

Brightside Specialty Pharmacy

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Patient Education for

BLISOVI FE 1.5-30 TABLET



If available, dispense patient package insert and explain to pt Take at the same time daily
Many drug-drug interactions possible with this drug Heavy smokers & age > 35 years may have increased cardiovascular risk Increased risk of blood clots; avoid prolonged immobility
This drug does not protect against sexually transmitted diseases. Iron supplements are a leading cause of poisoning in children. Not recommended during pregnancy.

If available, read the patient package insert Take at the same time every day
Review all drugs you are taking with your doctor Heavy smokers older than 35 yrs have higher risks Blood clot risk increases if days are spent in bed Use condoms to protect against diseases (STDs). Keep this product out of the reach of children. Not recommended during pregnancy.

.....Education Section.....

IMPORTANT:

HOW TO USE THIS INFORMATION: This is a summary and

does NOT have all possible information about this product. This information does not assure that this product is safe, effective, or appropriate for you. This information is not individual medical advice and does not substitute for the advice of your health care professional. Always ask your health care professional for complete information about this product and your specific health needs.

NORETHINDRONE/ETHINYL ESTRADIOL/FERROUS FUMARATE - ORAL

(nor-ETH-in-drone/ETH-i-nil ES-tra-DYE-ol/FER-us FUE-ma-rate)

COMMON BRAND NAME(S):

Estrostep Fe, Loestrin Fe

WARNING:

Do not use this medication if you smoke cigarettes/use

tobacco and are over 35 years old. Smoking raises your risk of stroke, heart attack, blood clots, and high blood pressure from hormonal birth control (such as the pill, patch, ring). The risk of these serious problems increases with age and with the number of cigarettes you smoke. Do not smoke or use tobacco.

Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children younger than 6 years. Keep this product out of reach of children. If overdose does occur, get medical help right away or call a poison control center.

USES:

This combination hormone medication is used to prevent

pregnancy. It contains 2 hormones: norethindrone (a progestin) and ethinyl estradiol (an estrogen). There is a small amount of iron (ferrous fumarate) in each of the 7 inactive tablets taken during the fourth week. The inactive pills do not contain any hormones. These tablets are meant to keep you in the habit of taking 1 tablet each day and do not have enough iron to treat iron deficiency.

Besides preventing pregnancy, birth control pills may make your periods more regular, decrease blood loss and painful periods, decrease your risk of ovarian cysts, and also treat

acne.

Using this medication does not protect you or your partner against sexually transmitted diseases (such as HIV, gonorrhea, chlamydia).

HOW TO USE:

Read the Patient Information Leaflet provided by

your pharmacist before you start using this product and each time you get a refill. The leaflet contains very important information on when to take your pills and what to do if you miss a dose. If you have any questions, ask your doctor or pharmacist.

Take this medication by mouth as directed by your doctor, usually once daily. Pick a time of day that is easy for you to remember, and take your pill at the same time each day.

If you are taking the chewable tablet, you may either swallow it whole or chew it thoroughly and swallow.

It is very important to continue taking this medication exactly as prescribed by your doctor. Follow the package instructions to find the first tablet, start with the first tablet in the pack, and take them in the correct order. Do not skip any doses. Pregnancy is more likely if you miss pills, start a new pack late, or take your pill at a different time of the day than usual.

Vomiting or diarrhea can prevent your birth control pills from working well. If you have vomiting or diarrhea, you may need to use a back-up birth control method (such as condoms, spermicide). Follow the directions in the Patient Information Leaflet and check with your doctor or pharmacist for more details.

Taking this medication after your evening meal or at bedtime may help if you have any stomach upset or nausea with the medication. You may choose to take this medication at another time of day that is easier for you to remember. No matter what dosing schedule you use, it is very important that you take this medication at the same time each day, 24 hours apart. Ask your doctor or pharmacist if you have any questions.

Your pill pack contains 21 pills with active medication. It also contains 7 reminder pills with iron. Take one active pill (with hormones) once daily for 21 days in a row. Take one inactive pill (with iron) once daily for 7 days in a row after you have taken the last active pill unless otherwise directed by

your doctor. You should have your period during the fourth week of the pack. After you have taken the last iron tablet in the pack, start a new pack the next day whether or not you have your period. If you do not get your period, consult your doctor.

If you are taking certain medications (such as levodopa, levothyroxine, penicillamine, tetracyclines, quinolones such as ciprofloxacin) that can interact with iron, ask your doctor whether you should throw away the reminder pills (iron tablets) each day rather than taking them. Iron can decrease the effect of these medications.

If this is the first time you are using this medication and you are not switching from another form of hormonal birth control (such as patch, other birth control pills), take the first tablet in the pack on the first Sunday following the beginning of your menstrual period or on the first day of your period. If your period begins on a Sunday, begin taking this medication on that day. For the first cycle of use only, use an additional form of non-hormonal birth control (such as condoms, spermicide) for the first 7 days to prevent pregnancy until the medication has enough time to work. If you start on the first day of your period, you do not need to use back-up birth control the first week.

Ask your doctor or pharmacist for information about how to switch from other forms of hormonal birth control (such as patch, other birth control pills) to this product. If any information is unclear, consult the Patient Information Leaflet or your doctor or pharmacist.

SIDE EFFECTS:

Nausea, vomiting, headache, bloating, breast

tenderness, swelling of the ankles/feet (fluid retention), or weight change may occur. Vaginal bleeding between periods (spotting) or missed/irregular periods may occur, especially during the first few months of use. If any of these effects last or get worse, tell your doctor or pharmacist promptly. If you miss 2 periods in a row (or 1 period if the pill has not been used properly), contact your doctor for a pregnancy test.

Remember that this medication has been prescribed because your doctor has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

This medication may raise your blood pressure. Check your blood pressure regularly and tell your doctor if the results are high.

Tell your doctor right away if you have any serious side effects, including: lumps in the breast, mental/mood changes (such as new/worsening depression), severe stomach/abdominal pain, unusual changes in vaginal bleeding (such as continuous spotting, sudden heavy bleeding, missed periods), dark urine, yellowing eyes/skin.

This medication may rarely cause serious (sometimes fatal) problems from blood clots (such as deep vein thrombosis, heart attack, pulmonary embolism, stroke). Get medical help right away if any of these side effects occur: chest/jaw/left arm pain, confusion, sudden dizziness/fainting, pain/swelling/warmth in the groin/calf, trouble speaking, sudden shortness of breath/rapid breathing, unusual headaches (including headaches with vision changes/lack of coordination, worsening of migraines, sudden/very

severe headaches), unusual sweating, weakness on one side of the body, vision problems/changes (such as double vision, partial/complete blindness).

A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

In the US -

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch.

In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

PRECAUTIONS:

See also Warning section.

Before using this medication, tell your doctor or pharmacist if you are allergic to ethinyl estradiol, norethindrone, or ferrous fumarate; or to other estrogens, progestins, or iron products; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: blood clots (for example, in the legs, eyes, lungs), blood clotting disorders (such as protein C or protein S deficiency), high blood pressure, abnormal breast exam, cancer (especially endometrial or breast cancer), high cholesterol or triglyceride (blood fat) levels, depression, diabetes, family or personal history of a certain swelling disorder (angioedema), gallbladder problems, severe headaches/migraines, heart problems (such as heart valve disease, irregular heartbeat, previous heart attack), history of yellowing eyes/skin (jaundice) during pregnancy or while using hormonal birth control (such as pills, patch), kidney disease, liver disease (including tumors), stroke, swelling (edema), thyroid problems, unexplained vaginal bleeding.

If you have diabetes, this medication may affect your blood sugar. Check your blood sugar regularly as directed and share the results with your doctor. Tell your doctor right away if you have symptoms of high blood sugar such as increased thirst/urination. Your doctor may need to adjust your diabetes medication, exercise program, or diet.

Tell your doctor if you just had or will be having surgery or if you will be confined to a bed or chair for a long time (such as a long plane flight). These conditions increase your risk of getting blood clots, especially if you are using hormonal birth control. You may need to stop this medication for a time or take special precautions.

Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products).

This medication may cause blotchy, dark areas on your face and

skin (melasma). Sunlight may worsen this effect. Limit your time in the sun. Avoid tanning booths and sunlamps. Use sunscreen and wear protective clothing when outdoors.

If you are nearsighted or wear contact lenses, you may develop vision problems or trouble wearing your contact lenses. Contact your eye doctor if these problems occur.

It may take longer for you to become pregnant after you stop taking birth control pills. Consult your doctor.

This medication should not be used during pregnancy. If you become pregnant or think you may be pregnant, tell your doctor right away. If you have just given birth or had a pregnancy loss/abortion after the first 3 months, talk with your doctor about reliable forms of birth control, and find out when it is safe to start using birth control that contains a form of estrogen, such as this medication.

This medication may decrease breast milk production. A small amount passes into breast milk and may have undesirable effects on a nursing infant. Consult your doctor before breast-feeding.

DRUG INTERACTIONS:

Drug interactions may change how your

medications work or increase your risk for serious side effects.

This document does not contain all possible drug interactions.

Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval.

Some products that may interact with this drug include: aromatase inhibitors (such as anastrozole, exemestane), ospemifene, tamoxifen, tizanidine, tranexamic acid, certain combination products used to treat chronic hepatitis C (ombitasvir/paritaprevir/ritonavir with or without dasabuvir).

Some drugs may cause hormonal birth control to work less well by decreasing the amount of birth control hormones in your body. This effect can result in pregnancy. Examples include griseofulvin, modafinil, rifamycins (such as rifampin, rifabutin), St. John's wort, drugs used to treat seizures (such as barbiturates, carbamazepine, felbamate, phenytoin, primidone, topiramate), HIV drugs (such as nelfinavir, nevirapine, ritonavir), among others.

Tell your doctor when you start any new drug, and discuss if you should use additional reliable birth control. Also tell your doctor if you have any new spotting or breakthrough bleeding, because these may be signs that your birth control is not working well.

This medication may interfere with certain laboratory tests (such as blood clotting factors, thyroid), possibly causing false test results. Make sure laboratory personnel and all your doctors know you use this medication.

OVERDOSE:

If someone has overdosed and has serious symptoms such

as passing out or trouble breathing, call 911. Otherwise, call a poison control center right away. US residents can call their local poison control center at 1-800-222-1222. Canada residents can call a provincial poison control center. Symptoms of overdose may include severe nausea and vomiting, sudden/unusual vaginal

bleeding.

NOTES:

Do not share this medication with others.

Keep all regular medical and laboratory appointments. You should have regular complete physical exams which include laboratory and medical tests (such as blood pressure, breast exam, pelvic exam, Pap smear) to monitor your progress and check for side effects. Follow your doctor's instructions for examining your breasts, and report any lumps right away. Consult your doctor for more details.

MISSED DOSE:

Refer to the product package information for advice

on missed doses. You may need to use back-up birth control (such as condoms, spermicide) to prevent pregnancy. Ask your doctor or pharmacist if you have any questions.

If you often forget to take your pills as directed, contact your doctor to discuss switching to another form of birth control.

STORAGE:

Store at room temperature away from light and moisture.

Do not store in the bathroom. Keep all medications away from children and pets.

Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company.

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