration, only.

Adults: 2.5mg (1 tablet) daily taken in the morning. This dose should not be exceeded as there is no additional antihypertensive effect. If blood pressure is not controlled, then an antihypertensive agent of another class should be used.

Elderly: Indapamide may have a more prolonged elimination time. Since the elderly are more susceptible to electrolyte imbalance and fluid loss it is advisable to monitor these patients frequently for evidence of such effects.

4.3 Contraindications

Use in patients with severe impairment of hepatic function, or severe degrees of renal insufficiency.

Use in patients with hypokalaemia.

Use in patients hypersensitive to the active ingredient.

4.4 Special warnings and precautions for use

Patients who are being treated with this preparation require regular supervision with monitoring of fluid and electrolyte state to avoid inadequate potassium supplementation or excessive loss of fluid.

The preparation should only be used with particular caution in elderly patients or those with potential obstruction of the urinary tract, or with disorders rendering their electrolyte balance precarious.

The preparation may induce hyperglacemia particularly in patients with latent diabetes, and may necessitate adjustment of control of hypoglycaemic agents in cases of diabetes mellitus.

As with all antihypertensive agents, a cautious dosage schedule is indicated in patients with severe coronary or cerebral arteriosclerosis or recent cerebrovascular accident.

In patients with hyperlipidaemia, serum lipids should be monitored regularly.

4.5 Interaction with other medicaments and other forms of interaction

When used in combination with other antihypertensive drugs, the dosage of these latter may require reduction.

Agelan may potentiate the action of diuretics, and when used in combination with these drugs, there may be a need for potassium supplementation.

Concurrent use with lithium therapy, may increase toxicity of the latter due to increased blood levels and a paradoxical anti-diuretic effect.

Diuretic induced hypokalaemia may be aggravated by corticosteroids, ACTH, carbenoxolone, amphotericin B.

Diuretic and anti-hypertensive effects will be diminished by concurrent use of non-steroidal anti-inflammatory drugs. Deterioration in renal function may also occur.

Diuretics potentiate the action of curare derivatives and antihypertensive drugs (e.g guanethidine, methyldopa, beta-blockers, vasodilators, calcium antagonists and ACE inhibitors)

4.6 Pregnancy and lactation

Agelan should not be recommended for use during the first trimester of pregnancy or during lactation unless the physician considers it necessary.

Teratogenic studies in animals have shown no adverse effects but experience of use in pregnant patients is limited.

4.7 Effects on ability to drive and use machines

Nil

4.8 Undesirable effects

Side effects include muscle cramps, fatigue, allergic reactions, especially skin lesions and syncope. Hypokalaemia may occur , less frequently hyperuricaemia.

4.9 Overdose

Possible signs of overdosage include electrolyte imbalance, hypotension, gastrointestinal disturbance and muscular weakness. There is no specific antidote to indapamide and treatment of overdosage is symptomatic and supportive. The stomach may be emptied by emesis or by gastric aspiration and lavage. Particular attention should be paid to correcting any electrolyte any electrolyte abnormalities.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Agelan tablets contain indapamide, a non-thiazide indole derivative of chlorosulphonamide. At therapeutic doses, indapamide induces some mild diuretic effect. Indapamide has been shown to decrease vascular smooth muscle reactivity and peripheral resistance. In doses of 2.5mg daily, indapamide has been shown to exert an antihypertensive effect; higher doses are not recommended as they increase diuretic activity but do not cause significant additional antihypertensive effect.

5.2 Pharmacokinetic properties

Indapamide is readily and completely absorbed from the gastro-intestinal tract. It is preferentially and reversibly taken up by circulating erythrocytes and about 71 to 79% of the drug is bound to plasma proteins. Indapamide has a terminal half-life of about 14 hours. It is extensively metabolised. About 70% of an oral dose is excreted via the kidneys and about 23% by the gastro-intestinal tract.

5.3 Preclinical safety data

No further relevant information other than which is included in the other sections of the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose Monohydrate, Calcium Hydrogen Phosphate Dihydrate, Maize Starch, Magnesium Stearate, Croscarmellose Sodium, Talc, Shellac, Castor Oil, Titanium

Dioxide (E171), Sucrose, Methyl parahydroxybenzoate, Propyl parahydroxybenzoate, Acacia, Opalux AS-F-1312 and macrogol 6000, Opalux consists of sucrose BP, purified water, sodium benzoate, polyvinylpyrrolidone, talc, titanium dioxide, ponceau 4R aluminium lake (E124), erythrosine aluminium lake (E127).

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

3 years

6.4 Special precautions for storage

Do not store above 25°C

Store in a dry place.

Store in the original package in order to protect from light

6.5 Nature and contents of container

Blister packs which consist of strips made from hard PVC with a foil lid.

Pack sizes: 28 tablets in blister packs of 14 (2X14); 30 tablets in blister packs of 15 (2X15).

6.6 Instructions for Use/handling

None.

7 MARKETING AUTHORISATION HOLDER

Antigen Pharmaceuticals Limited

Roscrea

Co.Tipperary

8 MARKETING AUTHORISATION NUMBER

PA 73/102/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24 February 1988 / 24 February 1998

10 DATE OF REVISION OF THE TEXT

September 2008