Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Axsain 0.075% w/w Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

capsaicin 0.075% w/w.

Excipient(s) with known effect
Each cream tube contains;
- 450 mg benzyl alcohol which is equivalent to 0.01 mg/mg
- 3.6g cetyl alcohol which is equivalent to 0.08 mg/mg

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

1. For the symptomatic relief of neuralgia associated with and following Herpes Zoster infections (post-herpetic neuralgia) after open skin lesions have healed.

2. For the symptomatic management of painful diabetic peripheral polyneuropathy.

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 the affected area 3 or 4 times daily. The cream should be gently rubbed in, there should be no residue left on the surface. Axsain 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 Axsain with the fingers. Do not apply near the eyes.

Patients using Axsain for the treatment of painful diabetic peripheral polyneuropathy should only do so under the direct supervision of a hospital consultant who has access to specialist resources. The recommended duration of use in the first instance is 8 weeks, since there is no clinical trial evidence of efficacy for treatment of more than 8 weeks duration. After this time, it is recommended that the patient's condition should be fully clinically assessed prior to continuation of treatment, and regularly re-evaluated thereafter, by the supervising consultant.

Not suitable for use in children.

4.3 Contraindications

Axsain cream is contra-indicated for use on broken or irritated skin.

Axsain Cream is contra-indicated in patients with hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Not for use under tight bandages.

Keep away from the eyes.

Skin irritation has been reported following application of Axsain. 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 Axsain, 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.

If the condition worsens, seek medical advice.

Excipient(s)

Benzyl alcohol
Benzyl alcohol may cause allergic reactions and mild local irritation

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

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 Axsain during pregnancy or lactation has not been established in either humans or animals. However, in the small amounts absorbed transdermally from Axsain 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

Axsain 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 Axsain 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, Website: www.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 renders skin insensitive to pain 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 as 2.5g/person/day in India and 5.0g/person/day in Thailand. Capsaicin content in capsicum fruit is approximately 1% therefore daily dietary intake of capsaicin may range from 0.5 - 1mg/kg/day for a 50kg person. Application of two tubes of Axsain Cream 0.075% (90g) each week results in a 9.6mg/day topical exposure. Assuming 100% absorption in a 50kg person, daily exposure would be 0.192mg/kg which is approximately one third to one quarter 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 Axsain for use in human pregnancy has not been established since no formal reproduction studies have been performed on 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 Axsain 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 Parafin
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 polypropylene cap, containing 45g 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

PA1986/088/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14 June 1994

Date of last renewal: 14 June 2009

10 DATE OF REVISION OF THE TEXT

March 2021