SCHEDULING STATUS: **S1**

PROPRIETARY NAME: **DYNEXAN OINTMENT**

(AND DOSAGE FORM) **(OINTMENT)**

COMPOSITION:

Each 10 g contains:

Tetracaine hydrochloride	50 mg
Extract of chamomile, arnica and salvia with aluminium triformate	1 g
Preservatives:	
Methyl hydroxybenzoate	0,0175 % m/m
Propyl hydroxybenzoate	0,0075 % m/m

Sugar free

PHARMACOLOGICAL CLASSIFICATION:

A 16.3 Surface anaesthetics

PHARMACOLOGICAL ACTION:

DYNEXAN OINTMENT is a local anaesthetic. The addition of mucilaginous substances also relieves irritation and enhances retention of the ointment to the mucous membrane.

INDICATIONS:

Painful and inflammatory affections of the lips, the oral mucous membrane and the gums, for relief of cold sores, mouth ulcers and denture irritation.

CONTRAINDICATIONS:

Hypersensitivity to any of the ingredients, to local anaesthetics of the ester type and to paraaminobenzoic acid and its derivatives. Patients with low plasma-cholinesterase concentrations or in those receiving anticholinesterases.

DOSAGE AND DIRECTIONS FOR USE:

Apply a pea-sized quantity of **DYNEXAN OINTMENT** on the affected part three times daily at intervals of 5 to 7 hours. If massaging is essential and possible, a pin-head sized quantity of **DYNEXAN OINTMENT** should be massaged in several times a day. When wearing new dental prostheses, the gums, palate and the prosthesis should be covered with a thin layer of **DYNEXAN OINTMENT**.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Allergic reactions may occur. The application of local anaesthetics to the skin for prolonged periods or to extensive areas should be avoided.

Tetracaine hydrochloride should be given with caution to patients with epilepsy, impaired cardiac conduction, shock or with liver damage. Patients with myasthenia gravis are particularly susceptible to the effects of local anaesthetics.

Tetracaine hydrochloride may antagonise the actions of sulphonamides. Swallowing may be impaired and it is advisable not to eat immediately after application.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

If sensitivity is suspected, discontinue use. Overdosage has not been previously reported. In case of overdosage the following effects may occur - numbness of the tongue and perioral region may appear as an early sign of systemic toxicity, excitation of the CNS with restlessness, excitement, nervousness, dizziness, tinnitus, blurred vision, nausea and vomiting, muscle twitching, tremors and convulsions may also occur. Excitation may be transient and followed by depression, with drowsiness, respiratory failure and coma. Simultaneous cardiovascular effects may occur and include myocardial depression and peripheral vasodilation, resulting in hypotension and bradycardia, arrhythmias and cardiac arrest.

Treatment:

With acute intoxication steps should be taken to maintain circulation and respiration and to control convulsions.

Treatment is symptomatic and supportive.

IDENTIFICATION:

A smooth, white to cream-coloured, homogenous ointment with an odour of eucalyptus.

PRESENTATION:

Aluminium tubes containing 10 g.

STORAGE INSTRUCTIONS:

Store in a cool dry place (below 25 °C).

Keep tightly closed.

KEEP OUT OF REACH OF CHILDREN.

REFERENCE NUMBER:

G2266 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE APPLICANT:

Adcock Ingram Limited

1 New Road

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