

IMPORTANT SAFETY INFORMATION

Indications and usage

Slynd[®] is a progestin indicated for use by females of reproductive potential to prevent pregnancy.

Contraindications

Slynd is contraindicated in females with renal impairment, adrenal insufficiency, a presence or history of cervical cancer or progestin sensitive cancers, liver tumors (benign or malignant) or hepatic impairment, and undiagnosed abnormal uterine bleeding.

Warnings and Precautions

Hyperkalemia: Slynd has anti-mineralocorticoid activity, including the potential for hyperkalemia in high-risk females. Check serum potassium levels prior

Important Safety Information continued on adjacent page.

References. 1. Slynd® Package Insert; 2019. 2. Data on file.

to starting treatment and during the first treatment cycle in females receiving daily, long-term treatment for chronic conditions or diseases with medications that may increase serum potassium concentration. Consider monitoring serum potassium concentration in females at increased risk for hyperkalemia i.e., those females who take a strong CYP3A4 inhibitor long-term and concomitantly with Slynd. Monitor females taking Slynd who later develop conditions and/or begin medication that put them at an increased risk for hyperkalemia.



Slynd has a manageable bleeding profile...¹ In clinical studies, over 13 cycles:

- Breakthrough bleeding improved over time¹
- At cycle 12, 50.6% of subjects reported amenorrhea^{2,a}
- Discontinuation rate due to bleeding irregularities was 3.5% of total subjects^{1,b}



- ^a No bleeding or spotting days reported during entire exposure cycle.
- ^b 91/2593 (3.5% of total subjects)
- ^c Maximum savings limits apply; patient out-of-pocket expense will vary depending on insurance coverage. Offer not valid for patients enrolled in Medicare, Medicaid, or other federal or state healthcare programs. Additional program terms, conditions, and eligibility criteria apply. Visit Slynd.com for details.
 ^d Text SLYND to 31700 to receive your Exeltis Women's Health Savings Card. Message and data rates may apply. Message frequency varies. Text STOP to opt
- Text SLYND to 31/00 to receive your Exeltis Women's Health Savings Card. Message and data rates may apply. Message frequency varies. Text STOP to opt out. Text HELP for help. For Privacy Policy: https://exeltisusa.com/privacy-policy/. For SMS Terms: https://exeltis.online/SMStext.

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (cont'd)

Thromboembolic Disorders: Discontinue Slynd if a thromboembolic event occurs and consider discontinuing Slynd in case of prolonged immobilization due to surgery or illness. When prescribing Slynd, consider the increased risk of thromboembolism inherent in the postpartum period and in females with a history of thromboembolism.

Bone Loss: Treatment with Slynd leads to decreased estradiol serum levels. It is unknown if this may cause a clinically relevant loss of bone mineral density.

Ectopic Pregnancy: Be alert to the possibility of ectopic pregnancy in females who become pregnant or complain of lower abdominal pain while on Slynd.

Risk of Hyperglycemia in Patients with Diabetes: Females with diabetes may be at greater risk of hyperglycemia and may require additional medication adjustments or monitoring. Progestins, including Slynd, may decrease insulin sensitivity.

Bleeding Irregularities and Amenorrhea: Females may experience irregular bleeding or amenorrhea, especially during the first three months of use. If bleeding persists, occurs after previously regular cycles, or if scheduled bleeding does not occur, evaluate for possible causes such as pregnancy or malignancy.

See accompanying full Prescribing Information and on slynd.com.

References. 1. Slynd® Package Insert; 2019. 2. Data on file.



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Adverse Reactions

Most common adverse reactions (>1%) are: acne, metrorrhagia, headache, breast pain, weight increased, dysmenorrhea, nausea, vaginal hemorrhage, decreased libido, breast tenderness, irregular menstruation.

To report SUSPECTED ADVERSE REACTIONS, contact Exeltis USA, Inc. at 1-877-324-9349 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Drug Interactions

Drugs or herbal products that induce certain enzymes (for example, CYP3A4) may decrease the effectiveness of Slynd or increase breakthrough bleeding. Counsel patients to use a back-up or alternative non-hormonal method of contraception when enzyme inducers are used with Slynd and to continue back-up non-hormonal contraception for 28 days after discontinuing the enzyme inducer. Drugs or products that inhibit CYP3A4 may increase Slynd systemic exposure.

Discontinue Slynd if pregnancy occurs.

Counsel patients that Slynd does not protect against HIV-infection (AIDS) and other sexually transmitted infections.

