

# **Zostrix**

## **Capsaicin USP 0.025% w/w Topical Cream**

### **Presentation**

A smooth white cream for topical application which contains 0.25 mg capsaicin per gram of cream.

### **Uses**

#### ***Actions***

Although the precise mechanism of action 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.

#### ***Pharmacokinetics***

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 Zostrix 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.

#### ***Indications***

For the symptomatic relief of pain associated with osteoarthritis

### **Dosage and Administration**

#### ***Adults and the elderly:***

For topical administration to unbroken skin. Apply only a small amount of cream (pea size) to affected area 4 times daily. These applications should be evenly spaced throughout the waking hours and not more often than every 4 hours. The cream should be gently rubbed in, there should be no residue left on the surface. Hands should be washed immediately after application of Zostrix unless hands and fingers are being treated. Zostrix 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.

## **Contraindications**

Zostrix Cream is contra-indicated on broken or irritated skin.

## **Warnings and Precautions**

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

Keep Zostrix 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 Zostrix Cream.

## ***Use during Pregnancy and Lactation***

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

## ***Effects on ability to drive and use machines***

The use of Zostrix is unlikely to have an effect on a person's ability to drive or use machines.

## ***Preclinical Safety Data***

The available animal toxicity 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 Zostrix 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 Zostrix Cream, will pose any significant hazard to humans.

## **Adverse Effects**

Zostrix may cause transient burning following application. This burning sensation generally disappears after several days of treatment, but may persist particularly when application schedules of less than four times daily are used. The burning can be enhanced if too much cream is used or if it is applied just before or after a bath or shower.

## **Interactions**

Not applicable

## **Overdosage**

Not applicable

## **Pharmaceutical Precautions**

Store below 25°C.

## **Medicines Classification**

General Sale Medicine

## **Package Quantities**

Aluminium tubes with spiked cap which contain 45 g of Zostrix Cream

## **Further Information**

Zostrix Cream also contains Purified Water, Sorbitol, Isopropyl myristate, Cetyl alcohol, White soft paraffin, Benzyl alcohol, Glyceryl stearate and Peg-100 stearate.

## **Name and Address**

AFT Pharmaceuticals Ltd  
9 Anzac Street (Level 2)  
Takapuna  
Auckland  
Email:customer.service@aftpharm.com

## **Date of Preparation**

25 June 2008