Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zacin 0.025% w/w Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Capsaicin 0.025% w/w.

Also contains Cetyl Alcohol 8.0% w/w.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream
A smooth white cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the symptomatic relief of pain associated with osteoarthritis.

4.2 Posology and method of administration

Adults and the elderly:

For topical administration to unbroken skin. Apply only a small amount of cream (pea size) to affected area 3 or 4 times daily. The cream should be gently rubbed in, there should be no residue left on the surface. Zacin may cause transient burning on application. The burning is observed more frequently when application schedules of more than 4 times daily are used. Hands should be washed immediately after application of Zacin unless hands and fingers are being treated. Zacin should not be applied near the eyes. Pain relief usually begins within the first week of treatment and increases with continuing regular application for the next two to eight weeks.

Not suitable for use in children.

4.3 Contraindications

Zacin cream is contra-indicated on broken or irritated skin.

Zacin Cream is contra-indicated in patients with known hypersensitivity to capsaicin or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Skin irritation has been reported following application of Zacin. The hands should be washed immediately after application of the cream, unless the hands are the treated areas, in which case, they should be washed 30 minutes after application.

Contact with eyes and mucous membranes should be avoided.

Patients should avoid taking a hot bath or shower just before or after applying Zacin, as it can enhance the burning sensation.

Patients and carers should avoid inhalation of vapours from the cream, as transient irritation of the mucous membranes of the eyes and respiratory tract (including exacerbation of asthma) has been reported.

Keep Zacin away from the eyes.

Medical advice should be sought if the condition worsens, or clears up then recurs.

Tight bandages should not be applied on top of Zacin cream.

4.5 Interaction with other medicinal products and other forms of interactions

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

The safety of Zacin during pregnancy and lactation has not been established, in either humans or animals. However, in the small amounts of absorbed transdermally from Zacin Cream, it is considered unlikely that capsaicin will cause any adverse effects in humans.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Zacin may cause skin irritation or transient burning on application. This burning is observed more frequently when application schedules of more than 4 times daily are utilised. The burning can be enhanced if too much cream is used and if it is applied just before or after a bath or shower.

Irritation of the mucous membranes of the eyes and respiratory tract (such as nasal and throat irritation) on application of Zacin cream has been reported rarely, resulting in symptoms such as coughing, sneezing and runny eyes. These events are usually mild and self-limiting. There have been a few reports of dyspnoea, wheezing and exacerbation of asthma.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Topical products for joint and muscular pain Capsaicin and similar agents, ATC code: M02A B01. Although the precise mechanism of action of capsaicin is not fully understood, current evidence suggests that capsaicin exerts an analgesic effect by depleting and preventing reaccumulation of Substance P in peripheral sensory neurons. Substance P is thought to be the principal chemomediator of pain impulses from the periphery to the central nervous system.

5.2 Pharmacokinetic properties

Absorption after topical application is unknown. Average consumption of dietary spice from capsicum fruit has been estimated at 2.5g/person/day in India and 5.0g/person/day in Thailand. Capsaicin content in capsicum fruit is approximately 1% therefore dietary intake of capsaicin may range from 0.5-1mg/kg/day for a 50kg person. Application of two tubes of Zacin Cream 0.025% (90g) each week results in 3.21mg/day topical exposure.

Assuming 100% absorption in a 50kg person, daily exposure would be 0.064mg/kg which is approximately one seventh to one eighth of the above mentioned dietary intake.

5.3 Preclinical safety data

The available animal toxicity data relating to capsicum, capsicum extracts and capsaicin do not suggest that, in usual doses, they pose any significant toxicity hazard to man. Thus, in both single and repeat dosing studies which have been reported, capsicum extracts and capsicum are generally well-tolerated at many times even the highest estimated human intakes. The safety of Zacin for use in human pregnancy has not been established since no formal reproduction studies have been performed in either animals or man. However, there is no reason to suspect from human or animal studies currently available that any adverse effects in humans are likely.

Studies reported in the published literature which relate to potential genotoxic and carcinogenic action of capsaicin have produced inconclusive and conflicting data. However, it is unlikely that capsaicin, in the quantities absorbed transdermally from Zacin Cream, will pose any significant hazard to humans.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified Water
Sorbitol Solution
Isopropyl Myristate
Cetyl Alcohol
White Soft Paraffin
Glyceryl Stearate and
PEG-100 Stearate (Arlacel 165)
Benzyl Alcohol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store below 25 °C.

6.5 Nature and contents of container

Aluminium tubes with epoxyphenolic lining and spiked cap, containing 45 g of cream.

6.6 Special precautions for disposal

No special requirements for disposal.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Teva B.V.
Swensweg 5
2031GA Haarlem
Netherlands

8 MARKETING AUTHORISATION NUMBER

PA1986/090/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16 April 1999

Date of last renewal: 16 April 2009

10 DATE OF REVISION OF THE TEXT

March 2019 CRN008RDG