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Slynd (drospirenone 4mg) Film-Coated Tablets Prescribing Information (UK)
Please consult the full Summary of Product Characteristics (SmPC) before prescribing

Product name and active ingredients: drospirenone 4mg white active film-coated tablets (Inactive ingredients: green placebo film-coated tablets). **Indication:** Contraception. **Dosage and administration:** One tablet to be taken orally each day for 28 consecutive days (one white active tablet daily during the first 24 days and one green inactive tablet daily during the 4 following days). Tablets must be taken every day at about the same time of the day so that the interval between two tablets is always 24 hours. Tablets should be taken in the order shown on the blister. Stickers marked with the 7 days of the week are provided. The woman should choose the sticker that starts with the day she begins taking the tablets and stick it on the blister. The first tablet of the treatment should be taken on the first day of menstrual bleeding. Thereafter tablet taking is continuous. A subsequent pack is started immediately after finishing the previous pack, without a break in daily tablet intake. For further information on how to start tablets and management of missed pills please refer to SmPC. *Paediatric population.* Safety and efficacy of Slynd have been established in women of reproductive age. Safety and efficacy are expected to be the same for post pubertal adolescents under the age of 18 and users 18 years and older. Use of this product before menarche is not indicated. **Contraindications:** Progestogen-only contraceptives (POCs) like Slynd should not be used in the presence of any of the following conditions: Active venous thromboembolic disorder, presence or history of severe hepatic disease as long as liver function values have not returned to normal, severe renal insufficiency or acute renal failure, known or suspected sex-steroid sensitive malignancies, undiagnosed vaginal bleeding, hypersensitivity to the active substance or to any of the excipients. Should any of the conditions appear for the first time during Slynd use, the medicinal product should be discontinued immediately. **Special warnings and precautions for use**: If any of the following conditions/risk factors is present, the benefits of Slynd should be weighed against the possible risks for each individual woman and discussed with the woman before she starts using Slynd: Hyperkalemia, circulatory disorders, loss of bone mineral density, breast cancer, other tumors, ectopic pregnancy, impaired liver function, diabetes, hypertension, chloasma, depressed mood and depression. In the event of aggravation, exacerbation or first appearance of any of these conditions, the woman should contact her physician and agree appropriate course of action. *Medical examination/ consultation:* Prior to initiation or reinstitution of Slynd a complete medical history (including family history) should be taken and pregnancy ruled out. Blood pressure measurement and physical examination should also be performed. *Changes in bleeding pattern:* Disruption of menstrual bleeding pattern may occur during use of hormonal contraceptives that inhibit ovulation, including Slynd. If symptoms persist an organic cause should be ruled out. *Reduced efficacy:* The efficacy of progestogen-only pill may be reduced in the event of e.g. missed tablets, gastro- intestinal disturbances or concomitant medication. *Laboratory tests:* The use of contraceptive steroids may influence the results of certain laboratory tests including biochemical parameters of liver, thyroid, adrenal and renal function, serum levels of (carrier) proteins e.g, corticosteroid binding globulin and lipid/lipoprotein fractions, parameters of carbohydrate metabolism and parameters of coagulation and fibrinolysis. **Interactions:** Interactions can occur between Slynd and other medicinal products that induce microsomal enzymes. This can result in increased clearance of sex hormones and may lead to breakthrough bleeding and/or contraceptive failure. Please refer to SmPC for full details of interactions. Pregnancy & Breast-feeding: Slynd should not be used during pregnancy – it is indicated to prevent pregnancy. Slynd may be used during lactation. **Undesirable effects:** Common (≥ 1/100 to <1/10): libido disorder, mood disturbances, headache, nausea, abdominal pain, acne, breast discomfort, metorrhagia, vaginal haemorrhage, dysmenorrhea, irregular menstruation, and increased weight. **Please refer to SmPC for full details of other side effects. Legal category:** POM**. Presentation and cost:** 3 x (24+4) tablets £14.70. **Marketing authorisation holder and number:** Exeltis healthcare S.L. Avenidaa Miralcampo 7, Azuqueca De Henaares, Gadalajara, 19200, Spain. PL 44081/0005. Further information available from Exeltis UK Limited, Two Snowhill, 7th Floor, Birmingham, B4 6GA. **Date of preparation of PI**: January 2024. **Job number**: EXE-E/IPR-SLY-1097v2

Adverse events should be reported. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Exeltis UK Limited on 01494 411775 or by email to uk.medinfo@exeltis.com