Public Summary

Summary for ARTG Entry:	283649 REDORMIN FORTE
ARTG entry for	Medicine Listed
Sponsor	SFI Australasia
Postal Address	PO Box 1027, CROWS NEST, NSW, 1585 Australia
ARTG Start Date	15/12/2016
Product Category	Medicine
Status	Active
Approval Area	Listed Medicines

Conditions

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

Products

1 . REDORMIN FORTE

Product Type Single Medicine Product **Effective Date** 25/06/2024

Permitted Indications

Helps enhance/promote healthy nerve conduction/transmission/neurotransmission

Traditionally used in Western herbal medicine to soporific/induces sleep

Enhance/promote/increase refreshing sleep

Decrease/reduce/relieve sleeplessness

Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness

Decrease/reduce time to fall asleep

Decrease/reduce/relieve disturbed/restless sleep

Traditionally used in Western herbal medicine to decrease/reduce/relieve disturbed/restless sleep

Enhance/promote/increase healthy sleep patterns

Maintain/support healthy sleeping patterns

Enhance/improve/promote/increase sleep quality/deep sleep

Traditionally used in Western herbal medicine to enhance/improve/promote/increase sleep quality/deep sleep

Help establish/restore/reset sleep-wake cycle (circadian rhythm)

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).

In rare cases, valerian may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes or unusual: fatigue, nausea, appetite loss, abdominal pain, dark urine or itching.

Additional Product information

Pack Size/Poison information	
Pack Size	**Poison Schedule**

Components

1 . Formulation 1

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	

Active Ingredients

Humulus lupulus flower Extract dry concentrate	**120 mg**
Equivalent: Humulus lupulus (Dry)	720 mg
Valeriana officinalis root Extract dry concentrate	**500 mg**
Equivalent: Valeriana officinalis (Dry)	2.5 g

Other Ingredients (Excipients)

colloidal anhydrous silica
croscarmellose sodium
hypromellose
indigo carmine
macrogol 20000
magnesium stearate
microcrystalline cellulose
stearic acid
titanium dioxide