

Clinical overview

Axsain (capsaicin 0.075% cream) is currently licensed in the UK and Ireland for the symptomatic relief of neuralgia associated with and following Herpes Zoster infections (post-herpetic neuralgia) after open skin lesions have healed, and for the symptomatic management of painful diabetic peripheral polyneuropathy.

Zacin® (Capsaicin Cream 0.025%) is currently licensed in the UK and Ireland for the symptomatic relief of pain associated with osteoarthritis.

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 re-accumulation of substance P in peripheral sensory neurons. Substance P is thought to be the principal chemo-mediator of pain impulses from the periphery to the Central Nervous System.

A 5-year Periodic Safety Update Report (PSUR) for Axsain® (Capsaicin Cream 0.075%) and Zacin® (Capsaicin Cream 0.025%) was recently completed and submitted by Cephalon to the MHRA. It included case reports and other data obtained from all Cephalon affiliates and licensing partners for the period 20 March 2003 to 19 March 2008.

The Axsain and Zacin SPCs are overall very similar, and thus lack the following statement with regard to instruction of use of capsaicin cream as mentioned in Martindale (34th Edition, 2005):

The hands should be washed after application of the cream, unless the hands are the treated areas, in which case, they should be washed 30 minutes after application.

In addition, Axsain SPC also lacks the following statement with regard to instruction of use of capsaicin cream which is mentioned in BNF (September 2008):

Not for use under tight bandages

In light of the above information the following changes to the SmPC are proposed:

Axsain

4.4 Special warnings and precautions for use

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.

Not for use under tight bandages

Zacin

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