ANTIPREG KIT

COMPOSITION : Each kit contains: One Mifepristone Tablet 200 mg & Four Misoprostol Tablets 200 mcg. INDICATION: It is indicated for the medical termination of intrauterine pregnancy through 63 days' pregnancy. For purposes of this treatment, pregnancy is dated from the first day of the last menstrual period in a presumed 28 day cycle with ovulation occurring at mid-cycle. DOSAGE & ADMINISTRATION: Day one: Mifepristone administration-One 200 mg tablet of Mifepristone is taken orally. Day three: Misoprostol administration-The patient returns to the doctor two days after ingesting mifepristone .- Unless abortion has occurred and has been confirmed by clinical examination or ultrasonographic scan, the patient takes misoprostol, 400µg for medical abortion up to 49 days of gestation or administer misoprostol 800µg Intravaginally/as needed for medical abortion up to 9 weeks (63 days) of gestation.During the period immediately following the administration of misoprostol, the patient may need medication for cramps or gastrointestinal symptoms. The patient should be given instructions on what to do if significant discomfort, excessive vaginal bleeding Day 14: Post-treatment examination-Patients will return for a follow-up visit approximately 14 days after the administration of Mifepristone to confirm by clinical examination or ultrasonographic scan that a complete termination of pregnancy has occurred.CONTRAINDICATIONS: Should not be prescribed to patients who have an ectopic pregnancy, have an intrauterine device (IUD) in place, have unconfirmed gestational age, have chronic adrenal failure, are on concurrent long term systemic corticosteroid therapy, have haemorrhagic disorders or using concurrent anticoagulation therapy, have inherited porphyria, have uncontrolled asthma, have known hypersensitivity to mifepristone, misoprostol, other prostaglandins.WARNINGS & PRECAUTIONS : Risk of infection and sepsis -Cases of serious bacterial infection, including very rare cases of fatal septic shock, have been reported following the use .Some patients presented without fever, with or without abdominal pain, but with leukocytosis with a marked left shift, tachycardia, hemoconcentration, and general malaise. A high index of suspicion is needed to rule out sepsis (from e.g. Clostridium sordellii) if a patient reports abdominal pain or discomfort or general malaise (including weakness, nausea, vomiting or diarrhoea) more than 24 hours after taking misoprostol Risk of bleeding: Prolonged heavy bleeding may be a sign of incomplete abortion or other complications and prompt medical or surgical intervention may be needed. These patients must seek immediate medical attention Embryotoxicity-Patients should be counselled that once the treatment is started, there are risks of embryotoxicity if the pregnancy is not terminated. Both mifepristone and misoprostol are embryotoxic and have been associated with fetal abnormalities Return to fertility -Patients should be advised of their immediate return to fertility after administration To avoid the potential exposure of a subsequent pregnancy to mifepristone and misoprostol, it is recommended that conception be avoided during the next menstrual cycle. Reliable contraceptive methods should therefore commence as early as possible.PREGNANCY & LACTATION:This product is used for pregnancy termination .it should not be used during breastfeeding. INTERACTION: Mifepristone-caution should be exercised when mifepristone is administered with drugs that are CYP3A4 substrates and have narrow therapeutic range, including some agents used during general anaesthesia. Due to the antiglucocorticoid activity of mifepristone, the efficacy of corticosteroid therapy, including inhaled corticosteroids, may be temporarily decreased following intake of mifepristone therapy should be adjusted. Misoprostol-.Misoprostol was not found to affect hepatic drug metabolism. No drug interactions have been attributed to misoprostol in extensive clinical trials. ADVERSE REACTIONS: The most frequent undesirable effects which were observed during treatment were vaginal bleeding, sometimes heavy and prolonged uterine cramping ,nausea, vomiting, diarrhoea and abdominal pain, headache, dizziness, chills and fever.(For details, please refer full prescribing information)

(For the use of a registered medical practitioner or hospital or laboratory only)