

Home

- 2. Junel Fe 1.5/30
- Side Effects

Junel Fe 1.5/30 Side Effects

Generic name: ethinyl estradiol / norethindrone

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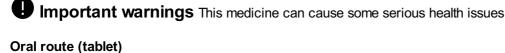
Serious side effects Other side effects Professional info

Note: This document provides detailed information about **Junel Fe 1.5/30** Side Effects associated with *ethinyl estradiol / norethindrone*. Some dosage forms listed on this page may not apply specifically to the brand name **Junel Fe 1.5/30**.

Applies to ethinyl estradiol / norethindrone: oral capsule liquid filled, oral tablet, oral tablet chewable.

Other dosage forms:

· oral tablet, oral tablet chewable



Junel®: Cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptive (COC) use.

This risk increases with age, particularly in women over 35 years of age, and with the number of cigarettes smoked.

For this reason, COCs, including Junel, are contraindicated in women who are over 35 years of age and smoke. Microgestin®: Cigarette smoking increases the risk of serious cardiovascular side effects from oral contraceptive use.

This risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age.

Women who use oral contraceptives should be strongly advised not to smoke.

Serious side effects of Junel Fe 1.5/30

Along with its needed effects, ethinyl estradiol/norethindrone may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur while taking ethinyl estradiol/norethindrone:

Incidence not known

- absent, missed, or irregular menstrual periods
- anxiety
- · change in vision
- · changes in skin color
- · chest pain or discomfort
- chills
- · clay-colored stools
- constipation
- cough
- · dark urine
- diarrhea
- · dizziness or lightheadedness
- fainting
- · fast heartbeat
- fever
- headache
- hives or welts
- itching skin
- · large, hive-like swelling on the face, eyelids, lips, tongue, throat, hands, legs, feet, or sex organs
- · loss of appetite
- medium to heavy, irregular vaginal bleeding between regular monthly periods, which may require the use of a pad or a tampon
- nausea
- · pain or discomfort in the arms, jaw, back, or neck
- · pain, tenderness, or swelling of the foot or leg
- pains in the chest, groin, or legs, especially in the calves of the legs
- pounding in the ears
- rash
- redness of the skin
- severe headaches of sudden onset
- slow or fast heartbeat
- stomach pain
- · sudden loss of coordination or slurred speech

- sweating
- · troubled breathing
- · unusual tiredness or weakness
- vomiting
- · vomiting of blood

Other side effects of Junel Fe 1.5/30

Some side effects of ethinyl estradiol / norethindrone may occur that usually **do not need medical attention**. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects.

Check with your health care professional if any of the following side effects **continue or are bothersome** or if you have any questions about them:

Incidence not known

- bloating
- · blotchy spots on the exposed skin
- breast enlargement or tenderness
- discouragement
- feeling sad or empty
- irritability
- itching of the vagina or outside genitals
- · loss of interest or pleasure
- · pain during sexual intercourse
- · stomach cramps
- thick, white curd-like vaginal discharge without odor or with mild odor
- tiredness
- · trouble concentrating
- · trouble sleeping
- trouble wearing contact lenses
- **Managing side effects** (general information)

For healthcare professionals

Applies to ethinyl estradiol / norethindrone: oral capsule, oral tablet, oral tablet chewable, oral tablet disintegrating.

General adverse events

The most frequently reported side effects were headache, vaginal candidiasis, nausea, menstrual cramps, breast tenderness, abdominal pain, mood changes, bacterial vaginitis, acne, irregular uterine bleeding, and weight gain. [Ref]

Genitourinary

- **Common** (1% to 10%): Vaginal candidiasis, menstrual cramps, breast tenderness, bacterial vaginitis, abnormal/irregular bleeding, metrorrhagia, irregular menstruation, menorrhagia, vaginal hemorrhage, breast pain, dysmenorrhea, vaginal hemorrhage, dysfunctional uterine bleeding
- Frequency not reported: Ovarian vein thrombosis, vaginitis, amenorrhea, breakthrough bleeding, breast
 enlargement, breast secretion, cervical erosion changed, cervical secretion, menstrual flow changed, diminution in
 lactation, spotting, temporary infertility after discontinuation of treatment, premenstrual syndrome, uterine fibroid
 disease exacerbated
- Postmarketing reports: Vaginal infection, pollakiuria, dysuria, ovarian cyst, pelvic pain, ovarian cyst rupture, pelvic fluid collection, nipple pain, nipple discharge, galactorrhea, fibrocystic breast change, breast disorder, breast mass, uterine leiomyomata size increased, cervical ectropion changed, endometrial hyperplasia, ovarian cyst, uterine enlargement^[Ref]

Cardiovascular

- Uncommon (0.1% to 1%): Blood pressure increased
- Frequency not reported: Deep vein thrombosis, myocardial infarction, hypertension, arterial thromboembolism, thrombophlebitis
- Postmarketing reports: Coronary artery thrombosis, palpitation, tachycardia, angina pectoris, hot flush, heart rate irregular^[Ref]

Gastrointestinal

- Common (1% to 10%): Nausea/vomiting, abdominal pain
- Frequency not reported: Abdominal cramps, bloating, colitis, dyspepsia, inflammatory bowel disease, Crohn's disease, ulcerative colitis, mesenteric thrombosis
- Postmarketing reports: Constipation, pancreatitis [Ref]

Nervous system

- Common (1% to 10%): Headache
- Frequency not reported: Migraine, dizziness, cerebral hemorrhage, cerebral thrombosis
- Postmarketing reports: Loss of consciousness, hyperesthesia, paresthesia, hypoesthesia, somnolence, sensory
 disturbance, transient ischemic attack, ischemic stroke, chorea, epilepsy exacerbated, dementia, hemiparesis^[Ref]

Oncologic

- Frequency not reported: Hepatic adenoma, hepatic carcinoma, benign liver tumor
- Postmarketing reports: Hemangioma of liver, breast cancer, ovarian cancer, endometrial cancer, uterine cancer^[Ref]

Endocrine

• Postmarketing reports: Hypothyroidism, hyperthyroidism^[Ref]

Psychiatric

- Common (1% to 10%): Mood swing, depression, mood changed, anxiety
- Frequency not reported: Nervousness
- **Postmarketing reports**: Insomnia, suicidal ideation, panic attack, libido changed, homicidal ideation, dissociation, bipolar disorder, mood disturbed, irritability^[Ref]

Dermatologic

- Common (1% to 10%): Acne
- Frequency not reported: Hirsutism, loss of scalp hair, melasma, chloasma, erythema multiforme, erythema nodosum, hemorrhagic eruption, photosensitivity, pruritus
- **Postmarketing reports**: Alopecia, generalized rash, allergic rash, skin discoloration, urticaria, angioedema, night sweats, angioedema, hirsutism, skin burning sensation, generalized erythema^[Ref]

Hepatic

- Frequency not reported: Liver disease, gallbladder disease, cholestatic jaundice, Budd-Chiari syndrome
- Postmarketing reports: Cholelithiasis, cholecystitis[Ref]

Hematologic

- Frequency not reported: Hemolytic uremic syndrome
- Postmarketing reports: Anemia [Ref]

Immunologic

• Postmarketing reports: Hypersensitivity reaction, anaphylactic/anaphylactoid reaction [Ref]

Ocular

- Frequency not reported: Corneal curvature change/steepening, contact lens intolerance, cataracts, retinal thrombosis
- Postmarketing reports: Vision blurred, vision impaired, corneal thinning, fungal infection, transient blindness^[Ref]

Respiratory

- Frequency not reported: Pulmonary embolism
- Postmarketing reports: Asthma exacerbated, dyspnea^[Ref]

Musculoskeletal

- Frequency not reported: Leg cramp, backache
- Postmarketing reports: Myalgia, arthralgia, back pain^[Ref]

Metabolic

- Common (1% to 10%): Weight fluctuation
- Frequency not reported: Tolerance to carbohydrates reduced

 Postmarketing reports: Appetite increased, appetite decreased, diabetes mellitus, hypoglycemia, hypocalcemia, triglycerides increased, blood glucose abnormal^[Ref]

Other

- Common (1% to 10%): Cervical smear abnormal, weight gain, edema
- Frequency not reported: Fatigue, porphyria, Vitamin B6 deficient
- Postmarketing reports: Weight decreased, peripheral edema, malaise, chest pain [Ref]

Renal

- Frequency not reported: Renal function impaired
- Postmarketing reports: Cystitis-like syndrome [Ref]

References

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Patient resources

- Junel Fe 1.5/30 birth control drug information
- Junel Fe 1.5/30

Other brands

Professional resources

Norethindrone, Ethinyl Estradiol and Ferrous Fumarate prescribing information

Other brands

Lo Loestrin Fe, Blisovi Fe 1/20, Loestrin 21 1/20, Hailey Fe 1/20, ... +82 more

Related treatment guides

Birth Control

Further information

Junel Fe 1.5/30 side effects can vary depending on the individual. Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

Note: Medication side effects may be underreported. If you are experiencing side effects that are not listed, submit a report to the FDA by following this guide.

Medical Disclaimer

DRUG STATUS

Availability

Rx Prescription only

Pregnancy & Lactation

& Risk data available

CSA Schedule*

N/A Not a controlled drug

Approval History

Drug history at FDA

User Reviews & Ratings

4.7 / 10

159 Reviews

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