Slynd®

DROSPIRENONE
4 mg

Exeltis
Rethinking healthcare.
Rethinking women's health.

For women who haven't found the right fit yet...

The first oestrogen-free drospirenone POP in the UK.[1,2]

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App store. Adverse events should also be reported to Exeltis UK Limited by email to pharmacovigilance.uk@exeltis.com

Slynd® is a progestogen-only pill (POP) indicated for contraception.[1]

This document is intended for UK healthcare professionals only

Click here to view Slynd® prescribing information

EXE-E/IPR-SLY-1716-v3 September 2025

Missed pill window and acceptability

Slynd® is the only POP in the UK with a 24 hour missed pill window.[1,2]

If >24 hours late contraceptive protection may be reduced, and users need to be guided on what to do.[1]

Missed any white (active tablet)[1]

Contraceptive protection may be reduced. A barrier method such as a condom should be considered for the next 7 days. The missed tablet should be taken as soon as remembered, even if this means taking two tablets at the same time. Following this, tablets are taken at the usual time. If tablets were missed in the first week after initiation and intercourse took place in the week before the tablets were missed, the possibility of a pregnancy should be considered. If tablets were missed in the third week of pill taking, the risk of reduced reliability is imminent because of the forthcoming 4-day HFI. However, by adjusting the tablet intake schedule, reduced contraceptive protection can still be prevented. The last missed tablet should be taken as soon as remembered, even if this means taking two tablets at the same time. Then continue to take the active tablets at the usual time. Do not take the placebo pills and continue straight on to the next active blister pack.

Slynd®[1]
(drospirenone)

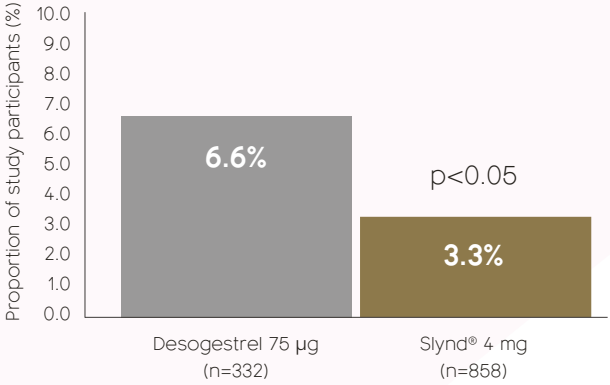
Missed any green (placebo tablet)[1]

This can be disregarded. However, any missed tablets should be discarded to avoid unintentionally prolonging the interval between active tablet taking.

Bleeding control

During clinical development, Slynd® acceptability was high, with lower bleeding-related drop-out rates vs. desogestrel 75 µg.[4-6]

Study drop-out rate due to abnormal uterine bleeding.[5,6]



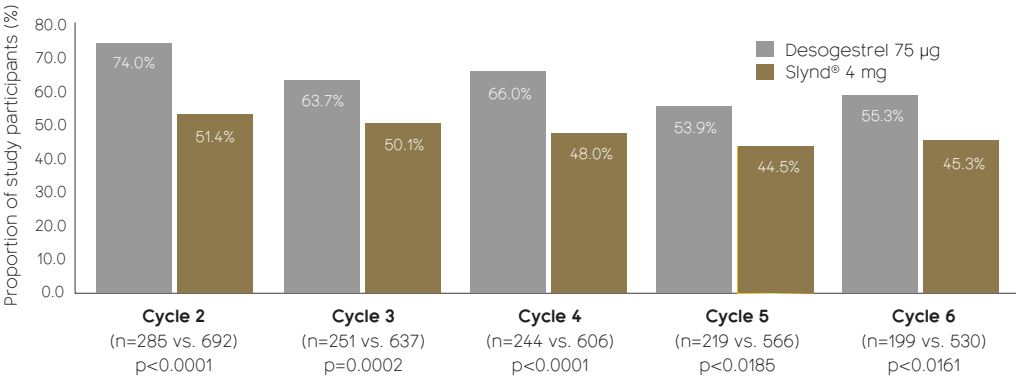
Adapted from Palacios *et al.* 2019.[5,6]

Slynd® acceptability[4]

82% of participants (n=515) and investigators in one Slynd® study assessed study drug acceptability as 'excellent' or 'good' by the final study visit.

Significantly fewer women taking Slynd® experienced unscheduled bleeding vs. desogestrel 75 µg during treatment cycles 2-6.[5,6]

Unscheduled bleeding during treatment cycles 2-6.[5,6]



Adapted from Palacios *et al.* 2019.[5,6]

Women experienced significantly fewer days of bleeding and/or spotting with Slynd® vs. desogestrel 75 µg across treatment periods.[5,6]

Cycles 2-4	Cycles 2-6	Cycles 2-9
Fewer days bleeding and/or spotting		
7.3	**10.0**	**13.2**
Desogestrel 75 µg vs. Slynd® Mean: 16.9 days vs. 9.6 days (n= 222 vs. 527); p<0.0001	Desogestrel 75 µg vs. Slynd® Mean: 23.7 days vs. 13.7 days (n= 172 vs. 422); p<0.0001	Desogestrel 75 µg vs. Slynd® Mean: 34.7 days vs. 21.5 days (n= 116 vs. 305); p=0.0003

Each woman's bleeding experience with Slynd® will differ.[2]

As with all POPs, bleeding with Slynd® can be unpredictable. Women may experience scheduled bleeding (during the HFI), unscheduled bleeding, or no bleeding at all.

Women report bleeding with Slynd® to be light or moderate, and both scheduled and unscheduled bleeding have been seen to decrease over the first year of use.[2]

Amenorrhoea
Within 9–12 months of Slynd® use, 30% of women will experience amenorrhoea.[2]

Tolerability

Slynd® has demonstrated an acceptable tolerability profile.[1]

Slynd® was generally well-tolerated by participants during clinical trials.

The most commonly reported adverse events (AEs) in long-term clinical trials of >9 cycles of treatment with Slynd® (2,700 women) were acne (3.8%), metrorrhagia (2.9%), headache (2.7%), and breast pain (2.2%).

Common AEs (≥1/100 to <1/10):

- Libido disorder
- Mood disturbances
- Headache
- Nausea
- Abdominal pain
- Acne
- Breast discomfort
- Metrorrhagia
- Vaginal haemorrhage
- Dysmenorrhea
- Menstruation irregular
- Weight increase

Uncommon AEs (>1/1,000 to <1/100): Vaginal infections, uterine leiomyoma, anaemia, hypersensitivity, appetite disorder, hyperkalaemia, anxiety symptoms, depression, depressed mood, dizziness, hot flush, hypertension, vomiting, diarrhoea, constipation, alopecia, hyperhidrosis, rash, seborrhoea, Pruritus, Dermatitis, amenorrhoea, menstrual disorders, pelvic pain, ovarian cyst, vulvovaginal dryness, vaginal discharge, fatigue, oedema peripheral, transaminases increased, blood bilirubin increased, blood creatine phosphokinase increased, gamma glutamyltransferase increased, blood triglycerides increased. **Rare AEs (≥1/10,000 to <1/1,000):** Contact lens intolerance, polyuria, breast cyst, cervical dysplasia, galactorrohoea, vulvovaginal Pruritus, weight decrease.

Special warnings and precautions for use.[1]

If any of the conditions/risk factors mentioned is present, the benefits of Slynd® should be weighed against the possible risks for each individual and discussed before starting Slynd®. In the event of aggravation, exacerbation, or first appearance of any of these conditions, the woman should contact her physician. The physician should then decide whether Slynd® use should be discontinued.

- Hyperkalaemia
- Circulatory disorders
- Loss of bone mineral density
- Breast cancer
- Other tumours
- Disturbances in liver function
- Hypertension
- Chloasma gravidarum
- Depressed mood
- Depression
- Suspected ectopic pregnancy (presenting with amenorrhoea or abdominal pain)
- Diabetic patients (particularly with vascular involvement)

Contraindications.[1]

POPs like Slynd® should not be used in the presence of any of the conditions listed below. Should any of the conditions appear for the first time during Slynd® use, the medicinal product should be discontinued immediately.

- 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

Adverse reactions have been reported in short- and long-term clinical trials with Slynd®. For further information about AEs, contraindications, and special warnings and precautions for use, please consult the Summary of Product Characteristics.

Slynd® (drospirenone) summary

The first oestrogen-free drospirenone POP in the UK.[1,2]

Slynd® offers women:

Drospirenone, which in therapeutic doses possesses mild **anti-androgenic and anti-mineralocorticoid** activity.[1,2]

Effective contraceptive protection when used correctly.[1,3]

A **24+4 active/placebo** dose regimen with a hormone free interval (HFI) developed to support scheduled bleeding.[1,4]

The only POP in the UK with a **24 hour missed pill window.**[1,2]

Significantly **fewer unscheduled bleeding** days per treatment cycle and a lower study drop-out rate due to bleeding disorders vs. desogestrel 75 µg.[5,6]

Common AEs seen with Slynd® are libido disorder, mood disturbances, headache, nausea, abdominal pain, acne, breast discomfort, metrorrhagia, vaginal haemorrhage, dysmenorrhoea, menstruation irregular, and weight increase.[1]

Bleeding days per treatment cycle: Cycle 2-4: desogestrel 16.9 days (n=222) vs. drospirenone 9.6 days (n=527), p<0.0001; Cycles 2-6: desogestrel 23.7 days (n=172) vs. drospirenone 13.7 days (n=422), p<0.0001; Cycle 2-9: desogestrel 34.7 days (n=116) vs. drospirenone 21.5 days (n=305), p=0.0003. **Study drop-out rate due to abnormal uterine bleeding:** desogestrel: 6.6% (n=322); drospirenone: 3.3% (n=858); p<0.05.[5,6]

FSRH and UKMEC

Slynd® is recommended as a contraceptive in the 2022 Faculty of Sexual and Reproductive Healthcare (FSRH) guidelines and is covered by POP guidance in the UK Medical Eligibility Criteria (UKMEC).[2,7]

Click here to learn more on the Exeltis Hub

This link will take you to a promotional website owned by Exeltis UK

Click here to view the Slynd® prescribing information

Abbreviations: AE, adverse event; FSRH, Faculty of Sexual and Reproductive Healthcare; HFI, hormone free interval; POP, progestogen-only pill; UKMEC, UK Medical Eligibility Criteria.

References:

1. Slynd® Summary of Product Characteristics.
2. FSRH Clinical Guidelines progestogen-only pills. 11/2022.
3. Palacios, S., *et al. BMC Women's Health*. 2020. 20:218.
4. Archer, D.F., *et al. Contraception*. 2015. 92:439-444.
5. Palacios, S., *et al. Arch Gynae Obs*. 2019. 300:1805-1812.
6. Palacios, S., *et al. PLOS ONE*. 2020. 15(6): e0231856.
7. UK Medical Eligibility Criteria. For Contraceptive Use. 2016 (Amended 2019).

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