

# **SUMMARY OF PRODUCT CHARACTERISTICS**

## **ATROGEL ARNICA GEL**

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

Atrogel 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

For a full list of excipients, see section 6.1

### **3 PHARMACEUTICAL FORM**

Gel.

It is a clear 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.

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

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

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

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.

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.

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 ≤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.

#### **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 %)

Hypromellose

### **6.2 Incompatibilities**

Not applicable

### **6.3 Shelf life**

24 months

### **6.4 Special precautions for storage**

This medicinal product does not require any special storage conditions.

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

Pack: White laminated multilayer polyethylene tube with a vapour block layer (SiOxlayer).

The opening is sealed with an aluminium peel-seal.

Closure: Polypropylene screw cap.

Pack size: 100 ml

### **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

## **7 REGISTRATION HOLDER**

Bioforce (UK) Ltd

2 Brewster Place

Irvine, Ayrshire

KA11 5DD, United Kingdom

Tel: 01294 277 344

enquiries@avogel.co.uk

**8 REGISTRATION NUMBER(S)**

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