



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Therapeutic Goods Act 1989
Approval under section 42DF for use of restricted representations by
Actor Pharmaceuticals Pty Ltd

I, Rowena Love, as a delegate of the Secretary to the Department of Health and Aged Care, on receipt of an application from Actor Pharmaceuticals Pty Ltd, have approved under section 42DF of the *Therapeutic Goods Act 1989*, the restricted representations identified in paragraph **(A)** for use in advertisements for the product identified in paragraph **(B)** when the circumstances identified in paragraph **(C)** are met:

Representations to the effect that the product is:

- A topical analgesic cream for the management of medically diagnosed painful diabetic neuropathy or postherpetic neuralgia’.

And representations that the product is for:

- Pain relief for diabetic neuropathy and postherpetic neuralgia.
- Pain relief for diabetic neuropathy and after shingles.
- Pain relief for diabetic neuropathy.
- Pain relief for postherpetic neuralgia (pain following shingles).

(B)

- ZOSTRIX HP capsaicin 0.075%w/w cream tube (AUST R 10344).

(C)

- The words: ‘A topical analgesic cream’ will precede all references to ‘management of pain associated with medically diagnosed diabetic neuropathy or postherpetic neuralgia (pain after shingles’) or words to that effect.
- The first reference to “diabetic neuropathy” and the first reference to “postherpetic neuralgia” (including “pain following shingles”, “pain after shingles” and “after shingles”) must be preceded by the term “medically diagnosed” written in full and presented in a manner that is prominently displayed or communicated.

Dated this 18th day of September 2024

Signed electronically,

Rowena Love

Delegate of the Secretary to the Department of Health and Aged Care
Advertising and Compliance Education and Policy Section
Regulatory Compliance Branch