Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Atrogel Arnica Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g of gel contains 500 mg of tincture from fresh *Arnica montana* L., flos (Arnica flower) equivalent to 120-200 mg of fresh Arnica flowers.
Extraction solvent: ethanol 50 % m/m.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gel.
It is a slightly cloudy, golden-brown to green-yellow coloured gel with a characteristic odour of Arnica.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A traditional herbal medicinal product for the symptomatic relief of muscular aches, pains and stiffness, sprains, bruises and swelling after contusions, exclusively based on long-standing use.

This product is indicated for use in adults and children.

4.2 Posology and method of administration

Posology

Adults: Apply 2 - 10 cm of gel gently to the affected area 2 to 4 times daily.
Children and older people: Apply similarly as described for adults (above).
Amount of gel to be applied is dependent on the size of the area of injury.

If the condition worsens or if symptoms do not improve within one week, a doctor should be consulted.

Method of administration
For cutaneous use only.

4.3 Contraindications

Hypersensitivity to Arnica preparations, other members of the Asteraceae (Compositae) family, or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

For cutaneous use only. Do not use on broken or irritated skin. Avoid contact with eyes and mucous membranes. Discontinue use if redness, irritation or dry skin occurs.

Do not exceed the stated dose.

If the condition worsens, or if symptoms do not improve within one week, or if adverse events not listed occur consult your doctor or pharmacist.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

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

4.7 Effects on ability to drive and use machines

Atrogel has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Common (>1/100 to ≤1/10)
Skin and subcutaneous tissue disorders.

- Contact dermatitis
- Itching
- Rash
- Dry Skin

The incidence is reported in studies to be between 5 and 10% for Atrogel.

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 balance 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

In case of overdose, irritation and redness may occur. Discontinue use.

In the unlikely event of internal ingestion, due to the irritant effect of Arnica, 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 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 required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended, unless necessary for the safe use of the product. Adequate tests on reproductive toxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol 96 %
Purified Water
Glycerol (85 %)
Ammonium acryloyldimethyltaurate/VP Copolymer

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years
Use within 6 months of opening. After opening, store below 25°C.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.
For storage conditions after first opening, see section 6.3.

6.5 Nature and contents of container

Pack: White laminated multilayer polyethylene tube with a vapour block layer. The opening is sealed with an aluminium peel-seal.
Closure: Polypropylene screw cap.
Pack sizes: 50 ml and 100 ml

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

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

7 REGISTRATION HOLDER

A. Vogel Ireland Ltd,
Unit 3D, Killeen Road,
Dublin 10
D10 TY20
Ireland

8 REGISTRATION NUMBER(S)

TR2309/001/001

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first registration: 14th of January 2011
Date of last renewal: 13th January 2016

10 DATE OF REVISION OF THE TEXT

August 2022