Slynd®
(drospirenone) tablets, 4mg

PATIENT INFORMATION

SLYND® (slind)
(drospirenone)
tablets, for oral use

Progestin pills help to lower the chance of becoming pregnant when taken as directed. They do not protect against HIV infection (AIDS) and other sexually transmitted diseases (STDs).

What is SLYND?
SLYND is a birth control pill (oral contraceptive) also called a POP (progestin only pill) that is used by females who can become pregnant to prevent pregnancy.

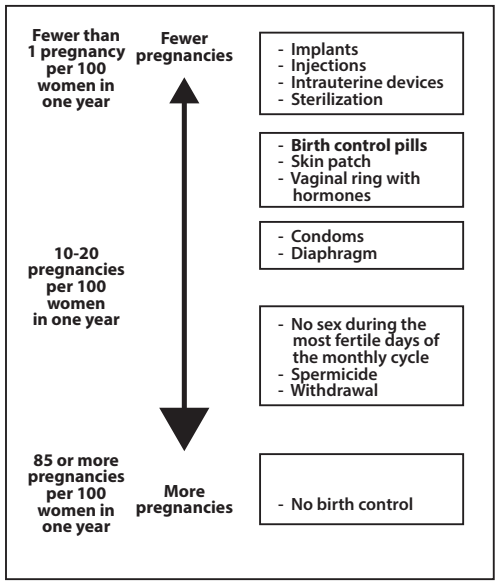
The progestin drospirenone may increase potassium levels in your blood. You should not take SLYND if you have kidney, liver or adrenal disease because this could cause serious heart problems as well as other health problems. Other medicines may also increase potassium levels in your blood. If you are currently on daily, long-term treatment for a chronic health condition with any of the medicines listed below, talk to your healthcare provider about whether SLYND is right for you. If you take any of the medicines listed below for a chronic health condition you should have a blood test to check the potassium level in your blood before you start taking SLYND and during the first month that you take SLYND.

- medicines to treat fungal infections, such as ketoconazole, itraconazole, or voriconazole
- medicines to treat Human Immunodeficiency Virus (HIV) infection or Hepatitis C infection, such as indinavir or boceprevir
- clarithromycin

How does SLYND work for contraception?
Your chance of getting pregnant depends on how well you follow the directions for taking your birth control pills. The better you follow the directions, the less chance you have of getting pregnant.

Based on the results of one clinical study of a 28-day regimen of SLYND about 4 out of 100 females may get pregnant within the first year they use SLYND.

The following chart shows the chance of getting pregnant for females who use different methods of birth control. Each box on the chart contains a list of birth control methods that are similar in effectiveness. The most effective methods are at the top of the chart. The box on the bottom of the chart shows the chance of getting pregnant for females who do not use birth control and are trying to get pregnant.



Do not take SLYND if you:
- have kidney disease or kidney failure.
- have reduced adrenal gland function (adrenal insufficiency).
- have or have had cervical cancer or any cancer that is sensitive to female hormones.
- have liver disease, including liver tumors.
- have unexplained vaginal bleeding.

Tell your healthcare provider if you have or have had any of these conditions. Your healthcare provider can suggest a different method of birth control.

If any of these conditions happen while you are taking SLYND, stop taking SLYND right away and talk to your healthcare provider. Use non-hormonal contraception when you stop taking SLYND.

Before you take SLYND, tell your healthcare provider about all of your medical conditions, including if you:
- are pregnant or think you may be pregnant.
- have ever had blood clots in your legs (deep vein thrombosis), lungs (pulmonary embolism) or a stroke or heart attack (myocardial infarction).
- have or have had depression.

Tell your healthcare provider about all the medicines you take including prescription and over-the-counter medicines, vitamins and herbal supplements, such as St. John's Wort.

SLYND may affect the way other medicines work, and other medicines may affect how well SLYND works.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take SLYND?
Read the detailed Instructions for Use at the end of this Patient Information leaflet about the right way to take SLYND.

What are the possible serious side effects of SLYND?
SLYND may cause serious side effects, including:
- **High potassium levels in your blood (hyperkalemia).** Certain medicines and conditions can also increase the potassium levels in your blood. Your healthcare provider may check the potassium levels in your blood before and during treatment with SLYND. **Call your healthcare provider or go to a hospital emergency room right away if you have signs or symptoms of high potassium levels in your blood including:**
  - weakness or numbness in an arm or leg
  - palpitations (feel like your heart is racing or fluttering) or irregular heartbeat
  - nausea
  - vomiting
  - severe pain in your chest
  - shortness of breath
- **Blood clot forming in blood vessels (thromboembolism problems).** Tell your healthcare provider if you have had a blood clot. Tell your healthcare provider if you plan to have surgery or are not able to be active due to illness or injury. **Call your healthcare provider or go to a hospital emergency room right away if you have:**
  - leg pain that will not go away
  - a sudden, severe headache unlike your usual headaches
  - sudden, severe shortness of breath
  - sudden change in vision or blindness
  - chest pain
  - weakness or numbness in your arm or leg
  - trouble speaking
- **Bone loss.** It is not known if the decrease in a sex hormone that happens with SLYND can result in decreased bone density (bone loss).
- **Cervical cancer.** See "Do birth control pills cause cancer?"
- **Liver problems, including rare liver tumors.** Call your healthcare provider right away if you have yellowing of your skin or eyes.
- **Ectopic pregnancy (pregnancy in your tubes).** If you get pregnant while using SLYND, you might have an ectopic pregnancy. That means that the pregnancy is not in the uterus. Ectopic pregnancy is a medical emergency that often requires surgery. If you have severe abdominal (belly) pain, call your healthcare provider or go to a hospital emergency room right away.
- **Risk of high blood sugar levels in people with diabetes.** If you have diabetes, you may need to monitor your blood sugar level more often or adjust your diabetes medicine.
- **Changes in menstrual bleeding.** Irregular vaginal bleeding, especially between menstrual periods, and irregular periods or the absence of menstrual periods are common side effects of SLYND, but can sometimes be serious. Tell your healthcare provider if you have any of these changes in menstrual bleeding.
- **Depression, especially if you have had depression in the past.** Call your healthcare provider immediately if you have any thoughts of harming yourself.

What are the most common side effects of SLYND?
The most common side effects of SLYND include:
- acne
- headache
- breast pain and tenderness
- weight gain
- menstrual cramps
- nausea
- severe vaginal bleeding
- less sexual desire

These are not all the possible side effects of SLYND.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

What else should I know about taking SLYND?
- If you are scheduled for any lab tests, tell your healthcare provider you are taking SLYND. Certain blood tests may be affected by SLYND.

How should I store SLYND?
- Store SLYND at room temperature between 68°F to 77°F (20°C to 25°C).
- **Keep SLYND and all medicines out of the reach of children.**

General information about the safe and effective use of SLYND.
Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use SLYND for a condition for which it was not prescribed. Do not give SLYND to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about SLYND that is written for health professionals.

Do birth control pills cause cancer?
Hormonal contraceptives do not appear to cause breast cancer. However if you have breast cancer now, have had it in the past, or you have (or have had) another cancer that may be sensitive to hormones, do not use hormonal contraceptives.

Women who use hormonal contraceptives may have a higher chance of getting cervical cancer. However, this may be due to other reasons such as having more sexual partners and exposure to the human papilloma virus (HPV).

What if I want to become pregnant?
You may stop taking SLYND whenever you wish. Consider a visit with your healthcare provider for a pre-pregnancy checkup before you stop taking SLYND.

What should I know about my period when taking SLYND?
Some females may miss a period. Irregular vaginal bleeding or spotting may happen while you are taking SLYND, especially during the first few months of use. If the irregular vaginal bleeding or spotting continues or happens again after you have had regular menstrual cycles call your healthcare provider. It is important to continue taking your pills on a regular schedule to prevent a pregnancy.

What if I miss my scheduled period when using SLYND?
Some females miss periods on hormonal birth control, even when they are not pregnant. However, if you go 2 or more months in a row without a period, or you miss your period after a month where you did not use all of your SLYND correctly, call you healthcare provider because you may be pregnant. Also call your healthcare provider if you have symptoms of pregnancy such as morning sickness or unusual breast tenderness. Stop taking SLYND if you are pregnant.

What are the ingredients in SLYND?
White tablets
Active ingredient: drospirenone

Inactive ingredients: microcrystalline cellulose, anhydrous lactose, colloidal silicon dioxide, magnesium stearate, polyvinyl alcohol partially hydrolyzed, talc, titanium dioxide, and polyethylene glycol.

Green tablets
Inactive ingredients: lactose monohydrate, corn starch, povidone 30000, colloidal silicon dioxide, magnesium stearate, hypromellose 2910, titanium dioxide, polysorbate 80, triacetin, FD&C blue 2 aluminum lake, and yellow ferric oxide.

INSTRUCTIONS FOR USE

SLYND (slind)
(drospirenone)
tablets, for oral use

Important Information about taking SLYND

Before you start taking SLYND

- Decide what time of day you want to take your pill. It is important to take it at the same time every day and in the order as directed on your blister pack.
- Have backup contraception (condoms or spermicide) available.

How to take SLYND

- Take **1** pill every day at the same time. Take the pills in the order directed on your blister pack.
- Both the white pills and the green pills should be swallowed whole.
- Do not skip your pills, even if you do not have sex often. If you miss pills (including starting the blister pack late) **you could get pregnant.** The more pills you miss, the more likely you are to get pregnant.
- If you have trouble remembering to take SLYND, talk to your healthcare provider. When you first start taking SLYND, spotting or light bleeding in between your periods may occur. Contact your healthcare provider if this does not go away after a few months.
- You may feel sick to your stomach (nauseous), especially during the first few months of taking SLYND. If you feel sick to your stomach, do not stop taking the pill. The problem will usually go away. If your nausea does not go away, call your healthcare provider.
- Missing pills can also cause spotting or light bleeding, even when you take the missed pills later. On the days you take **2** pills to make up for missed pills (see below), you could also feel a little sick to your stomach.
- Some females miss periods on hormonal birth control, even when they are not pregnant. However, if you miss a period and have not taken SLYND according to directions, or miss **2** periods in a row, or feel like you may be pregnant, call your healthcare provider. If you have a positive pregnancy test, you should stop taking SLYND.
- If you have vomiting or diarrhea within **3 to 4 hours** of taking your pill, take a new pill (the pill scheduled for the next day) from your blister pack within 12 hours of the usual time you take your pill, if possible. Continue taking all your remaining pills in order. Start the first pill of your next blister pack the day after finishing your current blister pack. This will be 1 day earlier than originally scheduled. Continue on your new schedule.
- If you have vomiting or diarrhea for more than 1 day, your birth control pills may not work as well. If you have sex within 7 days after 1 or more days of vomiting or having diarrhea, use an additional form of birth control, like condoms or spermicide, as back-up contraception.

When should I start taking SLYND?

If you start taking SLYND and you are not currently using a hormonal birth control method:

- Start SLYND on the first day (Day 1) of your natural menstrual period (Day 1 Start). Your healthcare provider should tell you when to start taking your birth control pill.

If you start taking SLYND and you are switching from another birth control pill:

- Start your new SLYND blister pack on the same day that you would start the next pack of your previous birth control method.
- Do not continue taking the pills from your previous birth control pack.

If you start taking SLYND and you are switching from a vaginal ring or transdermal patch:

- Start taking SLYND on the day you would have inserted the next ring or applied the next patch.

If you start taking SLYND and you are switching from a progestin-only method such as an implant or injection:

- Start taking SLYND on the day of removal of your implant or on the day when you would have had your next injection.

If you start taking SLYND and you are switching from an intrauterine device or system (IUD or IUS):

- Start taking SLYND on the day of removal of your IUD or IUS.

Keep a calendar to track your period:

SLYND Day 1 Start:
You will use a **Day 1 Start** if your healthcare provider told you to take your first pill (Day 1) on the **first day of your period.**

- Take **1** pill every day in the order of the blister pack, at the same time each day, for **28** days.
- After taking the last pill on **Day 28** from the blister pack, start taking the first pill from a new pack, on the same day of the week as the first pack. Take the first pill in the new pack whether or not you are having your period.

Instructions for using your pill blister pack:
Step 1. Look at your SLYND pill pack. See **Figure A.**
The SLYND pill pack has:

- **24 white** (active) pills with hormones for **Week 1 through Week 3** and the first 3 days of Week 4 (Days 1-24)
- **4 green** (inactive) pills without hormones for the last 4 days of **Week 4** (Days 25-28).

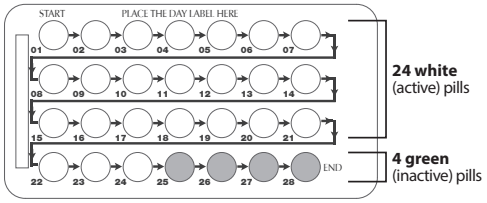


Figure A

Step 2.

Place the day label strip (see **Figure B**) that starts with the first day of your period (Day 1) on top of the pill blister pack over "Place the label here". See **Figure C.** For example, if your period begins on Monday, place the day label strip with Monday as the first day on the top of your pill pack. See **Figure C.**

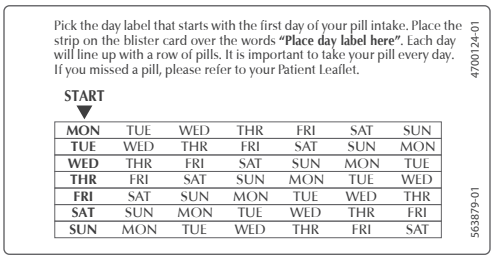


Figure B

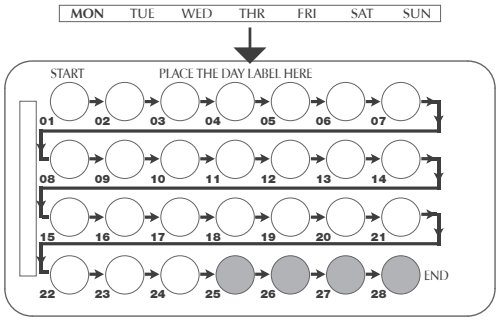


Figure C

Step 3.

Remove the white pill by pressing the pill through the foil at the bottom of the pill blister pack. Continue taking the white pills for 24 days.

Step 4.
In the middle of **Week 4** start taking the green pills. Take the green pill for **4 days.** Your period should start during this time.

Step 5.

When you have taken all of the green pills in your pill pack, get a new pill pack and start taking the white pills from the new pill blister pack at your usual time the following day, starting with the Day 1 pill.

For a Day 1 start:

- Begin your next pill pack on the same day of the week as your first cycle pill pack.

What should I do if I miss any SLYND pills?

If you miss 1 white pill (active pills):

- Take it as soon as you remember. Take the next pill at your regular time. This means you may take **2** pills in **1** day.
- Then continue taking **1** pill every day until you finish the pack.
- You do not need to use a back-up birth control method if you have sex.

If you miss 2 or more white pills (active pills), follow these steps:

- Take a pill as soon as you remember. Take the next pill at your regular time. This means you may take **2** pills in **1** day.
- Then continue to take **1** pill every day until you finish the pack (this will mean one or more missed white pills will remain in the blister pack).
- Use a non-hormonal birth control method (such as a condom or spermicide) as a back-up if you have sex during the first **7 days** after missing your pills.

If you miss 1 or more green pills (inactive pill):

- You do not need to take 1 or more missed green pills. Take the next green pill at your regular time, every day until you finish the pack (this means 1 or more missed green pill will remain in the blister pack).

If you have any questions or are unsure about the information in this leaflet, call your healthcare provider. You can ask your healthcare provider or pharmacist for information about SLYND that is written for health professionals.

This Patient Information and Instructions for Use has been approved by the U.S. Food and Drug Administration.

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