



Prior Authorization Protocol

MINASTRIN™ 24 FE (norethindrone acetate and ethinyl estradiol and ferrous fumarate) chewable tablets

NATL

Coverage of drugs is first determined by the member's pharmacy benefit. Please consult with or refer to the Evidence of Coverage document.

I. FDA Approved Indications:

- Use by females of reproductive age to prevent pregnancy

II. Health Net Approved Indications and Usage Guidelines:

- Medical justification as to why the patient requires a chewable product
OR
- Failure or clinically significant adverse effects to Lomedia™ 24 Fe and one other generic oral contraception, e.g. Norethindrone Acetate 1 mg/Ethinyl Estradiol 0.02 mg and Ferrous Fumarate 75 mg, Junel Fe 24, Gildess 24 Fe, Microgestin 24 Fe

III. Coverage is Not Authorized For:

- Non-FDA approved indications, which are not listed in the Health Net Approved Indications and Usage Guidelines section, unless there is sufficient documentation of efficacy and safety in the published literature

IV. General Information:

- Lomedia 24 Fe is the generic equivalent to Loestrin 24 Fe
- Black Box warning: cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptive use; smoking women over 35 years old should not use.

V. Therapeutic Alternatives:

Drug	Dosing Regimen	Dose Limit/Maximum Dose
Norethindrone Acetate 1 mg/Ethinyl Estradiol 0.02 mg and Ferrous Fumarate 75 mg (Junel™ Fe 24, Gildess™ 24 Fe, Microgestin™ 24 Fe)	<u>Oral Contraceptive</u> Day 1-24: 1 tablet PO QD	<u>Oral Contraceptive</u> 1 tablet PO QD
	<u>Ferrous Fumarate</u> Day 25-28: 1 tablet PO QD	<u>Ferrous Fumarate</u> 1 tablet PO QD



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Table with 3 columns: Drug, Dosing Regimen, Dose Limit/Maximum Dose. Row 1: Lomedia™ 24 Fe, Oral Contraceptive Day 1-24: 1 tablet PO QD, Oral Contraceptive 1 tablet PO QD. Row 2: Ferrous Fumarate Day 25-28: 1 tablet PO QD, Ferrous Fumarate 1 tablet PO QD.

*Requires Prior Authorization

VI. Recommended Dosing Regimen and Authorization Limit:

Table with 3 columns: Drug, Dosing Regimen, Authorization Limit. Row 1: Minastrin 24 FE, Oral Contraceptive Day 1-24: 1 tablet PO QD, Length of Benefit. Row 2: Ferrous Fumarate Day 25-28: 1 tablet PO QD.

VII. Product Availability:

Tablets: Each blister card contains 28 tablets in the following order: 24 white tablets each containing 1 mg norethindrone acetate and 20 mcg ethinyl estradiol, 4 brown tablets each containing 75 mg ferrous fumarate.

VIII. References:

- 1. Minastrin 24 Fe [Prescribing Information] Parsippany, NJ: Actavis Pharma, Inc; December 2014.
2. Lomedia 24 Fe [Prescribing Information]Glasgow, KY: Amneal Pharmaceuticals; October 2013.
3. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed January 6, 2016.
4. Estrogen-Progestin Combinations. American Hospital Formulary Service Drug Information. Available at: http://www.medicinescomplete.com/mc/ahfs/current/. Accessed January 4,2016.
5. Clinical Pharmacology Web site. Available at http://www.clinicalpharmacology-ip.com/. Accessed January 4,2016.

The materials provided to you are guidelines used by this health plan to authorize, modify, or determine coverage for persons with similar illnesses or conditions. Specific care and treatment may vary depending on individual needs and the benefits covered under your contract.