



Therapeutic Goods (Restricted Representations— Caruso’s Prostate Eze Max) Permission 2021

I, Nicole McLay, as delegate of the Secretary of the Department of Health, make the following permission.

Dated 2 July 2021

Nicole McLay
Assistant Secretary
Regulatory Compliance Branch
Health Products Regulation Group
Department of Health

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1 Name

This instrument is the *Therapeutic Goods (Restricted Representations—Caruso’s Prostate Eze Max) Permission 2021*.

2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	The day after this instrument is made.	3 July 2021

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under section 42DK of the *Therapeutic Goods Act 1989*.

4 Definitions

Note: A number of expressions used in this instrument are defined in subsection 3(1) of the Act, including the following:

- (a) advertise;
- (b) label;
- (c) listing number;
- (d) medicine;
- (e) Register;
- (f) therapeutic goods;
- (g) Therapeutic Goods Advertising Code.

In this instrument:

Act means *Therapeutic Goods Act 1989*.

assessed listed medicine means a medicine that is listed in the Register under section 26AE of the Act.

Caruso’s Prostate Eze Max means the assessed listed medicine, Caruso’s Prostate Eze Max, listing number 367190.

prominently displayed or communicated has the same meaning as in the Therapeutic Goods Advertising Code.

restricted representation means a representation referred to in section 42DD of the Act.

5 Permission

For subsection 42DK(1) of the Act, in relation to each item mentioned in the table in Schedule 1, the restricted representations specified in column 2 are permitted to be used in the advertisements specified in column 3, about the therapeutic goods specified in column 4, subject to the conditions (if any) specified in column 5.

Schedule 1—Permission: restricted representation

Note: See section 5.

Permitted use of restricted representation				
Column 1	Column 2	Column 3	Column 4	Column 5
Item	Restricted representation	Advertisement	Therapeutic goods	Condition
1	a representation that is to the effect that the therapeutic goods relieve night-time urinary frequency (nocturia) associated with medically diagnosed benign prostatic hypertrophy	an advertisement about the therapeutic goods that is: (a) on the label of the therapeutic goods; or (b) on the package in which the therapeutic goods are contained; or (c) on any material included with the package in which the therapeutic goods are contained	Caruso's Prostate Eze Max	the representation must be accompanied by an advisory statement, which is to the effect of the following: (a) if you have not had your symptoms diagnosed, or if your symptoms persist or worsen, consult a medical practitioner
2	a representation that is to the effect that the therapeutic goods relieve night-time urinary frequency (nocturia) associated with medically diagnosed benign prostatic hypertrophy	an advertisement about the therapeutic goods that is not: (a) on the label of the therapeutic goods; or (b) on the package in which the therapeutic goods are contained; or (c) on any material included with the package in which the therapeutic goods are contained	Caruso's Prostate Eze Max	the representation must be accompanied by an advisory statement, which is prominently displayed or communicated and to the effect of the following: (a) if you have not had your symptoms diagnosed, or if your symptoms persist or worsen, consult a medical practitioner