

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Atrogel Muscle Aches & Pains Arnica Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g gel contains:

500 mg extract (as liquid extract) of fresh Arnica Flowers (*Arnica montana* L.)
(equivalent to 120 - 200 mg fresh Arnica Flowers)

Extractant: ethanol 58 % v/v

Excipients with known effect:

1 g of gel contains 550 mg of ethanol (alcohol).

For a 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 used for the symptomatic relief of muscular aches, pains and stiffness, sprains, bruises and swelling after contusions, exclusively based on long-standing use.

4.2 Posology and method of administration

Adults: Apply 2 - 10 cm gently to the affected area 2 to 4 times daily.

Children 12 years and over and the elderly: Apply similarly as described for adults (above).

Not recommended for use in children under 12 years of age (see section 4.4 Special warnings and precautions for use).

For cutaneous use only.

4.3 Contraindications

Do not use in cases of known hypersensitivity to Arnica preparations, other members of the Asteraceae (Compositae) family, or one of the excipients.

4.4 Special warnings and precautions for use

Do not exceed the stated dose.

If the condition worsens, or if symptoms persist for more than two weeks, or if adverse events not mentioned in the package leaflet occur, consult a healthcare practitioner.

The use in children under 12 years of age has not been established due to lack of adequate data.

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.

It may cause a burning sensation on damaged skin.

In neonates (pre-term and term newborn infants), high concentrations of ethanol may cause severe local reactions and systemic toxicity due to significant absorption through immature skin (especially under occlusion).

Due to the alcohol content of this product, it should not be used near a naked flame or heat source.

Keep out of the sight and reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

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

Lactation: There is no evidence to suggest that the product should not be used during lactation.

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 $\leq 1/10$)

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 of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard

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 applicable.

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 size: 50 ml

100 ml

6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

A.Vogel Ltd
2 Brewster Place
Irvine, Ayrshire
KA11 5DD, United Kingdom

Tel: 01294 277344
enquiries@avogel.co.uk

8 REGISTRATION NUMBER(S)

THR 13668/0009

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

30/10/2006

10 DATE OF REVISION OF THE TEXT

06/10/2025