SCHEDULING STATUS: **S2**

PROPRIETARY NAME (AND DOSAGE FORM):

BETASLEEP (Capsule)

COMPOSITION:

Each capsule contains:

Diphenhydramine HCl	50 mg
Contains sugar: lactose	0.065 g

List of excipients: magnesium stearate 5,00 mg, starch 120,0 mg.

PHARMACOLOGICAL CLASSIFICATION:

A 2.2. Sedatives, hypnotics.

PHARMACOLOGICAL ACTION:

Diphenhydramine HCl has the general pharmacological actions of the H_1 - blocking antihistamines. It has pronounced sedative properties.

INDICATIONS:

BETASLEEP is indicated for the alleviation of temporary insomnia

CONTRAINDICATIONS:

Antihistamines are contraindicated in epileptics, pregnancy and lactation. Not to be taken by children under the age of twelve years.

WARNINGS and SPECIAL PRECAUTIONS:

If the condition persists for more than 10 days consult a doctor. The use of this medicine leads to drowsiness, which is aggravated by the simultaneous intake of alcohol and other CNS depressants.

Patients are warned not to drive motor vehicles, climb dangerous heights or operate dangerous machinery as impaired decision making could lead to accidents.

Contains lactose/fructose. Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take BETASLEEP.

INTERACTIONS:

The use of this medicine leads to drowsiness, which is aggravated by the simultaneous intake of alcohol and other CNS depressants (see WARNINGS and SPECIAL PRECAUTIONS).

PREGNANCY AND LACTATION:

Safety and/or efficacy has not been established.

DOSAGE AND DIRECTIONS FOR USE:

Take 1 to 2 capsules at night, 20 minutes before retiring. This product is intended for occasional use. Not to be used on successive nights or over periods exceeding several days.

SIDE-EFFECTS:

Antihistamines may cause lassitude, dizziness, gastrointestinal disturbances such as nausea, vomiting and gastric pain; headache, blurred vision, tinnitus; dryness of the mouth; muscular weakness and inco-ordination.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF TREATMENT:

Sedation and CNS depression. Accidental overdosage in children can lead to excitation, hyperpyrexia and convulsions. Use stimulants by injection where large doses have produced severe drowsiness.

IDENTIFICATION:

Orange capsule containing white powder.

PRESENTATION:

12 capsules blister-packed.

STORAGE INSTRUCTIONS:

Store in a cool (at or below 25 ºC) dry place. Keep out of reach of children.

REGISTRATION NUMBER:

C/2.2/653

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

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685

Private Bag X69,

Bryanston, 2021

www.adcock.co.za

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

12 February 1986