

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

#### **1. What Zacin Cream 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 to capsaicin or any of the other ingredients of this medicine (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 using this medicine.

##### **Zacin Cream contains benzyl alcohol and cetyl alcohol**

- This medicine contains 450 mg benzyl alcohol in each cream tube which is equivalent to 0.01 mg/mg. Benzyl alcohol may cause allergic reactions and mild local irritation.

- Cetyl alcohol may cause local skin reactions (e.g. contact dermatitis).

### **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 Cream 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 Cream, unless you are treating arthritic hand joints, when you should wait 30 minutes before washing your hands.

### **4. Possible side effects**

Like all medicines, this medicine 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 Cream 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 via HPRA Pharmacovigilance, Website: [www.hpra.ie](http://www.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 this medicine after the expiry date which is stated on the carton and tube. The expiry date refers to the last day of that month.

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 Cream contains**

- Zacin Cream contains 0.025% capsaicin as the active ingredient.
- The other ingredients are purified water, sorbitol solution, isopropyl myristate, cetyl alcohol, white soft paraffin, glycerol stearate, PEG-100 stearate and benzyl alcohol.

#### **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 g Zacin Cream.

**Marketing Authorisation Holder**

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

**Manufacturer**

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**This leaflet was last revised in April 2025.**