



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 242052 BOSENTAN SANDOZ bosentan (as monohydrate) 62.5 mg film-coated tablet blister pack

ARTG entry for Medicine Registered
Sponsor Sandoz Pty Ltd
Postal Address 54 Waterloo Road, Macquarie Park, NSW, 2113
Australia
ARTG Start Date 22/11/2016
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. BOSENTAN SANDOZ bosentan (as monohydrate) 62.5 mg film-coated tablet blister pack

Product Type	Single Medicine Product	Effective date	27/09/2018
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Permitted Indications

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

Bosentan (as monohydrate) is indicated for the treatment of:· idiopathic pulmonary arterial hypertension,· familial pulmonary arterial hypertension,· pulmonary arterial hypertension associated with scleroderma or,· pulmonary arterial hypertension associated with congenital systemic to pulmonary shunts including Eisenmenger's physiology, in patients with WHO functional Class II, III or IV symptoms

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Blister Pack	PVC/PVDC/Al	36 Months	Store below 25 degrees Celsius	Neither child resistant closure nor restricted flow insert	Protect from Light

Pack Size/Poison information

Pack Size

60

Poison Schedule

(S4) Prescription Only Medicine

Components

1. BOSENTAN SANDOZ bosentan (as monohydrate) 62.5 mg film-coated tablet blister pack

Dosage Form

Tablet, film coated

Route of Administration

Oral

Visual Identification

Bosentan 62.5 mg tablet is a light orange colour, round, biconvex film coated tablet. Each tablet contains 64.541 mg bosentan (as monohydrate) active substance.

Active Ingredients

bosentan monohydrate	64.451 mg
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