

HERWONT KIT

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only

Abbreviated Prescribing information for **HERWONT KIT** [(Combikit of Mifepristone Tablets I.P. 200 mg And Misoprostol Tablets I.P. 200 mcg)] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:- Mifepristone- The anti-progestational activity of mifepristone results from competitive interaction with progesterone at progesterone-receptor sites. Misoprostol:- Prostaglandin E1 causes myometrial contractions by interacting with specific receptors on myometrial cells.

INDICATION: herwont kit is indicated for early medical abortion up to 9 weeks (63 days) of gestation.

DOSAGE AND ADMINISTRATION: herwont kit is indicated for the medical termination of intrauterine pregnancy up to 63 days of gestation. For purposes of this treatment, pregnancy is dated from the first day of the last menstrual period in a presumed 28 days cycle with ovulation occurring at mid-cycle.

CONTRAINDICATION: History of allergy or known hypersensitivity to mifepristone, misoprostol or other prostaglandin Confirmed or suspected ectopic pregnancy or undiagnosed adnexal mass (the treatment procedure will not be effective to terminate an ectopic pregnancy) IUD in place Chronic adrenal failure Concurrent long-term corticosteroid therapy Haemorrhagic disorders or concurrent anticoagulant therapy Inherited porphyria

WARNINGS & PRECAUTIONS: Any intrauterine device [“IUD”] should be removed before treatment with mifepristone begins. Pregnancy termination by surgery is recommended in cases when herwont kit fails to cause termination of intrauterine pregnancy, Prolonged heavy bleeding may be a sign of incomplete abortion or other complications and requires prompt and immediate medical attention, Cases of serious bacterial infection, including very rare cases of fatal septic shock, have been reported, Mifepristone is contraindicated in confirmed or suspected ectopic pregnancy since it is not effective for terminating these pregnancies.

DRUG INTERACTIONS ketoconazole, itraconazole, erythromycin, and grapefruit juice may inhibit its metabolism, Misoprostol has not been shown to interfere with the beneficial effects of aspirin on signs and symptoms of rheumatoid arthritis.

ADVERSE REACTIONS: nausea, vomiting and diarrhoea. Pelvic pain, fainting, headache, dizziness and asthenia occurred rarely, aches/pains, asthenia, fatigue, fever, rigors, weight changes, rash, dermatitis, alopecia, pallor, breast pain, abnormal taste, abnormal vision, conjunctivitis, deafness, tinnitus, earache, upper respiratory tract infection, bronchitis, bronchospasm, dyspnea, pneumonia, epistaxis, chest pain, oedema, diaphoresis, hypotension, hypertension, arrhythmia, phlebitis, increased cardiac enzymes, syncope, GI bleeding, GI inflammation/infection, rectal disorder, abnormal hepatobiliary function, gingivitis, reflux, dysphagia, amylase increase, anaphylaxis, glycosuria, gout, increased nitrogen, increased alkaline phosphatase, : polyuria, dysuria, haematuria, urinary tract infection, anxiety, change in appetite, depression, drowsiness, dizziness, thirst, impotence, loss of libido, sweating increase, neuropathy, neurosis, confusion, arthralgia, myalgia, muscle cramps, stiffness, back pain, anaemia, abnormal differential, thrombocytopenia, purpura and ESR increased.

MARKETED BY:



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(Additional information is available on request)