

Package leaflet: Information for the user

Axsain® 0.075% w/w Cream Capsaicin 0.075% w/w

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What AXSAIN is and what it is used for

The name of this medicine is Axsain cream. The active ingredient in this medicine is capsaicin which is a naturally occurring substance found in plants.

Axsain cream is used to relieve pain arising from nerves near to the surface of the skin. This can happen after having Shingles (Herpes Zoster).

Axsain cream is also used to relieve pain in patients who have nerve damage to their hands or feet caused by diabetes.

2. What you need to know before you use AXSAIN CREAM

Do not use Axsain cream:

- If you are **allergic** (hypersensitive) to capsaicin or any of the other ingredients (listed in section 6).
- On broken or irritated skin.

This medicine is not suitable for use in children.

Warnings and precautions

Talk to your doctor or pharmacist before using **Axsain cream**

- Keep away from the eyes, nose and mouth (if it does accidentally get into your eyes, nose and mouth or onto broken or irritated skin, wash off with plenty of water).
- Wash your hands immediately after applying the cream, unless the hands are treated areas, in which case, they should be washed 30 minutes after applying.
- Avoid hot baths or showers immediately before or just after applying Axsain cream.
- Do not apply tight bandages on top of Axsain cream.
- Avoid breathing in any vapours from the cream, as this can cause irritation of the eyes and breathing difficulties (including making asthma worse).

Other medicines and Axsain cream

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast feeding, think you may be pregnant or planning to have a baby, you should ask your doctor or pharmacist for advice before taking Axsain.

Axsain Cream contains cetyl alcohol

Axsain may cause local skin reactions (e.g. contact dermatitis) due to the product containing cetyl alcohol.

3. How to use AXSAIN CREAM

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Axsain should be applied to the affected area 3 to 4 times a day, with a gap of at least 4hrs between each application.

A small amount of cream (about the size of a pea) should be rubbed onto the area to be treated with your fingers. Make sure that all the cream is rubbed in so it is no longer visible.

Wash your hands immediately after application of Axsain, unless you are treating nerve damage in your hands, when you should wait 30 minutes before washing your hands.

When using Axsain cream to relieve pain caused by nerve damage due to diabetes the treatment normally lasts for 8 weeks.

4. Possible side effects

Like all medicines Axsain can cause side effects, although not everybody gets them.

Axsain cream can cause a brief burning feeling when applied. This burning is more common when:

- The cream is used more than 4 times a day.
 - Too much cream is applied.
 - The cream is applied just before or after a hot bath or shower.
- Rarely when Axsain cream is applied the vapour can cause brief irritation of the eyes, nose, and throat, such as runny nose, cough or sneezing, breathlessness or worsening of asthma.
- Axsain may also cause irritation of the skin for example itching or stinging.

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 (see details below)

United Kingdom

The Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

Ireland

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.

5. How to store AXSAIN CREAM

Keep this medicine out of the sight and reach of children.

Store below 25°C.

Do not use after the expiry date printed on the carton and tube.

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 Axsain contains

Axsain cream contains 0.075% capsaicin as the active ingredient. It also contains purified water, sorbitol solution, isopropyl myristate, cetyl alcohol, white soft paraffin, glycerol stearate, PEG-100 stearate and benzyl alcohol as the inactive ingredients.

What Axsain cream looks like and contents of pack

Axsain cream is a white cream packed in aluminium tubes with epoxyphenolic lining and polypropylene spiked cap containing 45 gm Axsain cream.

Marketing Authorisation Holder

Teva B.V., Swensweg 5, 2031GA Haarlem, Netherlands

Manufacturer

Pharmasol Limited, North Way, Walworth Industrial Estate, Andover, Hampshire, SP10 5AZ, UK.

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