Public Summary

Summary for ARTG Entry:	367190 Caruso's Prostate Eze Max
ARTG entry for	Medicine Assessed Listed
Sponsor	Caruso's Natural Health Pty Ltd
Postal Address	PO Box 310, HORSLEY PARK, NSW, 2175 Australia
ARTG Start Date	26/05/2021
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.

Conditions applicable as specified in the document "Conditions - standard and specific: Applying to registered or listed therapeutic goods under section 28 of the Therapeutic Goods Act 1989".

Products

1 . Caruso's Prostate Eze Max

Product Type Single Medicine Product **Effective Date** 26/05/2021

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

For the relief of nocturia (night-time urinary frequency) associated with medically diagnosed benign prostatic hypertrophy.

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1 . Formulation 1

Dosage Form	Capsule, soft
Route of Administration	Oral
Visual Identification	

Active Ingredients

Cucurbita pepo seed Oil fixed	**160 mg**
Epilobium parviflorum herb Extract dry concentrate	**125 mg**
Equivalent: Epilobium parviflorum (Dry)	500 mg
lycopene	**2.1 mg**

Prunus africana stem bark outer Extract soft concentrate	**75 mg**
Equivalent: Prunus africana (Dry)	15 g
Serenoa repens seed Extract soft concentrate	**44 mg**
Equivalent: Serenoa repens (Dry)	660 mg

Other Ingredients (Excipients)

allura red AC
ascorbic acid
colloidal anhydrous silica
d-alpha-tocopherol
Gelatin
glycerol
hydrogenated vegetable oil
lecithin
Maize Oil
patent blue V
purified water
Soya Oil
titanium dioxide
yellow beeswax