How to manage the risk to your patients in Medical Termination of Pregnancy (MToP)

Please consult the mifepristone and misoprostol SmPC / prescribing information before performing a MToP.

As a reminder, the approved indication for MisoOne® as per the product license is medical termination of developing intra-uterine pregnancy, in sequential use with mifepristone, up to 49 days of amenorrhea.

- Mifepristone: **600 mg** oral dose
- Misoprostol: **400 mcg** oral dose (i.e. 1 tablet of MisoOne®) 36 to 48 h after mifepristone intake

The management of the risk to the patients consists of two steps:

1. Counselling
2. Verification of complete expulsion during the follow-up visit which must take place within a period of 14 to 21 days after administration of the mifepristone

To minimize the risk associated with MisoOne®, you are advised to counsel your patient regarding the following.

INFORMATION TO BE TAKEN INTO ACCOUNT DURING THE COUNSELLING

PATIENT MEDICAL HISTORY

MToP method is suitable in most women's cases. However, due to the prostaglandin intake, you have to consider the following pre-existing conditions before starting the procedure:

- **scarred uterus,**
- **cardiovascular risks (e.g being aged over 35 years with chronic smoking, hyperlipidaemia, diabetes),**
- **established cardiovascular disease**
- **Rhesus negative**

What to do:

- Discuss the medical history with the patient
- Treat the patients with caution when they have the pre-existing conditions

FERTILITY

This method has no influence on the fertility of the patient.

What to do:

- Discuss the choice of the contraception method with the patient preferably during the counselling visit in order to prescribe the most suitable method and start the contraception properly.

BLEEDING

Bleeding is a normal part of the abortion procedure and the patient should be aware of it.

What to do:

Instruct the patient on the following:

- Occurrence and intensity of prolonged vaginal bleeding:
  - Can start very quickly after misoprostol intake
  - Expulsion can occur within 4 hours, or during the next few days
  - Duration of about 12 days
- To contact physician immediately in case of abnormal bleeding:
  - More than 12 days and/or
  - More than 2 sanitary pads per hour for 2 hours
- Bleeding is not in any way proof of complete expulsion therefore a follow-up visit is required to confirm termination of the pregnancy
- If persistent bleeding occurs after the follow-up visit the patient needs to contact the doctor
- Persistent vaginal bleeding could signify incomplete abortion and appropriate treatment should be considered.

Note down on safety card:

- Phone number and address of the prescribing centre so the patient can contact you.
- Date of follow-up visit for the patient

INFECTIONS

Toxic or septic shocks following infections have been reported following MToP. Clinicians should be aware of this potentially fatal complication, particularly when misoprostol is given other than orally (i.e. vaginally or buccally).

These infections are the consequence of atypical pathogens.

What to do:

Instruct the patient on the following:

- Contact physician immediately in case of
  - Fever
  - Pain despite intake of painkillers

The patient safety card is available in the patient materials. Note down on safety card:

- Phone number and address of the prescribing centre so the patient can contact you.
- Date of follow-up visit for the patient

VERIFICATION OF COMPLETE EXPULSION

The medical ToP procedure consists of 3 steps:

- Mifepristone intake,
- MisoOne® intake,
- and the follow-up visit.

If the medical abortion is done with the regimen mentioned in MisoOne® SmPC, the risk of ongoing pregnancy is below 1%. This risk increases when other regimens are used. In case of ongoing pregnancy, it is essential the patient is informed about the potential risks due to mifepristone/MisoOne® (misoprostol) to decide to carry the pregnancy to term or not.

What to do:

During follow-up visit verify complete expulsion

In case the method failed, inform the patient about her options:

- Terminate the pregnancy. In this case a second method for ToP should be used
- Carry the pregnancy to term.

In case the patient decides to carry the pregnancy to term:

- Inform the patient about the risk of malformations of the newborn due to the exposure to drug(s)
- Special follow up with ultrasound scan monitoring in a specialised center.

Please report any case of safety events, incomplete or failed MToP to HPRA www.hpra.ie and also to Exelgyn Pharmacovigilance department (pv@nordicpharma.com).

A safety card to fill out is available for the patient in the patient leaflet. Please, note down the referent contact details and prescribing center to be used by the patient in case of disorders following the procedure.

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