

MICROGYNON TAB [LEVONORGESTREL+ETHINYLESTRADIOL 0.15/0.03MG].

Class: Contraceptive; Estrogen and Progestin Combination.

Indications:

Prevention of pregnancy; postcoital contraception

Available dosage form in the hospital:

[MICROGYNON TAB [LEVONORGESTREL+ETHINYLESTRADIOL 0.15/0.03MG

Trade Names:

Dosage: Adult: Females:

-Contraception, 28-day cycle: Oral:

-Schedule 1 (Sunday starter): Dose begins on first Sunday after onset of menstruation; if the menstrual period starts on Sunday, take first tablet that very same day. With a Sunday start, an additional method of contraception should be used until after the first 7 days of consecutive administration:

-For 21-tablet package: 1 tablet/day for 21 consecutive days, followed by 7 days off of the medication; a new course begins on the 8th day after the last tablet is taken

-For 28-tablet package: 1 tablet/day without interruption

-Schedule 2 (Day-1 starter): Dose starts on first day of menstrual cycle taking 1 tablet/day:

-For 21-tablet package: 1 tablet/day for 21 consecutive days, followed by 7 days off of the medication; a new course begins on the 8th day after the last tablet is taken

-For 28-tablet package: 1 tablet/day without interruption

-If all doses have been taken on schedule and one menstrual period is missed, continue dosing cycle. If two consecutive menstrual periods are missed, pregnancy test is required before new dosing cycle is started.

-Missed doses **monophasic formulations** (refer to package insert for complete information):

-One dose missed: Take as soon as remembered or take 2 tablets next day

-Two consecutive doses missed in the first 2 weeks: Take 2 tablets as soon as remembered or 2 tablets next 2 days. An additional method of contraception should be used for 7 days after missed dose.

-Two consecutive doses missed in week 3 or three consecutive doses missed at any time: An additional method of contraception must be used for 7 days after a missed dose:

- Schedule 1 (Sunday starter): Continue dose of 1 tablet daily until Sunday, then discard the rest of the pack, and a new pack should be started that same day.

-Schedule 2 (Day-1 starter): Current pack should be discarded, and a new pack should be started that same day.

-Missed doses **biphasic/triphasic formulations** (refer to package insert for complete information):

-One dose missed: Take as soon as remembered or take 2 tablets next day.

-Two consecutive doses missed in week 1 or week 2 of the pack: Take 2 tablets as soon as remembered and 2 tablets the next day. Resume taking 1 tablet daily until the pack is empty. An additional method of contraception should be used for 7 days after a missed dose.

-Two consecutive doses missed in week 3 of the pack: An additional method of contraception must be used for 7 days after a missed dose.

-Schedule 1 (Sunday starter): Take 1 tablet every day until Sunday. Discard the remaining pack and start a new pack of pills on the same day.

-Schedule 2 (Day-1 starter): Discard the remaining pack and start a new pack the same day.

-Three or more consecutive doses missed: An additional method of contraception must be used for 7 days after a missed dose.

-Schedule 1 (Sunday starter): Take 1 tablet every day until Sunday; on Sunday, discard the pack and start a new pack.

-Schedule 2 (Day-1 starter): Discard the remaining pack and begin new pack of tablets starting on the same day.

-Contraception, 91-day cycle (extended cycle regimen): Dose begins on first Sunday after onset of menstruation; if the menstrual period starts on Sunday, take first tablet that very same day. An additional method of contraception should be used until after the first 7 days of consecutive administration:

-Seasonale®: One active tablet/day for 84 consecutive days, followed by 1 inactive tablet/day for 7 days; if all doses have been taken on schedule and one menstrual period is missed, pregnancy should be ruled out prior to continuing therapy.

-Seasonique, LoSeasonique®: One active tablet/day for 84 consecutive days, followed by 1 low dose estrogen tablet/day for 7 days; if all doses have been taken on schedule and one menstrual period is missed, pregnancy should be ruled out prior to continuing therapy.

Missed doses:

-One dose missed: Take as soon as remembered or take 2 tablets the next day

-Two consecutive doses missed: Take 2 tablets as soon as remembered or 2 tablets the next 2 days. An additional nonhormonal method of contraception should be used for 7 consecutive days after the missed dose.

-Three or more consecutive doses missed: Do not take the missed doses; continue taking 1 tablet/day until pack is complete. Bleeding may occur during the following week. An additional nonhormonal method of contraception should be used for 7 consecutive days after the missed dose.

-Any number of pills during week 13: Throw away the missed pills and keep taking scheduled pills until the pack is finished. A back-up method of contraception is not needed

-Contraception, continuous use (extended cycle regimen): Oral: Lybrel®: Take one tablet daily, at the same time each day, without a tablet-free interval. Therapy should be initiated as follows:

- No previous contraception: Begin on the first day of menstrual cycle. Back-up contraception is not needed.
- Previously taking a 21-day or 28-day combination hormonal contraceptive: Begin on day 1 of the withdrawal bleed (at the latest, 7 days after the last active tablet). Back-up contraception is not needed.
- Previously using a progestin-only pill: Begin the day after taking a progestin only pill. Back-up contraception is needed for the first 7 days of therapy.
- Previously using contraceptive implant: Begin the day of implant removal. Back-up contraception is needed for the first 7 days of therapy.
- Previously using contraceptive injection: Begin when the next injection is due. Back-up contraception is needed for the first 7 days of therapy.

Missed doses:

- One dose missed: Take as soon as remembered then take the next tablet at the regular time (2 tablets in 1 day). An additional nonhormonal method of contraception should also be used for 7 consecutive days.
- Two consecutive doses missed: If remembered the day of the second missed tablet, take 2 tablets as soon as remembered, then 1 tablet the next day. If remembered the day after the second tablet is missed, take 2 tablets the day remembered, then 2 tablets the next day. An additional nonhormonal method of contraception should also be used for 7 consecutive days.
- Three or more consecutive doses missed: Take 1 tablet daily and contact healthcare provider; do not take the missed pills. An additional nonhormonal method of contraception should also be used for 7 consecutive days.

Renal Impairment:

Specific guidelines not available; use with caution and monitor blood pressure closely. Consider other forms of contraception.

Hepatic Impairment:

Contraindicated in patients with hepatic impairment.

Common side effect:

The following reactions have been associated with oral contraceptive use:

Increased risk or evidence of association with use:

Cardiovascular: Arterial thromboembolism, cerebral hemorrhage, cerebral thrombosis, hypertension, mesenteric thrombosis, MI, venous thrombosis (with or without embolism)

Gastrointestinal: Gallbladder disease

Hepatic: Hepatic adenomas, liver tumors (benign)

Local: Thrombophlebitis

Ocular: Retinal thrombosis

Respiratory: Pulmonary embolism

Adverse reactions considered drug related:

Cardiovascular: Edema, varicose vein aggravation

Central nervous system: Depression, migraine, mood changes

Dermatologic: Chloasma, melasma, rash (allergic)

Endocrine & metabolic: Amenorrhea, breakthrough bleeding, breast changes (enlargement, pain, secretion, tenderness), carbohydrate tolerance decreased, fluid retention, infertility (temporary), lactation decreased (with use immediately postpartum), menstrual flow changes, spotting

Gastrointestinal: Abdominal bloating, abdominal cramps, abdominal pain, appetite changes, nausea, weight changes, vomiting

Genitourinary: Cervical ectropion, cervical secretion/erosion, endocervical hyperplasia, fibroid enlargement, vaginal candidiasis, vaginitis

Hematologic: Folate decreased, porphyria exacerbation

Hepatic: Cholestatic jaundice, focal nodular hyperplasia

Neuromuscular & skeletal: Chorea exacerbation

Ocular: Contact lens intolerance, corneal curvature changes (steepening)

Respiratory: Rhinitis

Miscellaneous: Anaphylactic/anaphylactoid reactions (including angioedema, circulatory collapse, respiratory collapse, urticaria), SLE exacerbation

Adverse reactions in which association is not confirmed or denied: Acne, auditory disturbances, Budd-Chiari syndrome, cataracts, cervical smear abnormal, colitis, cystitis-like syndrome, dizziness, dysmenorrhea, erythema multiforme, erythema nodosum, headache, hemolytic uremic syndrome, hemorrhagic eruption, hirsutism, libido changes, nervousness, optic neuritis (with or without partial or complete loss of vision), pancreatitis, premenstrual syndrome, renal function impaired, scalp hair loss

Pregnancy Risk Factor: X.