



Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Abatacept) Instrument 2022

I, Jane Cook, as delegate of the Minister for Health and Aged Care, make the following instrument.

Dated 8 February 2022

Dr Jane Cook
Chief Medical Adviser
Health Products Regulation Group
Department of Health

Contents

1 Name.....	1
2 Commencement	1
3 Authority.....	1
4 Definitions	1
5 Declaration of serious scarcity	2
6 Substitution of scarce medicine by pharmacists.....	2
7 Period instrument in force.....	2
Schedule 1—Scarce medicine, substitutable medicine, dose unit equivalence and specific permitted circumstances	3
Part 1—Scarce medicine: abatacept single dose syringe	3
Part 2—Scarce medicine: abatacept prefilled autoinjector	5
Schedule 2—General permitted circumstances	6

1 Name

This instrument is the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Abatacept) Instrument 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 registered.	

Note: This table relates only to the provisions of this instrument as originally made.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 30EK 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) health practitioner;
- (b) medicine;
- (c) Register;
- (d) registration number.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

pharmacist has the same meaning as in subsection 30EK(6) of the Act.

prescriber means the person who:

- (a) is authorised under a law of a state or territory to prescribe medicine; and
- (b) prescribed the scarce medicine for the patient.

scarce medicine has the meaning given by section 5.

substitutable medicine has the meaning given by section 6.

suitably qualified health practitioner means a health practitioner who is:

- (a) a general practitioner; or
- (b) a nurse; or
- (c) a pharmacist; or
- (d) a rheumatologist.

5 Declaration of serious scarcity

For paragraph 30EK(1)(a) of the Act, a serious scarcity of the medicine specified in column 2 of each item in the tables in Part 1 and Part 2 of Schedule 1 (the *scarce medicine*) across the whole of Australia is declared.

6 Substitution of scarce medicine by pharmacists

For paragraph 30EK(1)(b) of the Act, in relation to each item mentioned in the tables in Part 1 and Part 2 of Schedule 1, the medicine specified in column 3 (the *substitutable medicine*) is permitted to be dispensed by a pharmacist in substitution for the scarce medicine specified in column 2, in the circumstances specified in:

- (a) column 5 of that item (the *specific permitted circumstances*); and
- (b) the table in Schedule 2 (the *general permitted circumstances*).

Note: Substitution is only permitted where both the specific permitted circumstances and the general permitted circumstances exist.

7 Period instrument in force

This instrument remains in force until 30 April 2022.

Schedule 1—Scarce medicine, substitutable medicine, dose unit equivalence and specific permitted circumstances

Note: See sections 5 and 6.

Part 1—Scarce medicine: abatacept single dose syringe

Scarce medicine, substitutable medicine, dose unit equivalence and specific permitted circumstances

Column 1	Column 2	Column 3	Column 4	Column 5
Item	Scarce medicine	Substitutable medicine	Dose unit equivalence	Specific permitted circumstances
1	ORENCIA abatacept (rch) 125 mg single dose syringe subcutaneous injection ultrasafe passive needle guard and flange extender, registration number 206764	ORENCIA abatacept (rch) 125 mg single dose ClickJect prefilled autoinjector, registration number 236039	one single dose ClickJect prefilled autoinjector of the substitutable medicine containing abatacept (rch) 125 mg is equivalent to one single dose syringe of the scarce medicine containing abatacept (rch) 125 mg	all of the following: (a) the patient is at least 18 years of age; (b) the pharmacist has advised the patient or person acting on behalf of the patient: (i) on the suitable instructions in relation to the administration process of the substitutable medicine; or (ii) to obtain instructions from the prescriber, or a suitably qualified health practitioner, in relation to the administration process of the substitutable medicine; and (c) the pharmacist has advised the patient, or person acting on behalf of the patient, of the number of dose units of substitutable medicine that must be administered to the patient in substitution for the prescribed dose of scarce medicine,

Scarce medicine, substitutable medicine, dose unit equivalence and specific permitted circumstances

Column 1	Column 2	Column 3	Column 4	Column 5
Item	Scarce medicine	Substitutable medicine	Dose unit equivalence	Specific permitted circumstances
				based on the dose unit equivalence specified in column 4

Part 2—Scarce medicine: abatacept prefilled autoinjector

Scarce medicine, substitutable medicine, dose unit equivalence and specific permitted circumstances

Column 1	Column 2	Column 3	Column 4	Column 5
Item	Scarce medicine	Substitutable medicine	Dose unit equivalence	Specific permitted circumstances
1	ORENCIA abatacept (rch) 125 mg single dose ClickJect prefilled autoinjector, registration number 236039	ORENCIA abatacept (rch) 125 mg single dose syringe subcutaneous injection ultrasafe passive needle guard and flange extender, registration number 206764	one single dose syringe of the substitutable medicine containing abatacept (rch) 125 mg is equivalent to one single dose ClickJect prefilled autoinjector of the scarce medicine containing abatacept (rch) 125 mg	all of the following: (a) the patient is at least 18 years of age; (b) the pharmacist has advised the patient or person acting on behalf of the patient: (i) on the suitable instructions in relation to the administration process of the substitutable medicine; or (ii) to obtain instructions from the prescriber, or a suitably qualified health practitioner, in relation to the administration process of the substitutable medicine; and (c) the pharmacist has advised the patient, or person acting on behalf of the patient, of the number of dose units of substitutable medicine that must be administered to the patient in substitution for the prescribed dose of scarce medicine, based on the dose unit equivalence specified in column 4

Schedule 2—General permitted circumstances

Note: See section 6.

General permitted circumstances

Column 1	Column 2
Item	Circumstances
1	the patient, or person acting on behalf of the patient, has evidence of a valid prescription for the scarce medicine, unless otherwise permitted by law
2	the pharmacist does not have access to the scarce medicine
3	the prescriber has not indicated on the prescription for the scarce medicine that substitution is not permitted
4	the pharmacist has exercised professional judgement and determined that the patient is suitable to receive the substitutable medicine
5	the amount of substitutable medicine dispensed would result in the patient receiving sufficient medicine to ensure an equivalent dosage regimen and duration to that prescribed in relation to the scarce medicine
6	the patient, or person acting on behalf of the patient, has consented to receiving the substitutable medicine
7	the pharmacist makes a record of dispensing the substitutable medicine in substitution of the scarce medicine at the time of dispensing
8	the pharmacist has an established procedure to notify the prescriber of the substitution at the time of, or as soon as practical after, dispensing the substitutable medicine
