

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, however the Axsain SPC has the following statement with regard to mucosal irritation and respiratory symptoms:

“Irritation of the mucous membranes of the eyes and respiratory tract (such as coughing, sneezing, runny eyes) on application of Axsain cream has been reported rarely. These events are usually mild and self-limiting. There have been a few reports of dyspnea, wheezing and exacerbation of asthma.”

The Zacin SPC currently lacks a similar statement, and the joint PSUR submitted by the company recommended that an identical statement is added to the Zacin SPC.

Following review of the PSUR, it is clear that there have been reports of similar symptoms associated with Zacin as well as with Axsain, and therefore I agree that it would be appropriate to add an identical statement to the Zacin SPC.

I therefore support the proposed addition of this statement to the Zacin SPC

