Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 147831 FLUDARABINE AMNEAL fludarabine phosphate 50 mg powder for injection vial

ARTG entry for	Medicine Registered
Sponsor	Juno Pharmaceuticals Pty Ltd
Postal Address	Level 2 6 Bond Street, South Yarra, VIC, 3141 Australia
ARTG Start Date	13/05/2009
Product category	Medicine
Status	Active
Approval area	Drug Safety Evaluation Branch

Conditions

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Products

1. FLUDARABINE AMNEAL fludarabine phosphate 50 mg powder for injection vial

Product Type Single Medicine Product **Effective date** 6/10/2017

Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

Treatment of B-cell chronic lymphocytic leukaemia

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Vial	Glass Type I Clear	48 Months	Store below 25 degrees Celsius	Not recorded	Not recorded

Pack Size/Poison information

Pack Size

1 x 5 mL vial

Poison Schedule

(S4) Prescription Only Medicine

Components

1. FLUDARABINE AMNEAL fludarabine phosphate 50 mg powder for injection vial

Dosage Form	Injection, powder for
Route of Administration	Intravenous
Visual Identification	white or almost white powder

Active Ingredients

Fludarabine phosphate	**50 mg**

Public Summary