### 1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

## SCHEDULING STATUS

**S4**

## PROPRIETARY NAME AND DOSAGE FORM

**A-LENNON DAPSONE** (tablet)

## COMPOSITION

Each tablet of A-LENNON DAPSONE contains 100 mg dapsone.

*Excipients:*

Hydrogenated vegetable oil, microcrystalline cellulose, polyvinylpyrrolidone, sodium starch glycollate, starch maize

Sugar free

## CATEGORY AND CLASS

A 20.2.4 Leprostatics

## PHARMACOLOGICAL ACTION

### Pharmacodynamic properties

Dapsone, a sulphone, is bacteriostatic *in vitro* and probably acts by preventing the use of certain bacteria of metabolites essential for their normal development. Dapsone is effective *in vitro* against a wide range of gram-positive and gram-negative bacteria but it is for its action against *Mycobacterium leprae* that is mainly employed.

## INDICATIONS

A-LENNON DAPSONE is indicated in the treatment of all types of leprosy; especially lepromatous and tuberculoid leprosy.

In addition, A-LENNON DAPSONE has also been found of value in the treatment of dermatitis herpetiformis.

A-LENNON DAPSONE is also of value in the treatment of toxoplasmosis and mycetoma (maduromycosis) and it has a suppressive action on malarial plasmodia.

## CONTRAINDICATIONS

A-LENNON DAPSONE is contraindicated in persons who have shown a previous hypersensitivity to the active ingredient.

A-LENNON DAPSONE should be used with caution in patients with cardiac or pulmonary disease, porphyria and patients with severe anaemia.

## WARNINGS AND SPECIAL PRECAUTIONS

A-LENNON DAPSONE should not be used in patients with severe anaemia.

It is recommended that regular blood counts be performed during treatment.

Patients deficient in glucose-6-phosphate dehydrogenase, or methaemoglobin reductase, or with haemoglobin M are more susceptible to the haemolytic effects of A-LENNON DAPSONE.

## INTERACTIONS

Excretion of A-LENNON DAPSONE is reduced, and plasma concentrations are increased by concurrent administration of probenecid.

Rifampicin increases the plasma clearance of A-LENNON DAPSONE.

Increased A-LENNON DAPSONE and trimethoprim concentrations have been reported following concurrent administration in AIDS patients.

## HUMAN REPRODUCTION

The benefits of A-LENNON DAPSONE in the treatment of leprosy outweigh any potential risk to the pregnant patient. Some leprologists recommend folic acid 5 mg daily for leprosy patients receiving A-LENNON DAPSONE during pregnancy.

A-LENNON DAPSONE diffuses into breast milk and there has been a report of haemolytic anaemia in a breast fed infant.

In general, treatment with A-LENNON DAPSONE for leprosy is continued in lactating mothers.

## DOSAGE AND DIRECTIONS FOR USE

It is important to not miss any doses and to take the tablets at the same time every day. Complete the course.

1. *Leprosy (Hansen's disease):*

*Adults:*

Oral, in combination with one or more other antileprosy agents, 50 mg to 100 mg of A-LENNON DAPSONE once a day; or 1,4 mg per kg of body weight once a day.

*Paediatric:*

Dosages must be reduced in children and low-weight patients.

Oral, in combination with one or more other antileprosy agents, 1,4 mg of A-LENNON DAPSONE per kg of body weight, once a day.

2. *Dermatitis herpetiformis suppressant:*

   *Adults:*

   Start with 50 mg daily gradually increased to 300 mg or more if required. This dose should be reduced to a minimum as soon as possible.

   Maintenance dosage can often be reduced in patients receiving a gluten-free diet.

   *Paediatric:*

   Dosages must be reduced in children and low-weight patients.

   Oral, initially 2 mg per kg of body weight daily. Doses may be increased if symptoms are not completely controlled. The dose should then be reduced to the lowest effective maintenance dose as soon as possible.

3. *Toxoplasmosis, mycetoma and malaria plasmodia:*

   When used for the treatment of toxoplasmosis, mycetoma (maduromycosis) and for its suppressive action on malaria plasmodia, the maximum dosage may be attained much more quickly and is about 200 mg daily.

The tablets should be taken with plenty of water.

For children the dose should be suitably adjusted to the body mass.

**SIDE EFFECTS**

Varying degrees of dose-related haemolysis and methaemoglobinaemia are the most frequently reported adverse effect.

Agranulocytosis has occurred less frequently following A-LENNON DAPSONE use in leprosy and skin disease.

Aplastic anaemia has been reported.

Peripheral neuropathy with motor loss has been reported in patients on A-LENNON DAPSONE for dermatological conditions. It may occur as part of leprosy reaction states and is not an indication to discontinue A-LENNON DAPSONE.

Rash and pruritus may develop.

Other adverse effects such as maculopapular rash, exfoliative dermatitis, toxic epidermal necrolysis, Stevens-Johnson syndrome, nausea, vomiting, anorexia, headache, hepatitis and psychosis occur infrequently. Fixed drug eruptions have occurred.

Dapsone-syndrome is a less frequent hypersensitivity reaction although it has been suggested that the incidence has increased since the introduction of multidrug therapy for leprosy. It occurs in the first 6 weeks of therapy and symptoms include rash, which is always present, fever, jaundice and eosinophilia.

Serious cutaneous reactions such as: exfoliative dermatitis, toxic erythema, erythema multiforme, toxic epidermal necrolysis, morbilliform and scarlatiniform reactions and erythema nodosum may occur.

## KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

### Symptoms

Vomiting, severe abdominal pain, tachycardia, jaundice, hyperexcitability leading to depression, electrolyte imbalance, convulsions, purpuric spots, haematuria, cyanosis from methaemoglobinaemia and coma.

### Treatment

Treatment is symptomatic and supportive.

## IDENTIFICATION

White, round, shallow biconvex tablet bisected one side and imprinted “C10” on the other side.

## PRESENTATION

100 tablets are packed in a 50 ml white polypropylene container and sealed with a white LLDPE cap with tamper evident seal together with a white polyurethane foam/rayon. The leaflet is placed on top of the foam insert/rayon.

100 tablets are packed in a 50 ml white HDPE bottle and sealed with a white opaque polypropylene screw cap with tamper evident seal together with a white polyurethane foam/rayon. The leaflet is placed on top of the foam insert/rayon.

**STORAGE INSTRUCTIONS**

Store at or below 25 °C.

Keep in original packaging until required for use.

**KEEP OUT OF REACH OF CHILDREN.**

**REGISTRATION NUMBER**

J/20.2.4/431

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION**

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

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

Date of registration: 24 May 1977

Date of the most recent amendment to the professional information as approved by the Authority: 24 May 1977

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