Public Summary

Summary for ARTG Entry:	191034 SOZOL pantoprazole (as sodium sesquihydrate) 20 mg enteric-coated tablet blister pack.
ARTG entry for	Medicine Registered
Sponsor	Apotex Pty Ltd
Postal Address	16 Giffnock Avenue, Macquarie Park, NSW, 2113 Australia
ARTG Start Date	21/03/2012
Product Category	Medicine
Status	Active
Approval Area	Drug Safety Evaluation Branch

Conditions

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Conditions Applying to Therapeutic Goods Accepted for Registration or Listing as Goods Currently Supplied at the Commencement of the Therapeutic Goods Act 1989"

Except where the sponsor has been contracted by an overseas partry to manufacturer the goods and that party will be responsible for placing the goods on the market in countries other than Australia, the sponsor must have and shall retain, while the goods remain listed, evidence necessary to substantiate and support the accuracy of the indications in relation to the listed goods, and upon the request of the Head, Office of Prescription Medicines Authorisation Branch, Therapeutic Goods Administration, shall produce such evidence to this officer.

The conditions applying to these goods when they are exported from Australia are given below:

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, other than condition No. 8 and condition No. 9.

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, other than condition No.11

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.

The therapeutic goods grouped in this registration/listing as export only goods under the following names are included in the Australian Register of Therapeutic Goods and may not be supplied in Australia. Export Name(s) to be added:

Products

1 . SOZOL pantoprazole (as sodium sesquihydrate) 20 mg enteric-coated tablet blister pack.

Product Type	Single Medicine Product	**Effective Date**	6/12/2022

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

1. For symptomatic improvement and healing of gastrointestinal diseases which require a reduction in acid secretion: i) Duodenal ulcer; ii) Gastric ulcer; iii) Gastro-oesophageal reflux disease (GORD): Symptomatic GORD. The treatment of heartburn and other symptoms associated with GORD; Reflux oesophagitis; iv) Gastrointestinal lesions refractory H2 blockers; v) Zollinger-Ellison Syndrome. Patients whose gastric or duodenal ulceration is not associated with ingestion of non-steroidal anti-inflammatory drugs (NSAIDs) require treatment with antimicrobial agents in addition to antisecretory drugs whether on first presentation or on recurrence. 2. Maintenance of healed reflux oesophagitis in patients previously treated for moderate to severe reflux oesophagitis. 3. Prevention of gastroduodenal lesions and dyspeptic symptoms associated with non-selective non-steroidal anti-inflammatory drugs (NSAIDs) in increased risk patients with a need for continuous non-selective NSAID treatment.

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	Al/Al	2 Years	Store below 25 degrees Celsius	Child resistant closure	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
100	(S4) Prescription Only Medicine
15	(S4) Prescription Only Medicine
56	(S4) Prescription Only Medicine
60	(S4) Prescription Only Medicine
140	(S4) Prescription Only Medicine
30	(S4) Prescription Only Medicine
5	(S4) Prescription Only Medicine
14	(S4) Prescription Only Medicine
50	(S4) Prescription Only Medicine
28	(S4) Prescription Only Medicine

Components

1 .

Dosage Form	Tablet, enteric coated
Route of Administration	Oral
Visual Identification	Yellow, oval, biconvex enteric-coated tablets, plain on both sides.

Active Ingredients

pantoprazole sodium sesquihydrate	**22.7 mg**
Equivalent: pantoprazole	20 mg

Other Ingredients (Excipients)

calcium stearate
colloidal anhydrous silica
crospovidone
hypromellose
iron oxide yellow
lecithin
macrogol 6000
mannitol
methacrylic acid copolymer
polysorbate 80
polyvinyl alcohol
purified talc
purified water
sodium carbonate
sodium hydroxide
sodium lauryl sulfate
sodium starch glycollate
titanium dioxide
xanthan gum

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