



## **Therapeutic Goods (Restricted Representations— Oral Iron Supplements) Permission 2022**

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

Dated 15 February 2022

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—Oral Iron Supplements) Permission 2022*.

## 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.	16 February 2022

Note: This table relates only to the provisions of this instrument as originally made.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) directions for use;
- (b) indication;
- (c) label;
- (d) medicine;
- (e) Register;
- (f) therapeutic goods;
- (g) Therapeutic Goods Advertising Code.

In this instrument:

*Act* means *Therapeutic Goods Act 1989*.

*active ingredient* has the same meaning as in the *Therapeutic Goods Regulations 1990*.

*capsule* has the same meaning as in TGO 101.

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

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

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

**specified goods** means a registered medicine, other than a prescription medicine, that:

- (a) contains elemental iron as an active ingredient; and
- (b) is manufactured in the dosage form of a capsule, tablet or liquid for oral administration; and
- (c) has directions for use included on the label that contain dosing instructions only in relation to adults or children aged 12 years and older.

**tablet** has the same meaning as in TGO 101.

**TGO 101** means the *Therapeutic Goods (Standard for Tablets, Capsules and Pills) (TGO 101) Order 2019*.

Note: TGO 101 may be accessed on the internet at [www.legislation.gov.au](http://www.legislation.gov.au).

## 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.

## 6 Repeals

Each instrument that is specified in Schedule 2 to this instrument is repealed as set out in the applicable items in that Schedule.

## Schedule 1—Permission: restricted representations

Note: See section 5.

Permitted use of restricted representations				
Column 1	Column 2	Column 3	Column 4	Column 5
Item	Restricted representations	Advertisements	Therapeutic goods	Conditions
1	a representation that is to the effect that the therapeutic goods are for the treatment or prevention of medically diagnosed iron deficiency or iron deficiency anaemia	an advertisement about the therapeutic goods including, but not limited to, an advertisement that is: <ul style="list-style-type: none"> <li>(a) on the label of the therapeutic goods;</li> <li>(b) on the package in which the therapeutic goods are contained;</li> <li>(c) on any material included with the package in which the therapeutic goods are contained</li> </ul>	specified goods for which an indication has been accepted in relation to the inclusion of the goods in the Register that relates to the treatment or prevention of iron deficiency or iron deficiency anaemia	
2	a representation that is to the effect that the therapeutic goods are for the treatment or prevention of iron deficiency or iron deficiency anaemia	an advertisement about the therapeutic goods including, but not limited to, an advertisement that is: <ul style="list-style-type: none"> <li>(a) on the label of the therapeutic goods;</li> <li>(b) on the package in which the therapeutic goods are contained;</li> <li>(c) on any material included with the package in which the therapeutic</li> </ul>	specified goods for which an indication has been accepted in relation to the inclusion of the goods in the Register that relates to the treatment or prevention of iron deficiency or iron deficiency anaemia	an advertisement about the therapeutic goods that is not: <ul style="list-style-type: none"> <li>(a) on the label of the therapeutic goods; or</li> <li>(b) on the package in which the therapeutic goods are contained; or</li> <li>(c) on any material included with the package in which the therapeutic goods are contained;</li> </ul> must be accompanied by a statement, which is prominently displayed or communicated, to the

<b>Permitted use of restricted representations</b>				
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>	<b>Column 5</b>
<b>Item</b>	<b>Restricted representations</b>	<b>Advertisements</b>	<b>Therapeutic goods</b>	<b>Conditions</b>
		goods are contained		effect of the following: (d) for use when iron deficiency or iron deficiency anaemia has been diagnosed by your doctor and a therapeutic iron supplement is recommended
3	a representation that is to the effect that the therapeutic goods may help relieve fatigue associated with iron deficiency or iron deficiency anaemia	an advertisement about the therapeutic goods including, but not limited to, an advertisement that is: (a) on the label of the therapeutic goods; (b) on the package in which the therapeutic goods are contained; (c) on any material included with the package in which the therapeutic goods are contained	specified goods for which an indication has been accepted in relation to the inclusion of the goods in the Register that relates to the treatment or prevention of iron deficiency or iron deficiency anaemia and relief of associated fatigue	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; must be accompanied by a statement, which is prominently displayed or communicated, to the effect of the following: (d) for use when iron deficiency or iron deficiency anaemia has been diagnosed by your doctor and a therapeutic iron supplement is recommended

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<b>Permitted use of restricted representations</b>				
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>	<b>Column 5</b>
<b>Item</b>	<b>Restricted representations</b>	<b>Advertisements</b>	<b>Therapeutic goods</b>	<b>Conditions</b>
4	a representation that is to the effect that the therapeutic goods may help relieve fatigue associated with medically diagnosed iron deficiency or iron anaemia	<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 for which an indication has been accepted in relation to the inclusion of the goods in the Register that relates to the treatment or prevention of iron deficiency anaemia and relief of associated fatigue	

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## **Schedule 2—Repeals**

Note: See section 6.

### ***Therapeutic Goods (Restricted Representations—Oral Iron Supplements) Permission 2021***

#### **1 The whole of the instrument**

Repeal the instrument.