



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

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

Dated 26 July 2021

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

Contents

1 Name.....	1
2 Commencement	1
3 Authority	1
4 Definitions	1
5 Permission.....	2
Schedule 1—Permission: restricted representation	3

1 Name

This instrument is the *Therapeutic Goods (Restricted Representations—Oral Iron and Folic Acid 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.	27 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Note: This table relates only to the provisions of this instrument as originally made.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) 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.

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 and folic acid as the only active ingredients; and
- (b) is manufactured in the dosage form of a capsule or tablet 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 a source of iron and folic acid for the treatment or prevention of iron and folate (or folic acid) deficiency 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>	<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 and folate (or folic acid) deficiency anaemia</p>	<p>an advertisement about the therapeutic goods that is not:</p> <p>(a) on the label of the therapeutic goods; or</p> <p>(b) on the package in which the therapeutic goods are contained; or</p> <p>(c) on any material included with the package in which the therapeutic goods are contained;</p> <p>must include a statement, which is prominently displayed or communicated and to the effect of the following:</p> <p>(d) for use when iron and folate (or folic acid) deficiency anaemia has been diagnosed by a doctor and a therapeutic oral iron and folic acid supplement is recommended for treatment or ongoing prevention</p>
2	<p>a representation that is to the effect of one or more of the following:</p> <p>(a) the therapeutic goods are a source of iron and folic</p>	<p>an advertisement about the therapeutic goods including, but not limited to, an</p>	<p>specified goods for which an indication has been accepted in relation to the inclusion of</p>	

Permitted use of restricted representation

Column 1	Column 2	Column 3	Column 4	Column 5
Item	Restricted representation	Advertisement	Therapeutic goods	Condition
	<p>acid for the treatment or prevention of medically diagnosed iron and folate (or folic acid) deficiency anaemia;</p> <p>(b) the therapeutic goods are for use when iron and folate (or folic acid) deficiency anaemia has been diagnosed by a doctor and a therapeutic oral iron and folic acid supplement is recommended for treatment or ongoing prevention;</p> <p>(c) the therapeutic goods are for the treatment and prevention of medically diagnosed iron and folate (or folic acid) deficiency anaemia</p>	<p>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>	<p>the goods in the Register that relates to the treatment or prevention of iron and folate (or folic acid) deficiency anaemia</p>	
3	<p>a representation that is to the effect that the therapeutic goods are for the treatment and prevention of megaloblastic anaemia associated with folate (or folic acid) deficiency</p>	<p>an advertisement about the therapeutic goods that is:</p> <p>(a) on the label of the therapeutic goods; or</p> <p>(b) on the package in which the therapeutic goods are contained; or</p> <p>(c) on any material included with the package in</p>	<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 megaloblastic anaemia associated with folate (or folic acid) deficiency</p>	

Permitted use of restricted representation				
Column 1	Column 2	Column 3	Column 4	Column 5
Item	Restricted representation	Advertisement	Therapeutic goods	Condition
		which the therapeutic goods are contained		
4	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 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 include 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 a doctor and a therapeutic iron supplement is recommended for treatment or ongoing prevention
5	a representation that is to the effect that the therapeutic goods are for the treatment or prevention of medically diagnosed iron	an advertisement about the therapeutic goods including, but not limited to, an advertisement that is:	specified goods for which an indication has been accepted in relation to the inclusion of the goods in the	

Permitted use of restricted representation				
Column 1	Column 2	Column 3	Column 4	Column 5
Item	Restricted representation	Advertisement	Therapeutic goods	Condition
	deficiency or iron deficiency anaemia	(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	Register that relates to the treatment or prevention of iron deficiency or iron deficiency anaemia	
6	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: (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	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 include 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

Permitted use of restricted representation				
Column 1	Column 2	Column 3	Column 4	Column 5
Item	Restricted representation	Advertisement	Therapeutic goods	Condition
				recommended for treatment or ongoing prevention
