



Actogest

The natural choice



Choose Natural

Contains the bio-identical progesterone

Choose Unique

Progesterone suppository in a unique formulation

Choose Convenience

Flexible vaginal or rectal administration

SmPc

∞ **Brand name:** Actogest, **Generic name:** Progesterone 400mg, **Dosage form:** Vaginal and rectal suppository, **Therapeutic indications:** Treatment of premenstrual syndrome, including premenstrual tension and depression, Treatment of puerperal depression, Luteal phase support as part of an Assisted Reproductive Technology (ART) treatment for women, **Administration:** For the treatment of premenstrual syndrome and puerperal depression: 400mg twice a day, by vaginal or rectal insertion. For premenstrual syndrome commence treatment on day 14 of menstrual cycle and continue treatment until onset of menstruation. If symptoms are present at ovulation commence treatment on day 12. For luteal phase support as part of an ART treatment: 400 mg administered vaginally twice a day starting at oocyte retrieval. The administration should be continued for 38 days, if pregnancy has been confirmed. **Use in special populations:** There is no experience in patients with impaired liver or renal function. Pediatric population: There is no relevant use in the pediatric population. Elderly: No clinical data have been collected in patients over age 65.

Contraindications: Hypersensitivity to the active substance or to any of the excipients, Undiagnosed vaginal bleeding, Known or suspected progesterone sensitive malignant tumors, Porphyria, Severe hepatic dysfunction or disease, Known missed abortion or ectopic pregnancy, active arterial or venous thromboembolism or severe thrombophlebitis, or a history of these events. **Special warnings and precautions for use:** Actogest is not indicated in threatened miscarriage. Treatment should be discontinued in the event of a missed miscarriage. Actogest should be discontinued if any of the following conditions are suspected: myocardial infarction, cerebrovascular disorders, arterial or venous thromboembolism (or pulmonary embolism), thrombophlebitis or retinal thrombosis. Patients with a history of depression need to be closely observed. Consider discontinuation if symptoms worsen. Because progesterone may cause some degree of fluid retention, conditions that might be influenced by this factor (e.g. epilepsy, migraine, asthma, cardiac or renal dysfunction) require careful observation. A decrease in glucose tolerance has been observed in a small number of patients on estrogen- progestin combination drugs. The mechanism of this decrease is not known. For this reason, diabetic patients should be carefully observed while receiving progestin therapy. Progesterone is metabolized in the liver and should be used with caution in patients with hepatic dysfunction. Sudden discontinuation of progesterone dosing may cause increased anxiety, moodiness, and increased sensibility to seizures.

Treatment of premenstrual syndrome and puerperal depression:

∞ Use rectally if barrier methods of contraception are used.

∞ Use rectally if patients suffer from vaginal infection (especially moniliasis) or recurrent cystitis or have recently given birth.

∞ Use vaginally if patients suffer from colitis or fecal incontinence.

Adverse Reactions: abdominal distension (swelling in the abdomen), abdominal pain, constipation, sleepiness, tiredness, hot flush, breast pain, **Fertility, pregnancy and lactation:** Pregnancy: Actogest should not be used during pregnancy except as indicated during the first trimester of pregnancy for use as part of an assisted reproduction (ART) treatment. There is limited and inconclusive data on the risk of congenital anomalies, including genital abnormalities in male or female infants, following intrauterine exposure during pregnancy. The rates of congenital anomalies, spontaneous abortion and ectopic pregnancies observed during the clinical trial were comparable with the event rate described in the general population although the total exposure is too low to allow conclusions to be drawn. Lactation: Progesterone is excreted in human milk and Actogest should not be used during breast-feeding.(4)

References

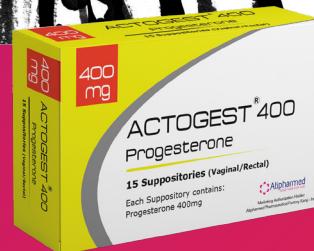
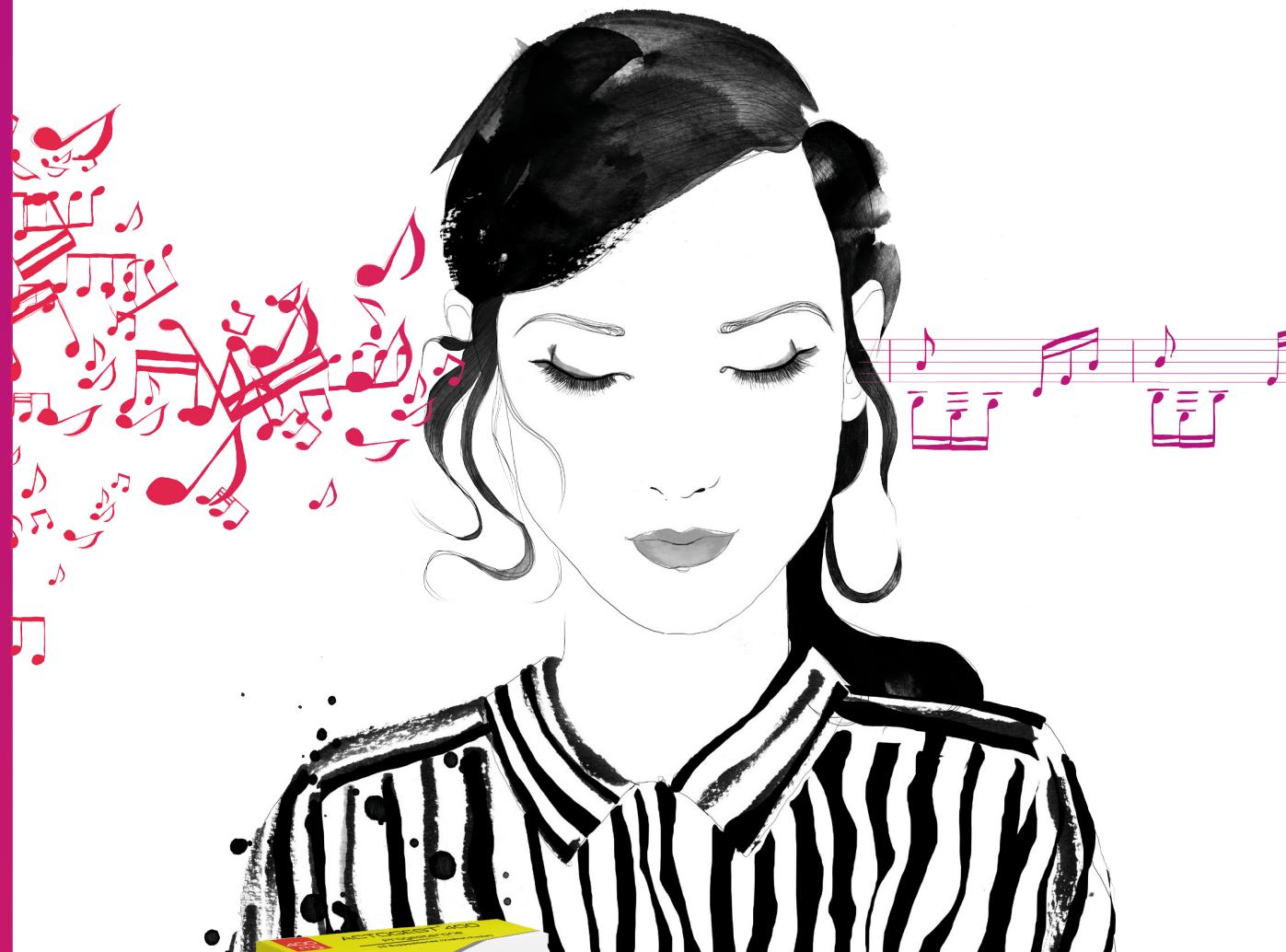
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 **Atipharm**
TOGETHER FOR YOU

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Naturally in tune



Actogest

PROGESTERONE SUPPOSITORIES 400 mg

Actogest The natural progesterone

- Actogest 400mg contains a Progesterone that is bioidentical
- Bioidentical Progesterone has fewer reported side effects ⁽¹⁾

Actogest Optimising absorption

- Actogest contains micronized Progesterone: small particle size ⁽²⁾
- Micronization promotes favorable drug pharmacokinetics:
 - » Increase progesterone release dissolution and absorption
 - » Increase Progesterone half-life
 - » Controlled and sustained plasma Progesterone level

Actogest In tune with her body

- Unique suppository ⁽³⁾
- Unlike an oral formulation, delivers Progesterone directly where it is needed
- Act locally, avoiding gastrointestinal and hepatic first pass metabolism
- Enhance Progesterone bioavailability

Actogest suppositories contain a unique vehicle

Suppocire BS2 wax

- Self-lubricating-aiding easy painless insertion
- Melts at body temperature
- Provides consistent and uniform delivery of each dose

Actogest Convenient and flexible use

Comfortable vaginal administration

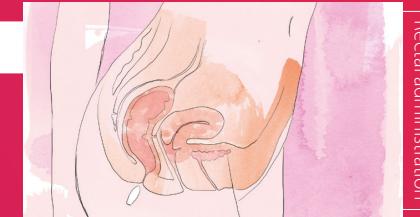
- Easy self-insertion by the patient
- No applicator required



vaginal administration

With the option of rectal insertion ^{1,2}

- Preferred in certain medical conditions ^{1,2}
- Sustained and similar plasma concentrations after vaginal and rectal administration ^{1,2}



Rectal administration

Dissolution rate comparison graph: Actogest 400mg vs Cyclogest 400mg suppository

