SCHEDULING STATUS

S0

1. NAME OF THE MEDICINE

NORFLEX HEAT RUB, 10 g Methyl Salicylate per 100 g, OINTMENT

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 g contains: Methyl Salicylate 10 g

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Yellowish, unctuous ointment with a distinctive methyl salicylate odour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the temporary relief from minor pain and stiffness of rheumatism and muscle soreness.

4.2 Posology and method of administration

Posology

Massage into the affected area three times daily as required. Wash hands after use.

Method of administration

Topical administration.

4.3 Contraindications

- Hypersensitivity to the active substance, methyl salicylate, or to any of the excipients.
- Do not apply to broken skin and excessively raw areas.
- Do not use on children under 5 years of age.

4.4 Special warnings and precautions for use

For external use only.

Avoid contact with eyes.

Exercise care with sensitive skins.

4.5 Interaction with other medicines and other forms of interaction

There have been reports that topical salicylates may potentiate the anticoagulant effects of warfarin.

4.6 Fertility, pregnancy and lactation

Pregnancy

Safety in pregnancy has not been established.

Breastfeeding

Safety in lactation has not been established.

4.7 Effects on ability to drive and use machines

Not applicable

4.8 Undesirable effects

Nervous system disorders	
Frequency unknown	Headache, symptoms of flushing may occur.
Skin and subcutaneous tissue disorder	
Frequency unknown	Skin sensitivity. Should this occur discontinue use immediately.
General disorders and administration site conditions	
Frequency unknown	Urticaria and angioneurotic oedema may occur in persons sensitive to aspirin following local application.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

Systemic poisoning may occur from application to large areas of the skin. In cases of accidental ingestion, the following symptoms may appear; the methyl salicylate may give rise to irritation of the gastric mucosa and resultant dyspepsia, erosion, ulceration, haematemesis and melaena.

Mild symptoms of intoxication could include dizziness, tinnitus, sweating, nausea and vomiting and mental confusion.

More serious signs of toxicity include hyperventilation, fever, ketosis and respiratory alkalosis and metabolic acidosis. Coma, cardiovascular collapse and respiratory failure may result.

Ingestion of relatively small amounts of methyl salicylate may cause severe poisoning and death.

Treatment in case of accidental swallowing

Empty the stomach by emesis or aspiration or gastric lavage with 5 % sodium bicarbonate solution.

Treatment of poisoning is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 13.6 Rubefacients

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Yellow soft paraffin

6.2 Incompatibilities

None known

6.3 Shelf life

2 years

6.4 Special precautions for storage

Keep tightly closed. Protect from light. Store at or below 25 °C.

6.5 Nature and contents of container

25 g aluminium tubes or plastic tubs

500 g plastic jar

6.6 Special precautions for disposal and other handling

No special precautions necessary.

7. HOLDER OF CERTIFICATE OF REGISTRATION

iNova Pharmaceuticals (Pty) Ltd

15E Riley Road, Bedfordview, 2007

8. REGISTRATION NUMBER

X /13.6/108

9. DATE OF FIRST AUTHORISATION

02 April 2002

10. DATE OF REVISION OF THE TEXT

22 November 2021