

MS-2 Step – Victorian Legislation

Information for registered nurse practitioners and endorsed midwives

OFFICIAL

Acknowledgement

This guidance uses the terms 'pregnant person' which is intended to be inclusive of anyone who may use other selfidentifying terms and aims to encompass all for whom this guidance is relevant.

Consumer Engagement Statement

All interactions between health care staff with consumers (pregnant person, women, mothers, patients, carers and families) should be undertaken with respect, dignity, empathy, honesty and compassion.

Health care staff should actively seek and support consumer participation and collaboration to empower them as equal partners in their care.

Purpose and Scope

The purpose of this document is to provide guidance on the practice of Nurse Practitioners and Authorised Midwives in the provision of medical abortion as outline in the Abortion Law Reform Act 2008.

This guidance is related to the administration, supply and prescription of MS 2-Step.

When providing medication abortion services, locally relevant policy and clinical governance frameworks should be developed in services, which include rationale and implications, and communicated to all clinicians utilising this guidance.

What is MS-2 Step?

MS-2 Step® is a registered trademark for a medicine used for medical termination of an intrauterine pregnancy. MS-2 Step has 2 medicines: Mifepristone and Misoprostol.

MS-2 Step is indicated in pregnant people for the medical termination of an intrauterine pregnancy, up to 63 days of gestation.

MS 2 Step medication used for medical termination of an intrauterine pregnancy. MS 2-step is a treatment option in reproductive healthcare, providing healthcare professionals with standardised recommendations helps to promote best practices, minimise risks, and improve outcomes for consumers. Amendments to restrictions in 2023 now authorise Registered Nurse Practitioners and Authorised Midwives to administer, supply and prescribe MS-2-Step for the purpose of medical termination of pregnancy.

Relevant Victorian and Federal Regulations and Legislation

In July 2023, the Therapeutic Goods Administration removed restrictions that had previously only allowed GPs and medical specialists to prescribe Mifepristone and Misoprostol (MS-2 step).

In Victoria this now means that Nurse Practitioners and Authorised midwives can supply, administer and prescribe this drug in accordance with Victorian legislation.

The legislation that directs this change are;

The Victorian Drugs, Poisons and Controlled Substances Act 1981# (DPCS Act) and Drugs, Poisons and Controlled Substances Regulations 2017iii (DPCS Regs) include requirements for registered health practitioners relating to Schedule 4 medicines. Schedule 4 medicines are known as 'Prescription Only Medicines'. Mifepristone and misoprostol are Schedule 4 medicines.

The Victorian Abortion Law Reform Act 2008^{iv} includes requirements for registered health practitioners relating to the termination of pregnancy. The term registered nurse is defined in the Abortion Law Reform Act 2008 as a person registered under the Health Practitioner Regulation National Law to practise in both the nursing and midwifery professions as a nurse or as a midwife. In this legislation the single term "registered nurse" is used to include both a nurse and a midwife.

There are no prohibitions under the DPCS Act or Abortion Law Reform Act 2008 to prevent a nurse practitioner or authorised midwife from administering, supplying or issuing a prescription for MS-2 Step for a person under their care, within the indicated timeframe, when an appropriate therapeutic need has been established.

The term 'supply' used in section 6 of the Abortion Law Reform Act 2008 includes issuing a prescription. The following section further explains the meaning of key terms.

Meaning of key terms

The following explanations are provided in relation to terms that are in common use within the DPCS Act and DPCS Regulations.

- 'Administer' means to personally introduce a medicine to a person's body or, in some cases, to personally supervise its introduction.
- 'Supply' "Supply" means to provide a medicine that is used or administered at a later time. The DPCS Act defines supply to include:
 - To supply, provide, give or deliver, whether or not for fee or reward
 - To direct a person to provide, give or deliver, i.e. to issue a prescription or an instruction to administer.
- 'Prescribe' is a term that commonly relates to the action of a practitioner who authorises treatment that may be carried out by another person. The DPCS Regs describe this action in accordance with the three different mechanisms by which the treatment may be authorised: namely 'issuing a prescription',

Prescribing MS-2 Step

The approved indication for MS-2 Step recommends that the duration of pregnancy (i.e., up to 63 days gestation) to be confirmed by ultrasound. RANZCOG guidelines recommend that the gestational age of the pregnancy be determined by clinical means or by ultrasound scan^v.

If an ultrasound is not possible, the last menstrual period date can be used, but with caution as gestation accuracy cannot be guaranteedvi.Ultrasound is beneficial to exclude ectopic pregnancy.

Determining whether to prescribe MS-2 Step involves a process of information gathering, clinical decision-making, communication, and ongoing evaluation, which collectively inform the decision to initiate the medication.

Options for treatment with MS-2 Step

A nurse practitioner or authorised midwife decides to initiate treatment with MS-2 Step for a consumer under their care, there are three options available under the DPCS Act

1. Administration

A nurse practitioner or authorised midwife can administer MS-2 Step to a consumer under their care.

Alternatively, a nurse practitioner or endorsed midwife may issue an instruction, such as a written order, for another registered nurse or other authorised person to administer to the woman.

2. Supply

A nurse practitioner or endorsed midwife can supply MS-2 Step to a consumer under their care. In this scenario, the nurse practitioner or endorsed midwife may access MS-2 Step obtained as imprest stock by their employer or under their own authorisation. A dispensing label will need to be placed on the MS-2 Step box before providing to the pregnant person.

3. Issue a prescription

A nurse practitioner or endorsed midwife can issue a prescription for MS-2 Step for a pregnant person under their care. A prescription is written instruction from a prescriber that provides a registered pharmacist with an authorisation to supply MS-2 Step to the pregnant person. The pharmacist will affix a label to the packaging that states the dosing instructions written on the prescription.

The role of registered health practitioners commencing treatment with MS-2 Step in Victoria

Health Practitioner	Administration	Supply	Issue a prescription
Medical Practitioner	Yes, for a woman under their care	Yes, for a woman under their care	Yes, for a woman under their care
Nurse Practitioner	Yes, for a woman under their care	Yes, for a woman under their care	Yes, for a woman under their care
Endorsed Midwife	Yes, for a woman under their care	Yes, for a woman under their care	Yes, for a woman under their care
Registered nurse	Yes, on an instruction from a prescriber	No	No
Registered midwife	Yes , on an instruction from a prescriber	No	No
Enrolled Nurse	Yes, on an instruction from a prescriber (where Notation is present)	No	No
Registered pharmacist	Yes, on an instruction from a prescriber	Yes, on a prescription	No

Case Studies

Issuing a prescription

Melissa is an authorised midwife working in a hospital. Following consultation, examination and in discussion with a person under her care Melissa's initiate's treatment with MS-2 Step. Melissa knows that a pharmacy located near to the hospital stocks MS-2 Step.

Melissa issues a prescription for MS-2 Step. She provides counselling and explains the dosing instructions for MS-2 Step. The prescription is provided to the person who attends the pharmacy. The pharmacist supplies MS-2 Step to the person and affixes a label that includes dosing instructions. The pharmacist provides counselling and answers any further questions the person has about MS-2 Step.

Supplying directly to the patient

David is nurse practitioner working in a public clinic. Following consultation, examination and partnership with a person under his care he decides to initiate treatment with MS-2 Step. David has an account with a wholesaler and has purchased MS-2 Step, which he stores in his consultation room for supply to persons under his care.

David accesses the MS-2 Step and places a dispensing label on the box that includes the dosing instructions. David provides counselling and responds to questions about MS-2 Step.

The person returns home and later than night takes Step 1 two hours after a meal. Step 2 is taken 36-48 hours later, as per the dosing instructions David placed on the box.

Supervising administration

Jane is an endorsed midwife working for a public health service. Following consultation, examination and partnership with a person under her care, Jane, initiates treatment with MS-2 Step. Jane considers it would be best if the person

took the dose under her supervision. The health service Jane works for holds a medicines permit and purchases MS-2 Step from a wholesaler. The MS-2 Step is stored as an 'imprest medicine'.

Jane accesses Step 1 (one mifepristone tablet) from the imprest cabinet and provides to person who swallows the tablet during the consultation. Jane makes a revisit appointment for her patient in 36-48 hours' time.

During the subsequent visit, Jane's patient is provided with Step 2 (four misoprostol tablets). The person holds four tablets in their mouth between the cheek and gum for 30 minutes before swallowing any tablet fragments with water.

In both instances of administration, Jane has checked to ensure the doses are taken on an empty stomach 2 hours before or 2 hours after a meal.

Documents to print or download from the Medicines and Poisons Regulation (MPR) website

The Medicines and poisons webpage http://www.health.vic.gov.au/dpcs on the Health.vic website under 'Documents to print or download', contains summaries of legislative requirements that relate to multiple and individual categories of health practitioner.

These documents are intended to assist health practitioners to comply with key legislative requirements, include the following:

- Issues relating to multiple categories of health practitioner, including:
 - possession and storage
 - supply, administration and recording
 - prescribing
 - criteria for lawful prescriptions
 - all reasonable steps and other key terms
 - schedule 2 and 3 poisons.
- Summaries that are specific to individual categories of health practitioner:
 - medical practitioners
 - pharmacists
 - nurses and midwives
 - nurses and midwives with registration endorsement (e.g. nurse practitioners, authorised midwives, etc.)
 - dentists (and other dental practitioners)
 - optometrists (and orthoptists)
 - podiatrists
 - veterinary practitioners.

¹ Therapeutic Goods Administration amendments to restrictions prescribing MS-2 step

[&]quot; Drugs and Poisons Act 1981/137

iii Drugs, poisons and controlled substances regulations-2017/018

iv Abortion Law Reform Act 2008

^v RANZCOG Abortion Care Clinical Guideline

vi Australia Pregnancy Care Guidelines