

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

[S0]

ACTIVEZE® ARNICA MASSAGE OIL Oil

Arnica montana L. (arnica) [maximum 5 % flower oil; 95 % sunflower oil carrier] oil

- D.33.6. Complementary Medicines: Discipline-Specific. Traditional Claims - Western Herbal Medicine.
- This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

Read all of this leaflet carefully because it contains important information for you

ACTIVEZE® ARNICA MASSAGE OIL is available without a doctor's prescription. Nevertheless, you still need to use ACTIVEZE® ARNICA MASSAGE OIL carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ACTIVEZE® ARNICA MASSAGE OIL with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

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

1. What ACTIVEZE® ARNICA MASSAGE OIL is and what it is used for

ACTIVEZE® ARNICA MASSAGE OIL has anti-inflammatory properties and is used topically to assist with the relief of muscular aches and pains, stiffness, sprains, bruises and swelling after injury. It may also be used for loosening and relaxing strained muscles both before and after sporting activity.

2. What you need to know before you use ACTIVEZE® ARNICA MASSAGE OIL

Do not use ACTIVEZE® ARNICA MASSAGE OIL:

- If you are hypersensitive (allergic) to Arnica or plants of the daisy family (*Asteraceae/Compositae*) or to any of the ingredients of ACTIVEZE® ARNICA MASSAGE OIL (listed in section 6 **Contents of pack and other information**).
- If you are taking any chronic medication do not use this product without consulting your medical practitioner.

Warnings and precautions

- ACTIVEZE® ARNICA MASSAGE OIL is for topical/external use only. This means you can use this product on intact skin but not in or near your eyes, nose, mouth or other sensitive areas.
- Do not use on broken, irritated or damaged skin.
- Do not bandage or apply with external heat (such as a heating pad) as this may result in excessive skin irritation or skin burn.
- Discontinue using this product if you experience redness, irritation, dry skin or any other unwanted effects.
- Consult a healthcare provider or doctor if symptoms persist or worsen.

Porphyria: Safety has not been established.

Tell your doctor if you are not sure about any of the above.

Other medicines and ACTIVEZE® ARNICA MASSAGE OIL

Always tell your healthcare provider if you are taking any other medicine, including complementary or traditional medicines. You can use this product with other oral medications as there are no known interactions with the topical use of arnica oil with other medicines. However, it is not advisable to use ACTIVEZE® ARNICA MASSAGE OIL together with other topical medicines (oils, creams or ointments).

Using ACTIVEZE® ARNICA MASSAGE OIL with food, drink and alcohol

There is no known interaction between the contents of ACTIVEZE® ARNICA MASSAGE OIL and food, drink and alcohol.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you might be pregnant or are planning to have a baby, please consult your doctor or pharmacist or other healthcare provider for advice before using this product.

Driving and using machines

ACTIVEZE® ARNICA MASSAGE OIL is for topical/external use only and should not affect your ability to drive or use machinery. However, if you think you are affected you should not drive or operate machinery until you feel better. It is not always possible to predict to what extent ACTIVEZE® ARNICA MASSAGE OIL may interfere with your daily activities. Ensure that you do not engage in the above activities until you are aware of the measure to which ACTIVEZE® ARNICA MASSAGE OIL affects you.

3. How to use ACTIVEZE® ARNICA MASSAGE OIL

Do not share medicines with any other person.

Always take ACTIVEZE® ARNICA MASSAGE OIL exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. You should check with your doctor, pharmacist or nurse if you are unsure.

The usual dose and directions for use for adults and children from 12 years is:

- Gently massage a small amount onto the affected joints and muscles.
- Repeat every 3 to 4 hours.
- Wash your hands thoroughly with soap and water after use.
- A capful of ACTIVEZE® ARNICA MASSAGE OIL may be added to bath water for added assistance in easing painful muscles and joints.

If you use more ACTIVEZE® ARNICA MASSAGE OIL than you should

In the event of overdose, consult your doctor or pharmacist. If neither are available, contact the nearest hospital or poison centre. Your skin may become red, dry or irritated. If this happens, stop using this product and thoroughly wash the product off the skin with soap and water.

If you forget to use ACTIVEZE® ARNICA MASSAGE OIL

Continue using ACTIVEZE® ARNICA MASSAGE OIL as prescribed when you remember. Do not apply more frequently to make up for the missed doses.

If you stop using ACTIVEZE® ARNICA MASSAGE OIL

If you are using the dose as indicated and as this product is for topical/external use only, it is unlikely that there should be withdrawal effects when you stop using this medication.

4. Possible side effects

ACTIVEZE® ARNICA MASSAGE OIL can have side effects.

Not all side effects reported for ACTIVEZE® ARNICA MASSAGE OIL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ACTIVEZE® ARNICA MASSAGE OIL, please consult your healthcare provider for advice.

If any of the following or other side effects occur, stop using this product and consult your doctor or pharmacist or go to the casualty department at your nearest hospital:

Allergic reactions such as: skin rashes, hives (skin bumps), itchiness, swelling of the face, lips mouth or throat, which may cause difficulty in swallowing or breathing. These are all very serious side effects. If you have them, you may have had a serious reaction to ACTIVEZE® ARNICA MASSAGE OIL. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Frequency unknown:

- Allergic eczema, contact dermatitis, skin irritation, rashes, itching skin and dry, scaly skin.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to the SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ACTIVEZE® ARNICA MASSAGE OIL.

5. How to store ACTIVEZE® ARNICA MASSAGE OIL

- Store all medicines out of reach of children.
- Store in a dry place at or below 25 °C.
- Protect from light and moisture.
- Keep in original packaging until use.
- Close cap firmly after use.
- Do not refrigerate.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label and carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of pack and other information

What ACTIVEZE® ARNICA MASSAGE OIL contains

Active ingredients	Per 100 ml
<i>Arnica montana</i> L. (arnica) [maximum 5 % flower oil; 95 % sunflower oil carrier] oil	3,0 % m/m

The other ingredients or excipients are: capric triglyceride, isopropyl myristate, paraffinum liquidum, *Sesamum indicum* (sesame) oil, *Simmondsia chinensis* (jojoba) oil, colourant.

What ACTIVEZE® ARNICA MASSAGE OIL looks like and contents of the pack

ACTIVEZE® ARNICA MASSAGE OIL contains 125 ml of oil in a transparent labelled plastic bottle with a green screw cap. It is packaged in a printed unit carton that includes a patient information leaflet.

Holder of Certificate of Registration

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This leaflet was last revised in

September 2024

Date of registration

To be allocated

Registration number

To be allocated

Professional Information

The ACTIVEZE® ARNICA MASSAGE OIL Professional Information may be obtained from the Nativa website (www.nativa.co.za).