ANNEXURE 1

WITDULSIES

Date of amendment:	23 March 2007	***Date of MCC approval:***	Implemented 23 March 2007

FINAL APPROVED ENGLISH PACKAGE INSERT

SCHEDULING STATUS:

S0

PROPRIETARY NAME (and dosage form):

WITDULSIES (Spirit)

COMPOSITION:

Each 5 ml contains :	Ethyl nitrite	93,75 mg
	Ethanol (100%)	42,60% v/v

PHARMACOLOGICAL CLASSIFICATION:

A 2.8 - Non-narcotic analgesics, antipyretics.

PHARMACOLOGICAL ACTION:

Witdulsies has proved to be a very useful diaphoretic acting as an effective sweating agent in chills. It reduces the temperature most successfully in feverish conditions by inducing vasodilation.

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INDICATIONS:

Witdulsies is an ideal preparation for the treatment of colds and fever. It may be used for the treatment of mild asthma attacks and dizziness.

CONTRA-INDICATIONS:

NOT FOR USE IN CHILDREN.

Patients with closed-angle glaucoma.

WARNINGS:

This product contains a high percentage of alcohol.

DOSAGE AND DIRECTIONS FOR USE:

Adults:

For colds: Take half a teaspoon (2,5 ml) in a wineglassful of water three times a day.

For asthma and dizziness: Take one (5 ml) teaspoonful in a wineglassful of water.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Large doses may cause flushing of the face, fainting, severe headache, throbbing in the head, nausea and vomiting.

Witdulsies should be used with caution in patients with marked anaemia, cerebral haemorrhage or coronary thrombosis.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Fainting should be treated by keeping the patient in a reclining position with the head lowered.

Methaemoglibinaemia has been reported in infants.

In the instances of severe toxicity contact a doctor immediately.

IDENTIFICATION:

Clear, bright, faintly yellow liquid.

PRESENTATION:

Packs of 20 ml.

STORAGE INSTRUCTIONS:

Store below 25ºC.

KEEP OUT OF REACH OF CHILDREN.

APPLICATION NUMBER:

B1183 (Act 101/1965)

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NAME AND BUSINESS ADDRESS OF THE APPLICANT:

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DATE OF PUBLICATION OF THIS PACKAGE INSERT:

04 April 1985