SCHEDULING STATUS:

SO

PROPRIETARY NAME (AND DOSAGE FORM): **REGMAKERS® TABLETS**

COMPOSITION:

Each tablet contains: Caffeine 150 mg

Excipients: Calcium carbonate light, citric acid monohydrate, magnesium stearate, maize starch, saccharin sodium (soluble)

Sugar Free

PHARMACOLOGICAL CLASSIFICATION:

A. 1.1 Central Analeptics

PHARMACOLOGICAL ACTION:

REGMAKERS TABLETS is a central nervous system stimulant.

INDICATIONS:

REGMAKERS TABLETS are indicated to help maintain a state of wakefulness and increased mental activity. Mental fatigue, in some users, may be temporarily warded off.

CONTRA-INDICATIONS:

REGMAKERS TABLETS are contra-indicated in patients with a history of cardiac disease, kidney disease, epilepsy and all convulsive states.

WARNING AND SPECIAL PRECAUTIONS

This product must be taken with care by persons with a history of peptic ulceration or hyperacidity.

With prolonged use some degree of tolerance and psychic dependence may occur.

Should be given with caution to patients with hyperthyroidism, hypertension, cardiac arrhythmias or other cardiovascular disease as these conditions may be exacerbated.

Low concentrations are found in breast milk. Caffeine crosses the placenta.

DOSAGE AND DIRECTIONS FOR USE:

Adults only: One or two tablets, followed by one tablet every three hours if necessary.

Not recommended for children under 12 years of age.

SIDE-EFFECTS

Therapeutic doses can cause insomnia, anxiety, restlessness, vertigo, palpitations, gastrointestinal bleeding, vomiting, abdominal pain, headache, and nausea.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

In the event of an overdose the following symptoms may occur: restlessness, sensory disturbances, maniacal behaviour, muscle tremor, delirium, diuresis, repeated vomiting with

extreme thirst, hyperthermia, tachycardia, palpitations, tachypnoea, electrolyte disturbances, convulsions and death.

If an overdosage is suspected the stomach should be emptied by emesis or gastric aspiration and lavage. Activated charcoal may be given. Treatment should be symptomatic and supportive.

IDENTIFICATION:

Biconvex, white, compressed tablets 10 mm in diameter, embossed on the one side with "R".

PRESENTATION:

REGMAKERS TABLETS are packed in:

Aluminium/PVC/PVDC Blister packs, blister strips of 10 tablets are packed in an outer cardboard carton.

Or

PVDC Cellophane packaging: Strips of cellophane containing 10 tablets are packed into cardboard catch-covers

STORAGE INSTRUCTIONS:

Store at or below 25 °C. KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

B955 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE APPLICANT:

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