PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:
S0

ActivEze® Freeze Spray (125 ml)
L-menthol , *Mentha x piperita* L. (peppermint oil).

Read all of this leaflet carefully because it contains important information for you.
ActivEze® Freeze Spray is available without a doctor's prescription. Nevertheless, you still need to use ActivEze® Freeze Spray carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share ActivEze® Freeze Spray with any other person.
- Ask your healthcare provider or pharmacist if your need more information or advice.

1. What ActivEze® Freeze Spray is and what it is used for
ActivEze® Freeze Spray is a cooling aerosol that works directly on painful, stiff joints and muscles, relieving aches and pain.

2. What you need to know before you use ActivEze® Freeze Spray. Do not use ActivEze® Freeze Spray
- If you are hypersensitive (allergic) to any of the ingredients in ActivEze® Freeze Spray listed in section 6).
- If you have epilepsy, asthma, persistent or chronic cough or other chronic lung conditions.
- Do not apply to broken, irritated or sensitive skin.
- If you are pregnant or breastfeeding (see **Pregnancy and breastfeeding**).

Warnings and precautions
- Topical 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 together with other topical products containing camphor, menthol, eucalyptol and/or eucalyptus essential oil.
- When spraying, be cautious not to breathe in the mist/vapour.
- Do not expose the area, where the product is applied, to sunlight.
- Do not tightly bandage or apply with external heat (such as an electric heating pad) as this may result in excessive skin irritation or skin burn.
- If accidental ingestion occurs, seek urgent medical attention or contact a Poison Information Centre.
- Stop using this product and get immediate medical attention if you experience redness, skin irritation, blistering or any other unwanted effects.
- Stop using this product and consult a healthcare provider or doctor if symptoms persist or worsen, reoccur, or are accompanied by a fever, rash or persistent headache.

Porphyria: Safety has not been established.
Tell your doctor if you are not sure about any of the above.

Other medicines and ActivEze® Freeze Spray
Products containing herbal ingredients may interact with some medication. Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicine). Before using ActivEze® Freeze Spray, consult your doctor, pharmacist or healthcare provider if you are using other products containing camphor, menthol, eucalyptol and/or eucalyptus essential oil.

Pregnancy and breastfeeding
- It is not advisable to use ActivEze® Freeze Spray while you are pregnant or breastfeeding as it contains menthol.
- 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 ActivEze® Freeze Spray.

If you use more ActivEze® Freeze Spray than you should
Your skin may become red, blister or become irritated. If this happens, stop using ActivEze® Freeze Spray and thoroughly wash the area where the product has been applied. Consult your doctor or healthcare provider if symptoms persist or worsen.

If you forget to use ActivEze® Freeze Spray
Continue using ActivEze® Freeze Spray as prescribed when you remember. Do not use more frequently to make up for the missed doses.

If you stop using ActivEze® Freeze Spray
Since this product is for topical use only, there should not be any withdrawal effects when you stop using this product.

4. Possible side effects
ActivEze® Freeze Spray can have side effects. Not all side effects reported for ActivEze® Freeze Spray are included in this leaflet. Should your general health worsen while taking this medicine, or if you experience any undesired effects while using this medicine, please consult your healthcare provider for advice. Like all medicines, this medicine can cause side effects although not everybody gets them.

If any of the following happens, stop using ActivEze® Freeze Spray and tell your doctor immediately 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.

Tell your doctor or pharmacist if you notice any of the following:
Frequency unknown:
- Skin irritation/rash, redness, burning, contact dermatitis, blistering
- Dizziness, headache, nausea

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® Freeze Spray.

What ActivEze® Freeze Spray looks like and contents of the packaging
ActivEze® Freeze Spray is available in a 125 ml white aerosol canister with a green cap and a patient information leaflet.

This leaflet was last revised in
August 2024

Date of registration
To be allocated

Registration number
To be allocated

Professional Information
Professional Information for ActivEze® Freeze Spray can be obtained from the Nativa website (www.nativa.co.za).