



**SUMMARY OF PRODUCT CHARACTERISTICS**  
**(SmPC)**

**NEUROGESIC<sup>®</sup> GREASELESS OINTMENT**

(Methyl Salicylate 15% w/w, Menthol 5% w/w)

## **1. NAME OF THE MEDICINAL PRODUCT**

Neurogesic<sup>®</sup> Greaseless Ointment

## **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

One gram of the ointment contains 150mg of Methyl Salicylate.

One gram of the ointment contains 50mg of Menthol

(For a full list of excipients, see section 6.1).

## **3. PHARMACEUTICAL FORM**

A smooth white homogenous greaseless Ointment.

## **4. CLINICAL PARTICULARS**

### **4.1 Therapeutic indications**

- Provides rapid relief from muscular aches, swelling and stiffness associated with rheumatism and musculo-skeletal disorder
- Provides sustained relief from pain of arthritis, backaches, muscle aches, sprains, cramps and other traumatic injuries.
- Provides fast soothing relief to sore and aching muscle.
- For sportsmen and women, when used before physical efforts, it both stimulates and loosens the muscles, thus preparing them for stressful action. It brings quick relief to sore, aching and tired muscles during and after exercises.

### **4.2 Posology and method of administration**

Apply generously and massage gently into the affected area until Neurogesic disappears. Repeat as necessary up to 4 times daily.

Neurogesic<sup>®</sup> Greaseless Ointment is administered by topical route.

### **4.3 Contraindications**

- Hypersensitivity to salicylate and other components of this drug.
- Aspirin induced bronchial asthma
- Break in the skin or open wound in area should be avoided
- Neurogesic<sup>®</sup> Greaseless Ointment is for external use only; avoid contact with eyes, mucous membranes

#### **4.4 Special warnings and precautions for use**

- Neurogesic<sup>®</sup> Greaseless Ointment is for external use only, avoids contact with eyes, mucous membranes, broken or irritated skin.
- If allergic reaction occurs discontinue usage.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

None known

#### **4.6 Pregnancy and lactation**

Methyl salicylate was administered topically to pregnant hamsters at 7d9h and the teratogenic results were compared with those obtained following oral treatment with the same compound. Both treatments produced the same defect in embryos recovered at day 9: failure of fusion of the neural tube, especially in the area of the developing brain. Analysis of serum salicylate levels following both treatments produced similar curves and indicated that teratogenic levels of salicylate can reach the maternal circulation after topical exposure (Overman and White, 1983).

#### **4.7 Effects on ability to drive and use machines**

Not applicable.

#### **4.8 Undesirable effects**

The preparation is usually well tolerated but occasionally, there may be allergic or non allergic contact dermatitis (with symptoms and signs such as itching, reddening, oedema and scaling of skin).

#### **4.9 Overdose**

The overdose is not possible as a result of local application of Neurogesic<sup>®</sup> Greaseless Ointment. In case of accidental ingestion, the stomach should be emptied by aspiration and lavage. Demulcent drinks may be given. Large volumes of fluid should be given provided renal function is adequate.

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Non-steroidal anti-inflammatory drugs: ATC code: M02AA

Mechanism of Action

Counter-irritation is thought to be effective at alleviating musculoskeletal pain as the irritation of the sensory nerve endings is thought to alter or offset pain in the underlying muscle or joints that are served by the same nerves [5]. This is thought to mask the underlying musculoskeletal pain and discomfort. When applied topically, methyl salicylate is thought to penetrate the skin and underlying tissues where it reversibly inhibits cyclooxygenase enzyme and locally and peripherally prevents the production of inflammatory mediators such as prostaglandin and thromboxane A<sub>2</sub>.

Methyl salicylate relieve musculoskeletal pain in the muscles, joints, and tendons by causing irritation and reddening of the skin due to dilated capillaries and increased blood flow. It is pharmacologically similar to aspirin and other NSAIDs but as a topical agent it primarily acts as a rubefacient and skin irritant. Counter-irritation is believed to cause a soothing sensation of warmth.

### Pharmacodynamic Effects

Neurogesic<sup>®</sup> Greaseless Ointment contains very powerful and deep penetrating active ingredients. Neurogesic<sup>®</sup> Greaseless Ointment is a very fast acting, efficient and non-irritant analgesic preparation.

## **5.2 Pharmacokinetic properties**

Approximately 12-20% of topically applied methyl salicylate may be systemically absorbed through intact skin within 10 hours of application, and absorption varies with different conditions such as surface area and pH. Dermal bioavailability is in the range of 11.8 – 30.7%. For the assessment of potential oral exposure to salicylates, bioavailability is assumed to be 100%.

Human data from experiments conducted with methyl salicylate, indicates that the dermal bioavailability is in the range of 11.8 – 30.7%.

## **5.3 Preclinical safety data**

Not applicable

# **6. PHARMACEUTICAL PARTICULARS**

## **6.1 List of excipients**

Triethanolamine 99%  
Polysorbate 80 (Tween 80)  
Lanolin  
Sorbitan monostearate  
Glyceryl monostearate  
Stearic acid  
Purified water ( to the Volume)

## **6.2 Incompatibilities**

Avoid the use of Neurogesic® Greaseless Ointment on open wounds and broken skin.

## **6.3 Shelf life**

4 years (48 months)

## **6.4 Special precautions for storage**

The ointment should be stored below 30°C protected from light.

## **6.5 Nature and contents of container**

Neurogesic® Greaseless Ointment is presented in 85g printed aluminum tube with aluminum seal covered with a white screw cap container packed in hardboard packaging with leaflet enclosed.  
Pack size: 35g and 85g

## **6.6 Special precautions for disposal <and other handling>**

Open the screw cap, use the top of the cap to break the seal on the tube then press the tube from the bottom.

Any unused product or waste material should be disposed of in accordance with local requirements.

## **7. Applicant/Manufacturer**

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