



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

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

Dated 12 March 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—Oral Iron Supplements) 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.	13 March 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Note: This table relates only to the provisions of this instrument as originally made.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 section 3 of the Act, including the following:

- (a) directions for use;
- (b) indication;
- (c) label;
- (d) medicine;
- (e) Register;
- (f) therapeutic goods; and
- (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.

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 the 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.

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 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"> (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	
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"> (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 	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	advertisements about the therapeutic goods that are not: <ul style="list-style-type: none"> (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

Permitted use of restricted representation				
Column 1	Column 2	Column 3	Column 4	Column 5
Item	Restricted representation	Advertisement	Therapeutic goods	Condition
		goods are contained		displayed or communicated and 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
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	advertisements about therapeutic goods that are 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 and 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