

Slayback Pharma announces launch of Merzee (norethindrone acetate and ethinyl estradiol capsules and ferrous fumarate capsules) 1 mg/20 mcg, generic equivalent of Taytulla®



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Slayback Pharma LLC →
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PRINCETON, N.J., Feb. 4, 2021 /PRNewswire/ -- Slayback Pharma LLC announces that it has launched Merzee (norethindrone acetate and ethinyl estradiol capsules and ferrous fumarate capsules) 1 mg/20 mcg and fulfilled customer orders for the product. With the launch, Slayback has effectively secured 180-day period of CGT exclusivity. Slayback's exclusivity does not restrict currently marketed generics of Taytulla from continued commercialization.



Ajay Singh, CEO of Slayback Pharma, said, "Slayback's launch has triggered the 180-day CGT exclusivity period for Merzee. We continue to remain focused on bringing high quality and affordable generics to the US market."

Merzee is available for shipment and can be ordered through your wholesaler/distributor. Please contact our customer service team at 1-844-566-2505.

See the following important safety information and refer to the package insert for full prescribing information.

What is Merzee Used for?

Merzee is an oral estrogen/progestin combination oral contraceptive (COC) used by women to prevent pregnancy. One capsule is taken daily in order as provided in the blister pack. The efficacy of Merzee in women who are obese (mass index (BMI) of $> 35 \text{ kg/m}^2$) has not been evaluated¹.

Important Safety Information for Merzee

WARNING CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR EVENTS

See Full Prescribing Information for complete boxed warning.

- Women over 35 years old who smoke should not use Merzee.
- Cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptive (COC) use.

Do not use Merzee if you:

- have had blood clots, a heart attack or stroke, uncontrolled high blood pressure
- have liver tumors or liver disease
- have unexplained vaginal bleeding
- are pregnant
- have had breast cancer or other estrogen- or progestin-sensitive cancer
- are taking Hepatitis C drugs containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir
- Allergic to any of the ingredients in Merzee

Stop using and discuss with your doctor before restarting:

- if a blood clotting occurs or an unexplained change or loss of vision occurs.
- at least 4 weeks before through 2 weeks after major surgery. Start no earlier than 4 weeks after delivery, or if you are breastfeeding.
- if you develop liver disease or yellowing of the skin or eyes occurs.
- if you have a history of or develop problems with your gallbladder
- if you are prediabetic or diabetic and should be monitored by your doctor
- have uncontrolled carbohydrate and lipid (fat) metabolic effects, discuss an alternative method of birth control with your doctor.
- if you have significant changes in headaches.
- if you have unusual or absent vaginal bleeding

Possible side effects

The most serious adverse events or side effects which could be life-threatening or lead to permanent disability are:

- cardiovascular events such as heart attack and stroke
- vascular problems such as clotting in lungs and deep veins
- liver disease

The most common adverse reactions reported are:

- irregular vaginal bleeding
- nausea
- breast tenderness
- headache

Merzee may cause decreased milk production in breastfeeding women.

In clinical trials the most common reported side effects were: headache, vaginal infections, nausea, menstrual cramps, breast tenderness, bacterial vaginitis, abnormal cervical smear, acne, mood swings, and weight gain.

Drug Interactions

Drugs like Merzee have seriously decreased the effects of thyroid hormone replacement drugs and lamotrigine. Do not take Merzee with hepatitis drugs containing ombitasvir/ paritaprevir/ritonavir, with or without dasabuvir.

Drugs or herbal products that trigger certain enzymes, including CYP3A4, may decrease the effectiveness of drugs like Merzee or increase breakthrough bleeding. Patients should use a back-up method or

7/8/22, 9:56 AM

Slayback Pharma announces launch of Merzee (norethindrone acetate and ethinyl estradiol capsules and ferrous fumarate capsule...

alternative method of contraception when these products are used with Merzee and other COCs.

You may report an adverse event related to Merzee made by Slayback Pharma by calling 1-844-566-2505 or emailing medical@slayback-pharma.com. If you prefer, you may contact the U.S. Food and Drug Administration (FDA) directly at fda.gov/medwatch or call 1-800-FDA-1088.

References:

Merzee full Prescribing Information⁽¹⁾. Slayback Pharma, 01/2021
Taytulla® is a registered trademark of Allergan Pharmaceuticals International Limited

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