1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS S0

PROPRIETARY NAME AND DOSAGE FORM

ENTRESSDRUPPELS H.M. (drops)

COMPOSITION

Each 5 ml of ENTRESSDRUPPELS H.M contains the alcoholic extracts of:

Tincture Asafoetida	1,208 ml
Valerian	183,300 mg
Cassia Bark	32,161 mg
Nutmeg	32,161 mg
Lavender Oil	0,016 ml
Rosemary Oil	0,004 ml

Excipients:

Ethanol, red sandalwood

Contains alcohol: 69 % *v/v*

Sugar free

CATEGORY AND CLASS

A 2.2 Sedatives, Hypnotics

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

The volatile principles of valerian, nutmeg, lavender, rosemary oil and asafoetida exert a carminative action. Valerian has been used in the treatment of nervousness, restlessness and sleeplessness.

INDICATIONS

ENTRESSDRUPPELS H.M has been used in the treatment of nervousness, restlessness and sleeplessness.

It has also been used in the treatment of pains associated with winds in the stomach and bowels.

CONTRAINDICATIONS

NOT FOR USE IN CHILDREN.

Postoperative biliary tract surgery, respiratory depression, asthma, heart failure, chronic lung diseases, elderly and debilitated patients.

History of alcoholism.

WARNINGS AND SPECIAL PRECAUTIONS

ENTRESSDRUPPELS H.M. contains a high percentage of alcohol.

DOSAGE AND DIRECTIONS FOR USE

For nervousness, restlessness and sleeplessness:

20 to 30 drops (1,5 ml to 2,0 ml) three or four times a day and at night.

For pains associated with winds in the stomach and bowels:

20 to 30 drops (1,5 ml to 2,0 ml) every half hour until pain is relieved(maximum of 10 ml per day).

Please consult your medical practitioner if pain does not subside in 10 days.

SIDE EFFECTS

Nausea, vomiting and urticaria.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Symptoms

See SIDE EFFECTS.

IDENTIFICATION

A clear, bright, reddish-brown liquid with a distinct odour of asafoetida.

PRESENTATION

20 ml is packed into a clear polyvinylchloride bottle with a metal screw cap closure.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Keep bottle tightly closed.

Keep in original packaging until required for use.

KEEP OUT OF THE REACH OF CHILDREN.

REGISTRATION NUMBER

B1206 (Act 101/1965)

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

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