Public Summary

Summary for ARTG Entry:	397133 X-Ade
ARTG entry for	Medicine Listed
Sponsor	Vitex Pharmaceuticals Pty Ltd
Postal Address	PO Box 321, ST CLAIR, NSW, 2759 Australia
ARTG Start Date	6/10/2022
Product Category	Medicine
Status	Active
Approval Area	Listed Medicines

Conditions

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 . X-Ade

Product Type Single Medicine Product **Effective Date** 6/10/2022

Permitted Indications

Maintain/support healthy sexual function

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

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

d-alpha-tocopheryl acid succinate	**82.64 mg**
Equivalent: d-alpha-tocopherol	100 IU
Eleutherococcus senticosus root and rhizome Extract dry concentrate	**40 mg**
Equivalent: Eleutherococcus senticosus (Dry)	200 mg
Epimedium grandiflorum herb Extract dry concentrate	**150 mg**
Equivalent: Epimedium grandiflorum (Dry)	3 g

heavy magnesium oxide	**49.75 mg**
Equivalent: magnesium	30 mg
nicotinamide	**30 mg**
Panax ginseng root Extract dry concentrate	**66.67 mg**
Equivalent: Panax ginseng (Dry)	200 mg
pyridoxine hydrochloride	**20 mg**
Equivalent: pyridoxine	16.45 mg
riboflavin	**5 mg**
Tribulus terrestris root Extract dry concentrate	**50 mg**
Equivalent: Tribulus terrestris (Dry)	2.5 g
Tribulus terrestris fruit Extract dry concentrate	**50 mg**
Equivalent: Tribulus terrestris (Dry)	2.5 g
zinc gluconate	**104.53 mg**
Equivalent: zinc	15 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate
colloidal anhydrous silica
crospovidone
sorbitol
stearic acid

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