



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 230280 Juno Pharmaceuticals Pty Ltd - IALURIL Prefill - Bladder instillation, barrier

ARTG entry for Medical Device Included Class III
Sponsor Juno Pharmaceuticals Pty Ltd
Postal Address Level 2 6 Bond Street, South Yarra, VIC, 3141
 Australia
ARTG Start Date 7/11/2014
Product category Medical Device Class III
Status Active
Approval area Medical Devices

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

Name	Address
IBSA Farmaceutici Italia Srl	Via Martiri di Cefalonia 2 , Lodi, 26900 Italy

Products

1. IALURIL Prefill - Bladder instillation, barrier

Product Type	Single Device Product	Effective date	7/11/2014
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GMDN 44670 Bladder instillation, barrier

Functional description Clear plastic pre-filled syringe containing a sterile aqueous solution of hyaluronic acid sodium salt (1.6%), sodium chondroitin sulphate (2%) and calcium chloride administered as a bladder instillation via a catheter.

Intended purpose iAluRil Prefill is indicated to re-establish the glycosaminoglycan layers (GAGs) of the urothelial vesical tissue in cases in which their loss can cause frequent and recurring problems such as Painful Bladder Syndrome (PBS), interstitial cystitis, treatment and prevention of recurrent urinary tract infection, cystitis as a result of Bacillus Calmette - Guerin therapy, or chemical and radiation therapy. iAluRil Prefill is also indicated in the cases where the loss of the glycosaminoglycan layers (GAGs) is associated with forms of chronic inflammation, in which their composition and integrity appears compromised in different ways.

Variant information Nil variant (as 1 device) NA

Specific Conditions

No Specific Conditions included on Record

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