1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

A-LENNON RESERPINE (tablet)

COMPOSITION

Each tablet of A-LENNON RESERPINE contains 0,25 mg reserpine.

Excipients:

Acacia powder, benzoic acid, ethyl parabenzoate sodium, lactose monohydrate, magnesium stearate, methyl parahydroxybenzoate sodium, propyl hydroxybenzoate sodium, purified talc, sodium benzoate, starch maize

Preservative:

Benzoic acid and benzoates 0,004 % *m/m*

Contains sugar: Lactose monohydrate 120,90 mg

CATEGORY AND CLASS

A 7.1.1 Rauwolfia and combinations

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Reserpine is an antihypertensive agent which causes depletion of biogenic amines at central and peripheral adrenergic neurons, leading to sympathetic nervous system dysfunction. This results in reduction in blood pressure and central nervous depression.

The hypotensive effect is mainly due to a reduction in cardiac output and peripheral resistance.

Pharmacokinetic properties

When given orally the full antihypertensive effect is only reached after several weeks of continued treatment.

Recovery of sympathetic function requires synthesis of new storage vesicles, which takes days to weeks after discontinuation of the medicine, therefore, the effect can persist for up to 6 weeks after treatment is discontinued.

INDICATIONS

Treatment of mild to moderate hypertension.

CONTRAINDICATIONS

Known hypersensitivity to A-LENNON RESERPINE or other rauwolfia alkaloids.

In patients with a history of mental depression, with active peptic ulcer, ulcerative colitis, gallstones, phaeochromocytoma, Parkinson's disease, epilepsy and patients undergoing electroconvulsive therapy. Safety in pregnancy and lactation has not been established. A-LENNON RESERPINE crosses the placenta and appears in breast milk (see HUMAN REPRODUCTION).

WARNINGS AND SPECIAL PRECAUTIONS

The anaesthetist should be aware that a patient undergoing anaesthesia is receiving A-LENNON RESERPINE treatment, as the effects of thiopentone and other central nervous system depressants may be enhanced by A-LENNON RESERPINE (see INTERACTIONS).

A-LENNON RESERPINE must be discontinued at the first sign of depression. Depression usually appears insidiously over many weeks or months and may not be attributed to the medicine because of the delayed and gradual onset of symptoms.

This depression may persist for several months after withdrawal of the medicine and may

be severe enough to result in suicide.

If used in patients requiring electroconvulsive therapy an interval of at least 7 to 14 days should be allowed to elapse between the last dose of A-LENNON RESERPINE and the commencement of the shock treatment.

A-LENNON RESERPINE should be used with caution in debilitated or elderly patients and in the presence of cardiac arrhythmias, myocardial infarction, severe cardiac damage, renal insufficiency, or allergic conditions such as bronchial asthma.

Patients taking A-LENNON RESERPINE are sensitive to adrenaline and other direct-acting sympathomimetic agents, which should not be given except to antagonise A-LENNON RESERPINE.

Excipients

Contains lactose monohydrate which may have an effect on the glycaemic control of patients with diabetes mellitus. Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take A-LENNON RESERPINE.

INTERACTIONS

The effects of indirect acting sympathomimetic agents such as ephedrine may be

decreased by A-LENNON RESERPINE.

The hypotensive effects of A-LENNON RESERPINE are enhanced by thiazide diuretics and other antihypertensive agents.

A-LENNON RESERPINE may cause excitation and hypertension in patients receiving monoamine oxidase inhibitors.

Concurrent administration of digitalis or quinidine may cause cardiac arrhythmias.

A-LENNON RESERPINE has been reported to produce falsely low results in colorimetric methods of determining urinary steroids and may cause decrease in the urinary excretion of catecholamines and vanillyl-mandelic acid.

The action of A-LENNON RESERPINE may be reduced by concurrent administration of non-steroidal anti-inflammatory medicines.

The effects of thiopentone and other central nervous system depressants may be enhanced by A-LENNON RESERPINE (see WARNINGS AND SPECIAL PRECAUTIONS).

HUMAN REPRODUCTION

Safety in pregnancy and lactation has not been established. A-LENNON RESERPINE crosses the placenta and appears in breast milk (see CONTRAINDICATIONS).

Respiratory distress, cyanosis, anorexia, hypothermia and lethargy may occur in infants whose mothers have received A-LENNON RESERPINE prior to delivery (see SIDE EFFECTS).

DOSAGE AND DIRECTIONS FOR USE

Take with meals or milk to reduce gastric irritation.

Dosage must be adjusted to meet the individual requirements of each patient, on the basis of clinical response. A lower dose is recommended in the elderly or severely debilitated. The usual dosage for adults is one tablet daily for about 2 weeks, then reduced to the lowest dose necessary to maintain the response.

A dose of one tablet daily should not be exceeded. A-LENNON RESERPINE is usually used in combination with a diuretic to reduce the required A-LENNON RESERPINE dose.

SIDE EFFECTS

Dizziness and nasal congestion.

Central nervous system symptoms including depression, drowsiness, inability to concentrate, lethargy and nightmares.

Symptoms of increased gastrointestinal tract motility including diarrhoea, abdominal cramps, and at higher doses increased gastric acid secretion. A-LENNON RESERPINE may precipitate biliary colic in persons with gallstones.

Breast engorgement and galactorrhoea, gynaecomastia, increased prolactin concentrations, decreased libido, impotence, sodium retention, oedema, increased appetite, mass gain, miosis, dry mouth, sialorrhoea and thrombocytopenic purpura have been reported.

Higher doses may cause flushing, bradycardia, severe depression which may lead to suicide and extrapyramidal effects.

Respiratory distress, cyanosis, anorexia, hypothermia and lethargy may occur in infants whose mothers have received A-LENNON RESERPINE prior to delivery (see HUMAN REPRODUCTION).

Withdrawal for A-LENNON RESERPINE or reduction of the dosage causes the reversal of many side effects although mental disorders may persist for weeks after the cessation of treatment.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Symptoms

Hypotension, coma, respiratory depression and hypothermia occur in overdosage.

Treatment

Treatment by gastric lavage. Further treatment is symptomatic and supportive. The patient must be observed for at least 72 hours.

If treatment with a vasopressor is necessary, one with a direct action on smooth muscle (phenylephrine, norepinephrine, metaraminol) should be used.

IDENTIFICATION

A white to off white, round, shallow, biconvex tablet, bisected on one side and imprinted “35” on other side.

PRESENTATION

28, 100, 500 or 1 000 tablets are packed in a white polypropylene container, together with a white foam insert and/or white rayon, and sealed with a white low density polyethylene tamper evident cap.

5 000 tablets are packed in an amber polyvinyl chloride container, together with a white foam insert, and sealed with a white polypropylene screw cap.

28 tablets are packed in a metallised polyester, laminant, opaque white linear low density polyethylene bag.

28 tablets are packed in a white high density polyethylene container together with a white foam plug and sealed with a white opaque polypropylene cap.

Not all packs and pack sizes are necessarily marketed.

STORAGE INSTRUCTIONS

Store at or below 25 °C in an airtight container.

Protect from light.

Keep in original packaging until required for use

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

B886 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE APPLICANT

PHARMACARE LIMITED

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Woodlands Drive

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DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

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