

## IMPORTANT SAFETY INFORMATION

### WARNING TO WOMEN WHO SMOKE

**Do not use FEMLYV if you smoke cigarettes and are over 35 years old. Smoking increases your risk of serious cardiovascular side effects (heart and blood vessel problems) from birth control pills, including death from heart attack, blood clots or stroke. This risk increases with age and the number of cigarettes you smoke.**

### What is FEMLYV?

FEMLYV is a birth control pill. It contains two female hormones, an estrogen called ethinyl estradiol, and a progestin called norethindrone acetate.

### Who should not take FEMLYV?

Your healthcare provider will not give you FEMLYV if you have ever had blood clots or are at a high risk for stroke, heart attack or other heart problems or abnormalities, breast cancer, liver disease, including liver tumors, take any Hepatitis C drug combination containing ombitasvir, paritaprevir, ritonavir, with or without dasabuvir, which may increase levels of the liver enzyme “alanine aminotransferase” (ALT) in the blood, or have any abnormal bleeding from the vagina. Tell your healthcare provider if you have ever had any of the above conditions (your healthcare provider may recommend another method of birth control). Do not take birth control pills if you smoke and are over 35 years old, are or think you are pregnant, or have any abnormal bleeding from the vagina.

### What else should I know about FEMLYV?

You should stop FEMLYV at least 4 weeks before you have surgery and not restart it until at least 2 weeks after the surgery, due to an increased risk of blood clots. If you are breastfeeding, consider another birth control method until you are ready to stop breastfeeding. Birth control pills that contain estrogen, like FEMLYV, may decrease the amount of milk you make. A small amount of the pill's hormones passes into breast milk.

### What are the most serious risks of taking FEMLYV?

Like pregnancy, birth control pills increase the risk of serious blood clots, especially in women who have other risk factors, such as smoking, obesity, or age greater than 35. This increased risk is highest when you first start taking birth control pills and when you restart the same or different birth control pills after not using them for a month or more. It is possible to die from a problem caused by a blood clot, such as a heart attack or a stroke.

Call your healthcare provider right away if you have leg pain that does not go away, sudden shortness of breath, sudden blindness (partial or complete), severe pain or pressure in your chest, sudden, severe headache unlike your usual headaches, weakness or numbness in an arm or leg, or trouble speaking, or yellowing of the skin or eyeballs.

### What are the common side effects of birth control pills?

The most common side effects of birth control pills are spotting or bleeding between menstrual periods, nausea, breast tenderness, and headache. These side effects are usually mild and usually disappear with time. The most common adverse reactions in clinical trials (greater than or equal to 2%) were: headache, vaginal candidiasis, nausea, menstrual cramps, breast tenderness, bacterial vaginitis, abnormal cervical smear, acne, mood swings, and weight gain.

These are not all the possible side effects of FEMLYV. For more information, ask your healthcare provider or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**Please see the full Prescribing Information, including BOXED WARNING, Patient Information.**