

Package Leaflet:
Information for the user



Atrogel

Arnica Gel

Tincture of fresh *Arnica montana*



Information

Read all of this leaflet carefully before you start using this product because it contains important information for you.

Always use this product exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 1 week.

What is in this leaflet

1. What Atrogel is and what it is used for
2. What you need to know before you use Atrogel
3. How to use Atrogel
4. Possible side effects
5. How to store Atrogel
6. Contents of the pack and other information

1. What Atrogel is and what it is used for

Atrogel is a traditional herbal medicinal product containing the tincture of fresh Arnica flowers.

It is used to relieve muscular aches and pains. This is exclusively based on long-standing use.

Used to help relieve symptoms including:

- Muscular aches, pains and stiffness
- Sprains
- Bruises
- Swelling after injury

Atrogel is for use in adults and children.

Do's and Don'ts for using Atrogel

2. What you need to know before you use Atrogel

Do not use Atrogel

- If you are allergic to:
 - Arnica or plants of the daisy (Asteraceae/Compositae) family. Arnica is a member of the daisy family.
 - Products containing Arnica.
 - Any of the other ingredients of this product (listed in section 6).

Warnings and precautions

- Do not use on broken, cut or irritated skin. This product may cause irritation.
- Do not use in or near your eyes, nose, mouth or other sensitive areas. This product may cause irritation.
- Do not use at more than the recommended dose.
- Talk to your doctor or pharmacist if your symptoms worsen or do not improve within 1 week.

Other medicines and Atrogel

- You can use this product with other medicines.
- If you are speaking to your doctor, pharmacist or nurse always remember to tell them about any medicines you are taking, including herbal remedies such as Atrogel.

Pregnancy and breast-feeding

- If you are pregnant or breast-feeding talk to your doctor before using this product.

Driving and using machines

- This product has no effect on your ability to drive or use machines.

Using

3. How to use Atrogel

Always take this product exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Recommended dose

Adults: Apply 2 - 10 cm of gel gently to the affected area. Use 2 to 4 times a day.

Children and older people: Follow the adult dose.

The amount of gel to be applied depends on the size of the area of injury.

For cutaneous use only. This means you can use this product on your skin but not in or near your eyes, nose, mouth or other sensitive areas. Do not apply if your skin surface is broken, cut or irritated.

When first opening the tube check that the seal is not broken. Remove seal before use.

If you use more Atrogel than you should

- Your skin may become red or irritated. If this happens stop using this product.



Using

If you swallow Atrogel by mistake

- Seek medical advice immediately and take this leaflet with you.

If you forget to use Atrogel

- Do not worry about a missed dose. Apply the next dose as usual.
- Do not apply a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product ask your doctor, pharmacist or nurse.



Side effects

4. Possible side effects

Like all products, this product can cause side effects, although not everybody gets them.

Side effects

Skin Reactions

- Itching
- Rash
- Skin reaction (contact dermatitis)
- Dry skin

Discontinue use. If you find these are troubling you, talk to your doctor or pharmacist.

These side effects are common and likely to affect less than 1 in every 10 people.

Reporting of side effects

- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.
- You can also report side effects directly 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

- By reporting side effects you can help provide more information on the safety of this medicine.



Information

5. How to store Atrogel

- Replace cap after use.
- Keep this product out of the sight and reach of children.
- Do not use this product after the expiry date which is stated on the carton and tube after EXP. The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage conditions.
- Do not use this product if you notice a change in appearance. It should be a slightly cloudy gel that is golden-brown to yellowy-green in colour.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Atrogel contains

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.

The other ingredients are ethanol, purified water, glycerol and ammonium acryloyldimethyltaurate/VP copolymer.

What Atrogel looks like and contents of the pack

Atrogel is a slightly cloudy gel that is golden-brown to yellowy-green in colour. Atrogel is available in 50 ml and 100 ml white plastic tubes. Not all pack sizes may be marketed.

Traditional Herbal Registration Holder and Manufacturer

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This leaflet was last revised in 04/2016.

You should also know

Do not use too much Atrogel as this may stain your clothes.

Bioforce runs a helpline by phone and email which can provide you with further information.

E-mail: enquiries@avogel.co.uk

Phone: **1 890 930 070**

You can get a larger print or audio version of this leaflet.
Call this number:
1 890 930 070

