MS-2 Step administration & Emergency Care

Therapeutic Goods Administration (TGA)

"The TGA's official position with regards to the clinical safety information of mifepristone + misoprostol (MS-2 Step) is detailed in the current approved Product Information (PI) for MS-2 Step available at:
https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/PICMI?OpenForm&t=PI&q=ms-2&r=/"

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MS-2 STEP PRODUCT INFORMATION (PI)

EXTRACTS

(Pg 9) 'The following risks related to the medical method must be taken into account and explained to the woman:

(Pg 10) The patient should be informed not to travel far away from the prescribing centre as long as complete expulsion has not been recorded. [Failure occurs in up to 7% of cases]

As per the Royal College of Obstetricians and Gynaecologists guidelines (The Care of Women Requesting Induced Abortion, September 2004), the following is recommended:

"…Urgent clinical assessment and emergency gynaecology admission must be available when necessary."

(Pg 11) Since heavy bleeding requiring haemostatic curettage occurs in up to 5% of cases during the medical method of pregnancy termination,..

(Pg 8) ***CONTRAINDICATIONS***

- *Lack of access to emergency medical care in the 14 days following start of the treatment (ie administration of mifepristone);*

ADVERSE EVENTS

(Pg 17) ***Table 1: Adverse Events for the Combined Use of Mifepristone and Misoprostol***

(Pg 18) Reproductive system and breast disorders

Very Common: Vaginal bleeding, Uterine spasm

Common: Prolonged post-abortion bleeding, Spotting, Severe haemorrhage, Endometritis, Breast tenderness, Heavy bleeding

(Pg 19) Bleeding is an almost constant part of the procedure, whatever the prostaglandin analogue used, and at any pregnancy term, although it is usually more abundant when pregnancy age increases. It can occur after mifepristone alone. When heavy, it usually reflects incomplete abortion and is observed in approximately 3 to 12% of cases, depending on the pregnancy age and the prostaglandin analogue used, and needs specific treatment. It can necessitate a blood transfusion in up to 0.2% of cases. It can be prolonged for several days after prostaglandin analogue administration and sometimes leads to a decrease in haemoglobin levels. This potentially severe complication justifies that after intake (i) follow-up takes place approximately 14 to 21 days after Mifepristone Linepharma administration to ensure that expulsion is complete with no persisting bleeding and (ii) until follow-up has taken place, the woman remains close to a facility where she can be treated at any moment in case of severe or prolonged bleeding. Refer to ***SPECIAL WARNINGS AND PRECAUTIONS FOR USE.***

https://www.tga.gov.au/sites/default/files/auspar-mifepristone-misoprostol-141013-pi.pdf