### Manufacturer warnings 7,8

# A medical abortion should not be used by women who have:

- any allergies to mifepristone or prostaglandins
- chronic adrenal failure
- any severe disease where it is necessary to take steroids (e.g. uncontrolled asthma)
- known or suspected hypo-coagulation diseases or are on anticoagulant therapy
- porphyria

#### A medical abortion should also not be used :

- if it has been more than 7 weeks since the last period
- if an IUD is in place
- if the pregnancy is ectopic (an ultrasound is essential to exclude this)
- where emergency medical help is not easily accessible in the 2 weeks after taking the drugs
- during breastfeeding
- if attending the follow-up visit cannot be guaranteed

# Higher risks and therefore special warnings exist for women :

- with (or risk factors for) cardiovascular disease
- with epilepsy
- with existing bleeding problems
- with adrenal gland conditions
- taking blood-thinning medications
- using certain steroid medications (eg for asthma)
- who have anaemia
- with liver or kidney failure
- with Crohn's disease or other bowel disease
- taking certain medications including over-the-counter preparations such as St Johns' Wort

There is very little research on the impact of medical abortion on women under 18 years of age. For this reason alone, it is NOT recommended for this age group.

### References

1. http://www.tga.gov.au/hp/information-medicines-mifepristonegymiso.htm

2. Royal Australian and New Zealand College of Obstetricians and Gynaecologists, *Termination of Pregnancy, A resource for health professionals* 

3. Gary, MM., Harrison DJ. *Analysis of severe adverse events related to the use of mifepristone as an abortifacient*. Annals of Pharmacotherapy 2006;40(2):191-7

4. Mulligan, E., Messenger, H. *Mifepristone in South Australia*. Australian Family Physician, Vol 40, No.5, May 2011

5. http://www.fda.gov/downloads/Drugs/DrugSafety/ PostmarketDrugSafetyInformationforPatientsandProviders/ UCM263353.pdf

6. Coleman, PK. Abortion and mental health: quantitative synthesis and analysis of research published 1995–2009, The British Journal of Psychiatry (2011) 199, 180–186. doi: 10.1192/bjp.bp.110.077230

7. GyMiso® (Misoprostol) Consumer Medicine Information and Product Information

8. Mifepristone Linepharma Consumer Medicine Information and Product Information



For a directory of supportive services :

www.pregnancycarenetwork.org.au

For more information:

www.ru486.org.au

For copies of this brochure:

enquiry@realchoices.org.au

A publication of Real Choices Australia Ltd September, 2013

## **Be informed about**

# Medical Abortion



## What you need to know about medical abortion

More than one adverse effect was reported for most patients, with approximately 23% of all adverse events considered serious.

### What is Medical Abortion?

Medical abortion is often referred to simply by the original name given to one of the drugs used, RU486.

RU486 is a drug called mifepristone that is used in combination with a second drug, misoprostol, to cause a medical abortion in women up to 9 weeks of pregnancy, although the TGA only recommends its use up to 7 weeks.<sup>1</sup> Using these 2 drugs in the manner prescribed will end a pregnancy in up to 92-95% of women.

#### **Mifepristone**

Mifepristone acts to block the hormone progesterone which essentially starves the embryo of nourishment. The embryo then detaches from the uterine wall. Mifepristone also causes softening and opening of the cervix.

#### Misoprostol

In a medical abortion misoprostol is used to cause uterine contractions in an attempt to expel the embryo from the woman's body. It is taken 24-48 hours following the mifepristone.

### Medical abortions require:

- at least 2 doctor's visits
- known blood group or a prior blood test. For women who have a negative blood group, an injection of Anti-D is required within 72 hours of the abortion
- an ultrasound, possibly via vaginal probe, to confirm how far along the pregnancy is and exclude ectopic pregnancy
- the first drug to be taken at the time of consultation
- the second drug to be taken between 24-48 hours later, either at another consultation, or at home
- an essential follow up appointment 14-21 days later, where either a blood test or further ultrasound will determine whether the abortion has been complete

### **Other Considerations:**

Women having a medical abortion must be near emergency medical care at least until the abortion process is complete.

The doctor must provide 24hr emergency phone support following administration of the drugs.

A support person is also needed for at least 24 hours or until expulsion of the embryo.

Cramping and bleeding can begin to occur within a few hours of taking the first medication.

The amount of pain and bleeding experienced varies widely, with pain being described as anything from 'uncomfortable' to 'excruciating'.

Pain relief may be provided by the doctor.

Bleeding lasts an average of 9-16 days with a range of up to 70 days reported. Bleeding can be very heavy.

Blood clots and other tissue, including a small embryo (which may be identifiable), will be expelled during this process. For some women, this can be very distressing.

Even if bleeding occurs, or if there is continued bleeding, or a lack of bleeding, it is possible that the abortion is not complete. A further surgical procedure would then be required.

Other side effects may be experienced.

## At least 2 doctor's visits An ultrasound Average 10-16 days of bleeding Stay close to emergency care See over for warnings

- Adverse side effects<sup>2</sup> (risks):
  Diarrhoea (up to 30%)
- Nausea (up to 70%)
- Vomiting (up to 45%)
- Dizziness, headache, chills, shivering and fever

In U.S. trials<sup>3</sup> of RU-486/misoprostol, at least 99% of patients experienced at least one of the following:

- abdominal pain
- (cramping) (97%)
   nausea (67%)
- nausea (67%)
- headache (32%)
- vomiting (34%)
- diarrhoea (23%)
- dizziness (12%)
- fatigue (9%)

- back pain (9%)
- uterine haemorrhage (7%)
- fever (4%)
- viral infections (4%)
- vaginitis (4%)
- Rigors (chills/shaking)3%)

An **Australian study**<sup>4</sup> found that RU486 abortions carried a higher risk of adverse events than surgical abortion, including that:

- 5.7% of women required hospital admission
- 3.3% of women sought Emergency Department hospital treatment
- 1 in 200 women suffered severe haemorrhage

**Death:** One death was reported in Australia and 14 known deaths worldwide<sup>5</sup> (at time of printing).

Up to 20% of women suffer serious, prolonged mental health problems following abortion<sup>6</sup>.

Immediate medical attention must be sought for ANY of these very serious side effects:

- fever of 38 °C or higher
- fainting
- fast heartbeat

• Ongoing stomach/abdominal pain or tenderness more than 24 hours after taking the misoprostol<sup>7,8</sup>