

		Drawing: <b>P031</b>
LEÓN FARMA MATERIAL TYPE: LEAFLET		Scale: Dimensions: <b>100 % 222 x 510 ± 1 mm</b>
Material # / Product : <b>PR DR SLYND 4MG 24+4 EXELTIS UK</b>		<b>Cause:</b> <input type="checkbox"/> LAUNCH <input type="checkbox"/> CUSTOMER CHANGE <input type="checkbox"/> INTERNAL CHANGE  <b>Laetus : *****</b> <input type="checkbox"/> ONLY FOR POSITION
Version: <b>E</b> Date: <b>08.03.22</b> Substitutes mat. #: -	Other: (if not specified)	
<b>Folded:</b> <b>Folded dimensions:</b> FOLD TO 170 X 37 MM		
<b>Pantones:</b> LINE 1: FRONT SIDE <b>BLACK</b> LINE 2: BACK SIDE <b>BLACK</b> LINE 3: TECHNICAL COLOUR <b>DRY COPY    PRINT SECURITY MARGINS    FINAL FOLDED</b>		
<small>(*) Customer shall be responsible for the contents of the approved artworks, text and colours of the printed material reflected in this drawing. Therefore, Customer shall bear any and all cost and/or expense, and it shall keep Leon Farma harmless from any claims, cost and/or expenses, related to the correctness and accuracy of such information.</small>		<small>(*) PLEASE DON'T DELETE ANY LAYERS FOR THE CORRECT REVISION    (**) PLEASE, MAKE SURE THE IMAGES HAVE A RESOLUTION AT LEAST 300 PP</small>
Drawed by: (Chemo Artwork Technician) <b>Manuel Mancilla</b> Approved by Customer: (Regulatory Affair or Quality Assurance) / Signature & Date		

**FRONT SIDE / PLEASE, INCLUDE YOUR DESIGN ON THIS KEYLINE**

LAETUS CENTERED WITHIN FINAL FOLDED 37 mm		LAETUS CENTERED WITHIN FINAL FOLDED 37 mm		148 mm	
					

**BACK SIDE / PLEASE, INCLUDE YOUR DESIGN ON THIS KEYLINE**

then start a new pack straightaway without a break in daily tablet intake. There is therefore no gap between two packs.	
You may have some bleedings during the use of Slynd, or you may also have no bleeding at all, but you must continue to take your tablets as normal without interruption.	
If you use Slynd in this manner, you are protected against pregnancy also during the 4 days when you are taking a placebo tablet.	
<b>Preparation of the blister</b> To help you keep track, 7 week stickers each with the 7 days of the week are provided into the pack. Choose the week sticker that starts with the day you begin taking the tablets (for example, if you start on a Thursday, use the week sticker that starts with "THU") and place it on the blister card over the words "Place day label here" so that the first day is above the tablet marked "START". There is now a day indicated above every tablet and you can see whether you have taken a certain pill. The arrows and the consecutive numbers show the order you are to take the pills.	
<b>Starting your first pack of Slynd</b> <ul style="list-style-type: none"> <li>If you have not used a hormonal contraceptive in the previous month Begin with Slynd on the first day of your period. When doing so, you are immediately protected against pregnancy and you do not need to use extra protective measures such as a condom.</li> <li>When changing from a combined pill, vaginal ring or transdermal patch You should start Slynd on the day after the last active tablet (the last tablet containing the active substances) of your previous pill or on the day of removal of your vaginal ring or transdermal patch (this means no tablet-, ring- or patch-free break). If you follow these instructions, additional contraceptive precautions are not necessary.</li> <li>You can also start Slynd at the latest on the day following the usual tablet-, ring-, patch-free break or placebo interval of your previous contraceptive. In this case, make sure you use an additional barrier method of contraception for the first 7 days of Slynd taking.</li> <li>When changing from another progestogen-only pill (POP) You may switch any day from other POP and start taking Slynd the next day. Additional contraceptive precautions are not necessary.</li> <li>When changing from a progestogen-only injection or implant or from a progestogen-releasing intrauterine system (IUS) You should start Slynd the day when the next injection is due or on the day that your implant or your IUS is removed. Additional contraceptive precautions are not necessary.</li> <li>After having a baby You can start Slynd any day between day 21 to 28 after having your baby. If you start later than day 28 but before the menstruation have returned, you must be sure that you are not pregnant and you must use a barrier method as a condom until you have completed the first 7 days of tablet-taking.</li> </ul>	
Information for breast-feeding women can be found in section 2 (Pregnancy and breast-feeding).	
After miscarriage or an abortion You should follow the advice of your doctor.	
Ask your doctor if you are still not sure when to start.	
<b>If you take more Slynd than you should</b> There have been no reports of serious harmful effects from taking too many Slynd tablets at one time. Symptoms that may occur are nausea, vomiting and slight vaginal bleeding.	
However, in case of overdose, ask your doctor for advice because blood tests should be done.	
<b>If you forget to take Slynd</b> You must take the tablets everyday around the same time of the day so that the interval between two tablets is always 24 hours. If you are less than 24 hours late in taking any single tablet, take the missed tablet as soon as it is remembered and take the next tablet at the usual time, even if this means taking two tablets at the same time. If you are more than 24 hours late in taking any white, active tablet, take the missed tablet as soon as it is remembered, even if this means taking two tablets at the same time, and use an additional method of contraception (such as a condom) for the next 7 days. Then, continue taking the tablets at your usual time. The more consecutive tablets you have missed, the higher the risk that the contraceptive efficacy is decreased.	
If you have forgotten a tablet in the first week starting the tablets, and you have had sex in the week before forgetting the tablet you must realize that there is a risk of pregnancy. In that case, contact your doctor.	
If you forgot to take the tablet between days 15 - 24 (third or fourth row), take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the white active tablets at the usual time. Instead of taking the green placebo tablets on this strip, throw them away, and start the next strip (the starting day will be different). By skipping the placebo interval, the contraceptive protection is maintained.	
The last 4 green tablets in the 4th row of the strip are the placebo tablets. If you forget one of these tablets, this has no effect on the reliability of Slynd. Throw away the forgotten placebo tablet.	
<b>What to do in the case of vomiting or severe diarrhoea</b> If you vomit or have severe diarrhoea, there is a risk that the active substance in the pill will not be fully absorbed by your body, the situation is almost the same as forgetting a tablet. In these cases, an additional method of contraception may be needed, ask your doctor for advice.	
If you vomit or have severe diarrhoea within 3-4 hours after taking your white active tablet of Slynd, you must take another white tablet from another blister pack as soon as possible. If possible, take it within 12 hours of when you normally take your pill. Additional contraceptive precautions are not necessary. If this is not possible or 12 hours have passed, you should follow the advice given in the section "If you forget to take Slynd" above.	
<b>If you stop taking Slynd</b> You can stop taking Slynd whenever you want. From the day you stop you are no longer protected against pregnancy.	
If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.	
<b>4. Possible side effects</b> Like all medicines, Slynd can cause side effects, although not everybody gets them. Serious undesirable effects associated with the use of Slynd are described in the paragraphs 'Breast cancer' and 'Thrombosis' in section 2 'What you need to know before you take Slynd'. Please read this section for additional information and consult your doctor at once where appropriate.	
Vaginal bleeding may occur at irregular intervals during the use of Slynd. This may be just slight staining which may not even require a pad, or heavier bleeding, which looks rather like a scanty period and requires sanitary protection. You may also not have any bleeding at all. The irregular bleedings are not a sign that the contraceptive protection of Slynd is decreased. In general, you need not take any action; just continue to take Slynd. If, however, bleeding is heavy or prolonged you should consult your doctor.	
If the bleeding is very frequent and irregular, another contraceptive method should be considered. If you don't have vaginal bleeding during the treatment, you may need to do a pregnancy test if you have not taken the tablets in accordance with the instructions in section 3 "How to take Slynd".	
The following side effects have been associated with the use of Slynd : Common: may affect up to 1 in 10 people - headache - nausea, abdominal pain - changes in sexual desire, altered mood - acne - breast discomfort, painful periods, bleeding and irregular menstrual periods - weight gain Uncommon: may affect up to 1 in 100 people - anaemia (decreased number of the red blood cells), fatigue (tiredness), fluid retention - dizziness, - vomiting, diarrhoea, constipation - vaginal infections - increased amount of the following, shown in blood tests: potassium, liver enzymes (ALT, AST, GGT), bilirubin, creatine phosphokinase, triglycerides - appetite changes - uterine leiomyoma (benign tumor of the uterus) - depressed mood, depression, anxiety - absence of menstrual periods, altered menstrual bleeding, pelvic pain, ovarian cysts, vaginal discharge and dryness - hair loss, increased sweating, itching, rash, seborrhoea (greasy skin), dermatitis (inflammation of the skin) - elevated blood pressure, hot flushes - hypersensitivity Rare: may affect up to 1 in 1,000 people: - contact lens intolerance - weight loss - excessive amount of urine - breast cyst, breast secretion, abnormal cervical smear, genital itching	
<b>Reporting of side effects</b> If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the MHRA Yellow Card Scheme at: <a href="http://www.mhra.gov.uk/yellowcard">www.mhra.gov.uk/yellowcard</a> or search the MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.	
<b>5. How to store</b> Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month. Store below 25°C. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.	
<b>6. Contents of the pack and other information</b> <b>What Slynd contains</b> <b>White active film-coated tablets:</b> - The active substance is drospirenone. Each white active film-coated tablet contains 4 mg of drospirenone. - The other ingredients are: Tablet core: microcrystalline cellulose ; lactose; silica, colloidal anhydrous (E551); magnesium stearate (E470b) Tablet coat: poly(vinyl alcohol); titanium dioxide (E171); Macrogol; talc (E553b) <b>Green placebo film-coated tablets:</b> The green placebo film-coated tablets do not contain active substance. Tablet core: lactose monohydrate; maize starch; povidone; silica, colloidal anhydrous (E551); magnesium stearate (E470b) Tablet coat: hypromellose (E464); triacetin; polysorbate 80 (E433); titanium dioxide (E171); Indigo carmine aluminium lake (E132); yellow iron oxide (E172)	
<b>What Slynd looks like and contents of the pack</b> Each blister of Slynd contains 24 active film-coated tablets and 4 placebo film-coated tablets. The active tablet is a round, white tablet with the letters "E" and "D" debossed on opposite sides, with a diameter of 5 mm. The placebo tablet is a round, green tablet with the letter "E" and the number "4" debossed on opposite sides, with a diameter of 5 mm.	
In addition to the carton box, a carton case for the blister is enclosed. Slynd is available in calendar-packs of 1, 3, 6 and 13 blisters, each with 28 tablets. Not all pack sizes may be marketed.	
<b>Marketing Authorisation Holder</b> Exeltis healthcare S.L. Avenida Miralcampo 7, Azuqueca De Henares Guadalajara, 19200, Spain <b>Manufacturer</b> Laboratorios Leon Farma, S.A. Poligono Industrial Navatejera, C/ La Vallina S/N, Villaquilambre, Leon, Spain	
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LEÓN CODE	