Public Summary

Summary for ARTG Entry:	156293 NUROFEN ZAVANCE 256mg ibuprofen sodium sugar coated tablet blister pack
ARTG entry for	Medicine Registered
Sponsor	Reckitt Benckiser Pty Ltd
Postal Address	PO Box 20097 World Square, Sydney, NSW, 2002 Australia
ARTG Start Date	28/10/2008
Product Category	Medicine
Status	Active
Approval Area	Non-Prescription Medicines

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 . NUROFEN ZAVANCE 256mg ibuprofen sodium sugar coated tablet blister pack

Product Type	Single Medicine Product	**Effective Date**	20/01/2023

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

Temporary relief of pain (and discomfort) associated with headache, migraine headache, tension headache, sinus pain, toothache, dental procedures, backache, muscular aches and pains, period pain, sore throat, arthritis, rheumatic pain where inflammation is present, and the aches and pains associated with colds and flu. Reduces fever.

Warnings

No Warnings included on Record

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Blister Pack	PVC/PE/PVDC/Al	20 Months	Store below 30 degrees Celsius	Child resistant closure	Not recorded
Blister Pack	PVC/PVDC/Al	20 Months	Store below 30 degrees Celsius	Child resistant closure	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
8	Not scheduled. Not considered by committee
10	Not scheduled. Not considered by committee
96	(S2) Pharmacy Medicine
2	Not scheduled. Not considered by committee
40	(S2) Pharmacy Medicine
4 (samples)	Not scheduled. Not considered by committee
12	Not scheduled. Not considered by committee
80	(S2) Pharmacy Medicine
4	Not scheduled. Not considered by committee
24	Not scheduled. Not considered by committee

6 (samples)	Not scheduled. Not considered by committee
72	(S2) Pharmacy Medicine
16	Not scheduled. Not considered by committee
48	(S2) Pharmacy Medicine
20	Not scheduled. Not considered by committee

Components

1 .

Dosage Form	Tablet, sugar coated
Route of Administration	Oral
Visual Identification	A white to off-white, round, biconvex, sugar coated tablet printed with an identifying logo in black on one face.

Active Ingredients

ibuprofen sodium dihydrate	**256 mg**

Other Ingredients (Excipients)

Acacia
butan-1-ol
carmellose sodium
colloidal anhydrous silica
croscarmellose sodium
dimeticone 1510
ethanol absolute
ethanol
industrial methylated spirit
iron oxide black
isopropyl alcohol
lecithin
macrogol 6000
magnesium stearate
microcrystalline cellulose
propylene glycol
purified talc
purified water
Shellac
strong ammonia solution
sucrose
sulfuric acid
titanium dioxide
xylitol

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