

Package leaflet: Information for the user

ZACIN® 0.025% w/w Cream Capsaicin 0.025% 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 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 of the 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 ZACIN is and what it is used for
2. What you need to know before you use ZACIN
3. How to use ZACIN
4. Possible side effects
5. How to store ZACIN
6. Contents of the Pack and other information

1. What ZACIN is and what it is used for

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

ZACIN cream is used to relieve the pain from osteoarthritis.

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

Do not use ZACIN 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 **Zacin 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 the treated areas, in which case, they should be washed 30 minutes after applying.
- Avoid hot baths or showers immediately before or just after applying ZACIN cream.
- Do not apply tight bandages on top of ZACIN 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 Zacin 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 are planning to have a baby, ask your doctor or pharmacist for advice before taking ZACIN.

ZACIN Cream contains cetyl alcohol

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

3. How to use ZACIN 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.

ZACIN should be applied to the affected area 4 times a day, with a gap of at least 4 hrs 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 ZACIN, unless you are treating arthritic hand joints, when you should wait 30 minutes before washing your hands.

4. Possible side effects

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

ZACIN cream can cause a 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 ZACIN 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.

ZACIN 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 ZACIN 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 ZACIN contains

ZACIN cream contains 0.025% 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 ZACIN cream looks like and contents of the pack

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