Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nelsons Arnicare Arnica Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g cream contains:
Arnica montana tincture 1X (0.9% w/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 bruises.

4.2 Posology and method of administration

For cutaneous use only
Wash hands before and after use.
Adults, the elderly and children over 2 years: Apply to the affected area 4 times a day, as required.
Not recommended for children under 2 years.
If symptoms worsen or persist after using the product for two weeks, a doctor or qualified healthcare practitioner should be consulted.

4.3 Contraindications

Hypersensitivity to the active ingredient or to plants of the Asteraceae (Compositae) family or to any of the excipients listed in 6.1.

4.4 Special warnings and precautions for use

Do not exceed the stated dose
Avoid contact with eyes and mucous membranes.
Not to be applied to broken or irritated skin. Discontinue use if skin becomes red, dry or irritated.
This product is not recommended for children under 2 years of age and medical advice should be sought.
This product contains Cetostearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).
This product contains propyl parahydroxybenzoate (E216) and methyl parahydroxybenzoate (E218), which may cause allergic reactions (possibly delayed).

4.5 Interaction with other medicinal products and other forms of interactions

None reported
No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.
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 operate machines have not been performed.

4.8 Undesirable effects

Hypersensitivity (contact dermatitis, itching skin rash) has been reported. The frequency is not known.
If other adverse reactions not mentioned above occur, a doctor or a qualified healthcare practitioner 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. Website: www.hpra.ie

4.9 Overdose

If accidentally ingested, due to the irritant effect of the product, symptoms of intoxication may include gastro-intestinal and nervous system disturbances; dizziness, diarrhoea, shivering and palpitations. Respiratory difficulties may occur at very high doses. Treatment of the overdose: the stomach should be emptied by aspiration or lavage if the patient has not already vomited. Demulcent drinks such as milk should be given.

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
Cocoa butter
Glycerol E422
Cetostearyl alcohol & PEG-20 Stearate
Cetostearyl alcohol
Cetyl palmitate
Glyceryl monocaprylate
Methyl parahydroxybenzoate E218
Propyl parahydroxybenzoate E216

6.2 Incompatibilities

Not 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 sizes: 25g, 30 g and 50 g.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements for disposal.

7 MARKETING AUTHORISATION HOLDER

Nelsons GmbH
Heegbarg 2
22391 Hamburg
Germany

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Nelsons GmbH
Heegbarg 2
22391 Hamburg
Germany

8 MARKETING AUTHORISATION NUMBER

HOA22892/004/001

8 REGISTRATION NUMBER(S)

HOA22892/004/001

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first authorisation: 9th November 2018

10 DATE OF REVISION OF THE TEXT

November 2021