



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 281241 SODIUM VALPROATE JUNO sodium valproate 400 mg/4mL solution for injection, ampoule

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 13/12/2017
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. SODIUM VALPROATE JUNO sodium valproate 400 mg/4mL solution for injection, ampoule

Product Type	Single Medicine Product	Effective date	12/02/2019
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Permitted Indications

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

Sodium valproate Juno is used for the treatment of patients with epilepsy or mania, who would normally be maintained on oral sodium valproate, and for whom oral therapy is temporarily not possible.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Ampoule	Glass Type I Clear	36 Months	Store below 30 degrees Celsius	Not recorded	Do not Freeze

Pack Size/Poison information

Pack Size	Poison Schedule
10 ampoules	(S4) Prescription Only Medicine

Components

1. SODIUM VALPROATE JUNO sodium valproate 400 mg/4mL solution for injection, ampoule

Dosage Form Injection, solution

Route of Administration Intravenous Infusion
 Intravenous

Visual Identification Sodium valproate Juno 400 mg/4 mL is a clear colourless sterile solution presented in transparent colorless type 1 glass ampoules of 5 ml in 10 pack

Active Ingredients

sodium valproate **400 mg**

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