

DYDROGESTERON

Class: Progestin

Indications: Labeled Indications

Note: Not approved in U.S. and/or Canada

Abnormal uterine bleeding: Treatment of abnormal uterine bleeding

Amenorrhea: Treatment of secondary amenorrhea

Dysmenorrhea: Treatment of dysmenorrhea

Endometriosis: Treatment of endometriosis

Infertility: Treatment of infertility due to luteal insufficiency

Irregular menstrual cycle: Treatment of irregular menstrual cycle

Menopause: Treatment of menopausal symptoms in combination with continuous or cyclic estrogen therapy

Pregnancy loss: May be indicated to reduce risk of threatened or recurrent pregnancy loss in some countries (consult specific product labeling)

Premenstrual syndrome: Treatment of symptoms of premenstrual syndrome

Use: Unlabeled

Part of assisted reproductive technology (ART) for infertile women

Available dosage form in the hospital: DYDROGESTERON 10MG TAB

Trade Names:

Dosage: Females:

-Abnormal uterine bleeding: Oral: Initial: 10 mg twice daily for 5-7 days to stop bleeding. For continued prevention the dose is 10 mg twice daily on days 11-25 of cycle

-Amenorrhea, secondary: Oral: 10 mg twice daily on days 11-25 of cycle. **Note:** Endometrium should be adequately primed with estrogen (exogenous or endogenous). A dose of 10 mg once daily for 14 consecutive days of each 28-day cycle has shown efficacy in premenopausal women with normal estrogen levels (Panay, 2007).

-Dysmenorrhea: Oral: 10 mg twice daily on days 5-25 of cycle

-Endometriosis: Oral: 10 mg twice daily or three times daily on days 5-25 of cycle, or continuously

-Infertility:

Due to luteal insufficiency: Oral: 10 mg once daily on days 14-25 of cycle for ≥ 6 consecutive cycles

Luteal phase support in assisted reproductive technology (ART) (unlabeled use; Ganesh, 2011):

Oral: 10 mg twice daily, starting on first day of embryonic transfer and continued through week 12 of pregnancy

-Irregular menstrual cycle: Oral: 10 mg twice daily on days 11-25 of cycle

-Menopause: Oral:

In combination with cyclic estrogen therapy: 10 mg once daily for the last 12-14 days of cycle.

May increase to 10 mg twice daily if evidence (eg, ultrasound, biopsy) of lack of response or withdrawal bleeding occurs.

In combination with continuous estrogen therapy: 10 mg once daily for 14 consecutive days of a 28-day cycle

-Pregnancy loss, recurrent: Oral: 10 mg twice daily. May be taken through week 20 of pregnancy. **Note:** Efficacy compared to placebo has been reported with treatment through week 12 of pregnancy when started in weeks 4-5 (El-Zibdeh, 2005).

-Pregnancy loss, threatened: Oral: Initial: 40 mg loading dose, followed by 10 mg every 8 hours until symptoms resolve. **Note:** Administration of 10 mg twice daily (with or without a 40 mg loading dose) has also demonstrated efficacy (Carp, 2012).

-Premenstrual syndrome: Oral: 10 mg twice daily on days 11-25 of cycle.

Renal Impairment:

No dosage adjustment provided in manufacturer's labeling (has not been studied).

Hepatic Impairment:

No dosage adjustment provided in manufacturer's labeling (has not been studied); use caution in patients with hepatic impairment and discontinue therapy if severe hepatic impairment occurs.

Common side effect:

1% to 10%:

Central nervous system: Headache, migraine

Endocrine & metabolic: Amenorrhea, hypermenorrhea, oligomenorrhea

Gastrointestinal: Nausea

Genitourinary: Breast tenderness, dysmenorrhea, mastalgia

Pregnancy Risk Factor: An increased risk of adverse fetal events has not been observed in clinical trials using dydrogesterone in early pregnancy (limited data). A specific pattern of birth defects has not been observed in available case reports (Queisser-Luft, 2009).