1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S2

PROPRIETARY NAME (and dosage form):

PARAGORIESE-ELIKSER (tincture)

COMPOSITION:

Each 5 ml contains:	Opium tincture	0,25 ml
	Aniseed oil	0,015 ml
	Camphor	14,97 mg
	Benzoic acid	24,95 mg
	Ethanol (100%)	58,5% v/v

PHARMACOLOGICAL CLASSIFICATION:

A 2.7 - Narcotic analgesics.

PHARMACOLOGICAL ACTION:

Paragoriese-Elikser in addition to having analgesic and narcotic actions also has central stimulant actions. It depresses the thalamus, sensory cortex, and respiratory and cough centres. It increases tone in involuntary muscle, especially the sphincters of the gastro-intestinal tract.

INDICATIONS:

The treatment of diarrhoea, abdominal pain and for the treatment of cough.

CONTRA-INDICATIONS:

NOT TO BE USED FOR INFANTS AND CHILDREN.

It is contra-indicated in respiratory depression, especially in the presence of cyanosis and excessive bronchial secretion. It is also contra-indicated in the presence of acute alcoholism, delirium tremens and convulsive disorders. It should not be given during an attack of bronchial asthma or in heart failure secondary to chronic lung disease.

It should be given with caution to patients with hypothyroidism, adrenocortical insufficiency, impaired liver function, prostatic hypertrophy, or shock.

WARNINGS:

This product contains a high percentage of alcohol.

DOSAGE AND DIRECTIONS FOR USE:

NOT TO BE USED FOR INFANTS AND CHILDREN.

Adults

One to two medicine measures (5-10 ml) up to four times daily.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

The commonest are nausea, loss of appetite, constipation, confusion and sweating. Dry mouth, facial flushing, vertigo, bradycardia, palpitations, faintness, sedation, restlessness and changes of mood.

Habitual use may lead to drug dependence of the morphine type.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Coma, pinpoint pupils, depressed respiration and cyanosis, fall in body temperature and flaccid skeletal muscles.

The stomach should be emptied by aspiration and lavage; a 0,02% aqueous solution of potassium permanganate may be employed. A saline purgative such as sodium sulphate, 30 g in 250 ml of water, should be given to aid peristalsis. Intensive supportive therapy may be necessary to correct respiratory failure and shock. In addition, the specific antagonist naloxone hydrochloride is used to counteract very rapidly the severe respiratory depression and coma produced by excessive doses of narcotic analgesics. Naloxone hydrochloride 400 ug is given subcutaneously, intramuscularly, or intravenously, repeated at intervals of 2 or 3 minutes if necessary. In children, a dose of 5-10 ug per kg body weight may be given, while in neonates, a dose of 10 ug per kg body weight may be given.

IDENTIFICATION:

A bright, brown liquid with the odour of camphor.

PRESENTATION:

Clear PVC bottles of 20 ml.

STORAGE INSTRUCTIONS:

Store below 25 ºC.

Keep container tightly closed.

KEEP OUT OF REACH OF CHILDREN.

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NAME AND BUSINESS ADDRESS OF THE APPLICANT:

Pharmacare Limited

Building 12 Healthcare Park

Woodlands Drive

Woodmead 2148

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