

Public Summary

Summary for ARTG Entry: 65529 ZELDOX ziprasidone hydrochloride 80mg capsule blister pack

ARTG entry for Medicine Registered
Sponsor Pfizer Australia Pty Ltd
Postal Address 38-42 Wharf Road, WEST RYDE, NSW, 2114
 Australia
ARTG Start Date 29/10/2001
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. ZELDOX ziprasidone hydrochloride 80mg capsule blister pack**

Product Type Single Medicine Product **Effective date** 26/08/2016

Warnings

See Product Information and Consumer Medicine Information for this product

Standard Indications**Specific Indications**

Zeldox (ziprasidone) is indicated for: (i) the treatment of schizophrenia, related psychoses, prevention of relapse and for maintenance of clinical improvement during continuation therapy; and (ii) as monotherapy for the short term treatment of acute manic or mixed episodes associated with bipolar I disorder.

Additional Product information**Container information**

Type	Material	Life Time	Temperature	Closure	Conditions
Blister Pack	Al/Al	4 Years	Store below 30 degrees Celsius	Not recorded	Not recorded

Pack Size/Poison information**Pack Size**

20 capsules

60 capsules

Poison Schedule

(S4) Prescription Only Medicine

(S4) Prescription Only Medicine

Components**1. Medicine Component****Dosage Form**

Capsule, hard

Route of Administration

Oral

Visual Identification

No.2 blue cap/white body capsule marked "Pfizer" and "ZDX 80"

Active Ingredients

Ziprasidone hydrochloride

90.6 mg

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