



Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Cefaclor) Instrument 2023

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

Dated 27 April 2023

Nicholas Henderson
Acting First Assistant Secretary
Medicines Regulation Division
Health Products Regulation Group
Department of Health and Aged Care

Contents

1 Name.....	1
2 Commencement	1
3 Authority.....	1
4 Definitions	1
5 Declaration of a serious scarcity	2
6 Substitution of scarce medicine by pharmacists.....	2
7 Period instrument in force.....	2
8 Repeals.....	2
Schedule 1—Scarce medicine, substitutable medicine, dose unit equivalence and specific permitted circumstances	3
Schedule 2—General permitted circumstances	6

1 Name

This instrument is the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Cefaclor) Instrument 2023*.

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	1 May 2023.	1 May 2023

Note: This table relates only to the provisions of this instrument as originally made.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) medicine.

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.

5 Declaration of a 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 table in 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 table in Schedule 1, each 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 September 2023.

8 Repeals

Unless repealed earlier, this instrument is repealed at the start of 1 October 2023.

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

Note: See sections 5 and 6.

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	<p>each of the following medicines:</p> <p>(a) KEFLOR cefaclor 125mg/5mL (as monohydrate) powder for oral liquid bottle, registration number 58651;</p> <p>(b) CECLOR cefaclor 125mg/5mL (as monohydrate) powder for oral liquid bottle, registration number 54899</p>	<p>a medicine that:</p> <p>(a) is manufactured in the dosage form of a powder for oral liquid; and</p> <p>(b) when reconstituted—contains 250mg/5mL of the active ingredient cefaclor</p>	<p>125mg of cefaclor is equivalent to 2.5mL of cefaclor 250mg/5mL in an oral liquid</p>	<p>the pharmacist has:</p> <p>(a) advised the patient, or person acting on behalf of the patient, of the number of dose units of substitutable medicine that must be taken by the patient in substitution for the prescribed dose of scarce medicine, based on the dose unit equivalence specified in column 4; and</p> <p>(b) ensured that the correct number of dose units of substitutable medicine that must be taken by the patient in substitution for the prescribed dose of scarce medicine is written on the dispensing label in millilitres; and</p> <p>(c) if multiple bottles of substitutable medicine are dispensed—ensured that the patient’s treatment course will be completed prior to the expiry of each bottle; and</p> <p>(d) ensured that the patient, or person acting on behalf of the patient, has access to</p>

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
				information to support them in administering the substitutable medicine
2	<p>each of the following medicines:</p> <p>(a) KEFLOR cefaclor 250mg/5mL (as monohydrate) powder for oral liquid bottle, registration number 58653;</p> <p>(b) CECLOR cefaclor 250mg/5mL (as monohydrate) powder for oral liquid bottle, registration number 347593</p>	<p>a medicine that:</p> <p>(a) is manufactured in the dosage form of a powder for oral liquid; and</p> <p>(b) when reconstituted—contains 125mg/5mL of the active ingredient cefaclor</p>	<p>250mg of cefaclor is equivalent to 10mL of cefaclor 125mg/5mL in an oral liquid</p>	<p>the pharmacist has:</p> <p>(a) advised the patient, or person acting on behalf of the patient, of the number of dose units of substitutable medicine that must be taken by the patient in substitution for the prescribed dose of scarce medicine, based on the dose unit equivalence specified in column 4; and</p> <p>(b) ensured that the correct number of dose units of substitutable medicine that must be taken by the patient in substitution for the prescribed dose of scarce medicine is written on the dispensing label in millilitres; and</p> <p>(c) if multiple bottles of substitutable medicine are dispensed—ensured that the patient’s treatment course will be completed prior to the expiry of each bottle; and</p> <p>(d) ensured that the patient, or person acting on behalf of the patient, has access to information to support them in administering</p>

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
				the substitutable medicine

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
