



# **Therapeutic Goods (Restricted and Prohibited Representations—*Vitex Agnus-Castus*) Permission 2021**

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

Dated 28 June 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 and Prohibited Representations—Vitex Agnus-Castus) 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.	29 June 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Note: This table relates only to the provisions of this instrument as originally made.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) listed goods;
- (c) medicine;
- (d) Register;
- (e) therapeutic goods.

In this instrument:

**Act** means *Therapeutic Goods Act 1989*.

**listed medicine** means a medicine that is included in the part of the Register for goods known as listed goods.

**prohibited representation** means a representation referred to in subsection 42DJ(1) of the Act.

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

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*specified goods* means a listed medicine that is included in the Register, and contains *Vitex agnus-castus*.

## **5 Permission**

- (1) For subsection 42DK(1) of the Act, in relation to each item mentioned in the table in Schedule 1, the representations specified in column 2 (to the extent that those representations are restricted representations) 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.
- (2) For subsection 42DK(3) of the Act, in relation to each item mentioned in the table in Schedule 1, the representations specified in column 2 (to the extent that those representations are prohibited representations) 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

Note: See section 5.

Permitted use of restricted and prohibited representations				
Column 1	Column 2	Column 3	Column 4	Column 5
Item	Representation	Advertisement	Therapeutic goods	Conditions
1	a representation to the effect that <i>Vitex agnus-castus</i> may affect hormones and medicines, such as oral contraceptives, antipsychotic medicines or medicines for Parkinson's disease	<p>an advertisement about the therapeutic goods including, but not limited to, an advertisement that is:</p> <p>(a) on the label of the therapeutic goods;</p> <p>(b) on the package in which the therapeutic goods are contained;</p> <p>(c) on any material included with the package in which the therapeutic goods are contained</p>	specified goods	<p>the representation must include a statement to the effect of the following:</p> <p>(a) always consult a health professional before use</p>

Note 1: The determination under subsection 26BB(1) of the Act requires the following warning statement to be used on the label for goods included in the Register on or after 2 March 2020, or released for supply after 2 March 2021, containing *Vitex agnus-castus* for internal use:

“*Vitex agnus-castus* may affect hormones and medicines such as oral contraceptives. Consult your health professional before use” (or words to that effect).

Note 2: The representation in column 2 of item 1 in the table in this Schedule, together with the statement in column 5, satisfies the requirement specified in that determination.