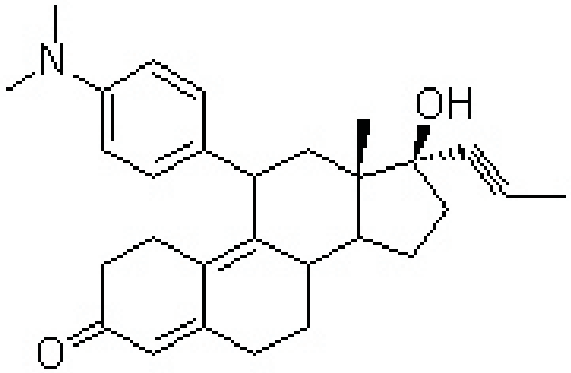
Taj Pharmaceuticals Ltd.

Mifepristone

CAS No. : 84371-65-3

Molecular Formula C29H35NO2
Molecular Weight 429.60
CAS Number 84371-65-3



Chemical data

Formula C29H35NO2
Mol. mass 429.60 g/mol

Pharmacokinetic data

Bioavailability 69%
Metabolism hepatic
Half life 18 hours
Excretion Fecal: 83%; Renal: 9%

DOSAGE

Treatment with Mifeprex and misoprostol for the termination of pregnancy requires three office visits by the patient. Mifeprex should be prescribed only by physicians who have read and understood the prescribing information. Mifeprex may be administered only in a clinic, medical office, or hospital, by or under the supervision of a physician, able to assess the gestational age of an embryo and to diagnose ectopic pregnancies. Physicians must also be able to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through others, and be able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.
Day One: Mifeprex Administration

Patients must read the MEDICATION GUIDE and read and sign the PATIENT AGREEMENT before Mifeprex is administered.

Three 200 mg tablets (600 mg) of Mifeprex are taken in a single oral dose.

Day Three: Misoprostol Administration

The patient returns to the health care provider two days after ingesting Mifeprex. Unless abortion has occurred and has been confirmed by clinical examination or ultrasonographic scan, the patient takes two 200 µg tablets (400 µg) of misoprostol orally.

Day 14: Post-Treatment Examination

Patients will return for a follow-up visit approximately 14 days after the administration of Mifeprex. This visit is very important to confirm by clinical examination or ultrasonographic scan that a complete termination of pregnancy has occurred.

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SIDE EFFECTS

The following adverse reactions have also been reported during post-approval use of Mifeprex and misoprostol. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. No causal relationship between these events and Mifeprex and misoprostol has been established:

Allergic reaction (including rash, hives, itching), hypotension (including orthostatic), lightheadedness, loss of consciousness, post-abortal infection (including endomyometritis, parametritis), ruptured ectopic pregnancy, shortness of breath, and tachycardia (including racing pulse, heart palpitations, heart pounding).

PRECAUTIONS

Each patient must understand:

* the necessity of completing the treatment schedule, including a follow-up visit approximately 14 days after taking Mifeprex;
* that vaginal bleeding and uterine cramping probably will occur;
* that prolonged heavy vaginal bleeding is not proof of a complete abortion;
* that if the treatment fails, there is a risk of fetal malformation;
* that medical abortion treatment failures are managed by surgical termination; and
* the steps to take in an emergency situation, including precise instructions and a telephone number that she can call if she has any problems or concerns.

Another pregnancy can occur following termination of pregnancy and before resumption of normal menses. Contraception can be initiated as soon as the termination of the pregnancy has been confirmed, or before the woman resumes sexual intercourse.

This medication should not be used if you have certain medical conditions or other problems. Before using this medicine, consult your doctor if you have any of the following: undiagnosed abdominal growth (adnexal mass), certain adrenal gland problem (chronic adrenal failure), bleeding problem (e.g., coagulopathy), certain blood disorder (inherited porphyrias), IUD (intrauterine birth control device) in place, pregnancy longer than 7 weeks, proven or possible abnormal pregnancy outside the womb (ectopic pregnancy), unable to return for a doctor's visit in 48 hours and again in 14 days, unable to easily get emergency help in the 2 weeks after taking mifepristone.

INTERACTION

Although specific drug or food interactions with mifepristone have not been studied, on the basis of this drug's metabolism by CYP 3A4, it is possible that ketoconazole, itraconazole, erythromycin, and grapefruit juice may inhibit its metabolism (increasing serum levels of mifepristone). Furthermore, rifampin, dexamethasone, and certain anticonvulsants (phenytoin, phenobarbital, carbamazepine) may induce mifepristone metabolism (lowering serum levels of mifepristone).

Based on in vitro inhibition information, coadministration of mifepristone may lead to an increase in serum levels of drugs that are CYP 3A4 substrates. Due to the slow elimination of mifepristone from the body, such interaction may be observed for a prolonged period after its administration. Therefore, caution should be exercised when mifepristone is administered with drugs that are CYP 3A4 substrates and have narrow therapeutic range, including some agents used during general anesthesia.

DRUG DESCRIPTION

Mifepristone is a synthetic steroid compound used as a pharmaceutical. It is used as an abortifacient in the first two months of pregnancy, and in smaller doses as an emergency contraceptive.

Other medical applications of mifepristone that have been studied in Phase II clinical trials include regular long-term use as an oral contraceptive, and treatment of: uterine fibroids, endometriosis, major depression with psychotic features, glaucoma, meningiomas, breast cancer, ovarian cancer, prostate cancer, and some types of Cushing's syndrome.

Mifepristone blocks the hormone progesterone needed to maintain the pregnancy. Because this hormone is blocked, the uterine lining begins to shed, the cervix begins to soften and bleeding may occur. With the later addition of the second medication, misoprostol, the uterus contracts and the pregnancy is usually expelled within 6 to 8 hours.

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:
http://www.tajapi.com
or by contacting the sponsor, Taj Pharmaceuticals Limited., at:
91 022 30601000.
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