

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nelsons Rhus tox Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of cream contains:

Toxicodendron quercifolium (Rhus toxicodendron) 6X (9 % v/w)

Excipients with known effect:

Cetostearyl alcohol 2.75% w/w

Propyl parahydroxybenzoate (E216) 0.15% w/w

Methyl parahydroxybenzoate (E218).0.30% w/w

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Cream

A smooth white to off-white cream

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

A homeopathic medicinal product used within the homeopathic tradition for the symptomatic relief of rheumatic aches and pains.

4.2 Posology and method of administration

For cutaneous use only

Wash hands before and after use

Adults, the elderly and children over 12 years: Apply to the affected area 3 times a day.

This product is not recommended for use in children under 12 years of age.

If the symptoms worsen or do not improve after 7 days, a doctor or qualified healthcare practitioner should be consulted.

4.3 Contraindications

Hypersensitivity to Rhus toxicodendron or any of the excipients listed in 6.1.

4.4 Special warnings and precautions for use

Do not exceed the stated dose

Do not use on broken skin.

Discontinue use if skin becomes red, irritated or sore.

If the symptoms worsen or do not improve after 7 days, a doctor or qualified healthcare practitioner should be consulted.

If joint pain is experienced, accompanied by the swelling of the joints, redness or fever, a doctor or qualified healthcare practitioner should be consulted.

This product is not recommended for use in children under 12 years of age and medical advice should be sought.

Contains methyl parahydroxybenzoate and propyl parahydroxybenzoate. May cause allergic reactions (possibly delayed).

This product contains Cetostearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).

4.5 Interaction with other medicinal products and other forms of interactions

None known

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy and lactation: There is no evidence of the safety of the product in human pregnancy or lactation, nor is there any evidence from animal studies. Although no adverse events have been observed, the use of this product during pregnancy and lactation should be avoided unless under the guidance of a doctor.

Studies on the effects on fertility have not been performed.

4.7 Effects on ability to drive and use machines

Studies on the effects on the ability to drive or use machinery have not been performed.

4.8 Undesirable effects

None known

If any adverse reactions occur, a doctor or pharmacist should be consulted.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk of the medicinal product. Healthcare professionals are asked to report any suspected adverse

reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

No cases of overdose have been reported.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not applicable

5.2 Pharmacokinetic properties

Not applicable

5.3 Preclinical safety data

Not applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified Water
Glyceryl monostearate & Macrogol stearate
Apricot kernel oil
Theobroma oil
Glycerol (E422)
Cetostearyl alcohol & PEG-20 stearate
Cetostearyl alcohol
Cetyl palmitate
Glyceryl monocaprylate
Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate (E216)

6.2 Incompatibilities

None known

6.3 Shelf life

3 years
Use by 3 months from the date of opening.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Epoxy phenolic lacquered aluminium tube with polypropylene/polyethylene cap.
Pack size: 30g.

6.6 Special precautions for disposal

There are no special precautions for disposal.

7 MARKETING AUTHORISATION HOLDER

A. Nelson & Co Limited
5-9 Endeavour Way
Wimbledon
London
SW19 8UH
UK

8 MARKETING AUTHORISATION NUMBER

HOA1149/010/001

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first authorisation: 9th November 2018