

OPILL- norgestrel tablet
Redpharm Drug

Opill[®] Norgestrel tablets 0.075 mg - Drug Facts

Active ingredient (in each tablet)

Norgestrel 0.075 mg

Purpose

Daily Oral Contraceptive

Use

To prevent pregnancy

Warnings

Allergy alert: Do not use if you are allergic to this product or any of its ingredients, such as FD&C yellow No. 5 (tartrazine). People allergic to aspirin often have a tartrazine allergy too. Symptoms may include hives, facial swelling, asthma (wheezing), shock, skin reddening, rash, blisters. If an allergic reaction occurs, stop use and seek medical help right away.

Sexually transmitted diseases (STDs) alert: This product does **not** protect against HIV/AIDS or other STDs.

Do not use

- if you **have or ever had** breast cancer
- if you are already pregnant or think you may be pregnant
- together with another birth control pill, vaginal ring, patch, implant, injection or an IUD (intra-uterine device)
- as an emergency contraceptive (morning after pill). This product does not prevent pregnancy when used after unprotected sex
- if you are male

Ask a doctor before use if

- you currently have vaginal bleeding between your periods and you have not already talked to a doctor
- you have liver problems
- you **have or ever had** any cancer

Ask doctor or pharmacist before use if

- you are taking a prescription drug for seizures, tuberculosis, HIV/AIDS, pulmonary hypertension
- you are taking a supplement containing St John's Wort (an herbal ingredient)

- if you have taken ulipristal acetate (an emergency contraceptive, or morning after pill) in the past 5 days

See the enclosed leaflet for a detailed list of medicines that may interact with this product.

When using this product

- **you are likely to experience changes in your menstrual periods**, such as irregular periods, spotting or bleeding between your periods, or you may stop having periods. To prevent pregnancy, keep taking the product.
- you may experience headaches, dizziness, nausea, increased appetite, abdominal pain, cramps or bloating
- **talk to a doctor (but continue taking every day) if**
- you have repeated vaginal bleeding brought on by sex
- you start having periods that last more than 8 days or are unusually heavy
- you start having migraines with aura (headaches that start with changes in vision) or your migraine headaches get worse
- **take a pregnancy test or talk to a doctor if**
- your period is late after missing any tablets in the last month
- you have not had a period for 2 months or think you may be pregnant

Seek medical help right away if

- you have sudden or severe persistent pain in your lower belly mostly on one side (you could have an ectopic pregnancy)
- you develop yellowing of your skin or whites of your eyes especially with fever, tiredness, loss of appetite or dark colored urine

Stop use and ask a doctor if

- you become pregnant

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- **take 1 tablet at the same time every day**
- this product will work best to prevent pregnancy when taken exactly as directed
- you can start on any day of the month
- use a condom (or another barrier method) every time you have sex during the first 2 days of use (48 hours) after you start your first pack of this product, because it takes 2 days for this product to start working

See the enclosed leaflet for more information on how to switch from another contraceptive method.

- **never skip your daily tablet**
- to prevent pregnancy, take this product every day, even when you bleed or have spotting
- when you finish this pack, start the next one the following day without a break
- **if you are more than 3 hours late taking your tablet or miss taking your**

tablet on 1 more days:

- take 1 tablet immediately, as soon as you remember that you missed it
- then go back to taking your daily tablet at your usual time
- use a condom (or another barrier method) every time you have sex during the next 2 days (48 hours), because it takes 2 days for this product to start working again
- **if you vomit** for any reason **or have severe diarrhea within 4 hours** of taking your daily tablet, use a condom (or another barrier method) every time you have sex for the next 2 days (48 hours), because the medicine may not have been fully absorbed
- you should continue to see your healthcare provider(s) for routine healthcare visits

When to use a condom (or another barrier method)

- every time you have sex for the next 2 days (48 hours):
- after you start your first pack of this product
- if you take a tablet more than 3 hours late or miss a tablet on 1 or more days
- if you vomit or have a severe diarrhea within 4 hours of taking a tablet

Other information

- contains FD&C yellow No. 5 (tartrazine) as a color additive
- **read the instructions, warnings and enclosed product leaflet before use**
- as with any birth control method, this product does not prevent pregnancy all the time
- this product will work best if you take it exactly as directed
- store between 20°-25°C (68°-77°F)
- do not flush tablets. Dispose via a take-back option or see www.fda.gov/drugdisposal

Inactive Ingredients

cellulose, FD&C Yellow No. 5, lactose, magnesium stearate, polacrillin potassium

Questions or comments?

Call 1-877-414-6859

Consumer information leaflet

Opill® Norgestrel tablets 0.075mg

Daily Oral Contraceptive

FDA APPROVED

What you need to know

Before you use Opill®, read this information carefully and take Opill® exactly as directed.

Keep this leaflet as it contains important information.

DP30705

What this leaflet covers

1. What is Opill[®]?
2. Is Opill[®] right for you?
3. How to take Opill[®]?
4. Tips to help you remember to take Opill[®] on-time
5. When to talk to a doctor or pharmacist?
6. What could happen to your periods while taking Opill[®]?
7. Other questions you may have

Before you start...

Two things you need to know.

It's very important to take Opill[®] every single day at the same time:

- Without breaks
- Even if you have changes in your menstrual period



same time every day

It takes 2 days for Opill[®] to start working so use a condom (or other barrier method) every time you have sex for the next 2 days (48 hours):



- After you start your first pack of Opill[®]
- If you take a tablet more than 3 hours late or miss a tablet on 1 or more days
- If you vomit or have severe diarrhea within 4 hours of taking a tablet

OPILL[®] WILL WORK BEST IF YOU TAKE IT EXACTLY AS DIRECTED

1. What is Opill[®]?

Opill[®] is a **daily oral contraceptive** (also called a **birth control pill**) used by women to prevent pregnancy.

Opill[®] is **NOT** an emergency contraceptive (morning after pill). You should not take Opill[®] to try to prevent pregnancy **after** unprotected sex because it will not work.

Opill[®] does **NOT** protect against HIV/AIDS or other sexually transmitted diseases (STDs). You should use condoms to protect against HIV/AIDS or other STDs.

1. Is Opill[®] right for you?

Most women can use Opill®. However, do not use Opill®:

- If you have or ever had **breast cancer**, because some breast cancers are sensitive to hormones like the one in Opill®.
- If you know that you are **already pregnant or think you may be pregnant**.
- Together with another **birth control** pill, vaginal ring, patch, implant injection or an IUD (intra-uterine device).
- If you are **allergic to this product or any of its ingredients, such as the color additive FD&C yellow No. 5 (tartrazine)**. People allergic to aspirin often have a tartrazine allergy too. Symptoms may include: hives, facial swelling, asthma (wheezing), shock, skin reddening, rash, blisters. If an allergic reaction occurs, stop use and seek medical help right away.

Talk to a doctor before starting Opill® if:

- You currently have vaginal bleeding between your periods and you have not already talked to a doctor, because it could be the sign of a condition that should be treated.
- You have liver tumors or a liver disease.
- You have or ever had any cancer, because some cancers are sensitive to hormones like the one in Opill®.
- **How to take Opill®?**
- **Take 1 tablet at the same time every single day** (and no later than 3 hours from the time you took your tablet the day before). **Never skip your daily tablet.**
- Never take a break between packs. When you finish one pack (all 28 tablets), you should start the next pack the following day.
- Take Opill® every single day, even when you have your period, or if you have spotting or bleeding between periods.
- Do not skip tablets even if you do not have sex very often.

To start using Opill®:

- You can start your first pack on any day.
- **If you are switching from another oral contraceptive, vaginal ring, or patch**, start taking Opill® the day after you stop the other method.
- You must take your daily tablet at the same time of day every single day.
- You must use a condom (or another barrier method) every time you have sex during the first 2 days (48 hours) because it takes 2 days to start working.

What if I am late taking my tablet?

Less than 3 hours late:

Don't worry. Take 1 tablet immediately and go back to taking your tablet at your usual time the following day.

More than 3 hours late OR you missed one or more tablets:

- Take 1 tablet immediately, as soon as you remember.
- Then, go back to taking your tablet at your usual time. This means you may take 2 tablets in 1 day.
 - For example, if you usually take your tablet at night, but forget and remember in the morning, take 1 tablet when you remember and take 1 tablet again at the usual time that night.
- You must use a condom (or another barrier method) every time you have sex during

the 2 days (48 hours) after you restart Opill[®], because it takes 2 days to start working again.

- **Take a pregnancy test or talk to a doctor** if your period is later after missing any tablets in the last month.

What if I vomit or have severe diarrhea within 4 hours of taking my tablet?

- Use a condom (or another barrier method) every time you have sex for the next 2 days (48 hours) because the medicine may not have been fully absorbed.
- The next day, take your daily tablet at your usual time.
- **Tips to help you remember to take Opill[®] on-time**

Choose a convenient time of day. It is best to link this to something you already do at **the same time every day**. For example, when you wake up or when you brush your teeth.

Set reminders. Consider using your smartphone to set a daily alarm, and put reminders in visible places such as bathroom mirror, phone or coffee machine.

Buy a new pack of Opill[®] before finishing the pack so you can start the next pack on time.

1. When to talk to a doctor or pharmacist?

What if I am taking other medicines or herbal products?

Talk to a doctor or pharmacist if you are taking or start to take any of the following medications, as these may make Opill[®] less effective:

- Certain drugs to treat
- - Seizures (*barbiturates, carbamazepine, oxcarbazepine, phenytoin, topiramate, primidone*)
- - Tuberculosis (*rifampin, rifabutin*)
- - Pulmonary hypertension (*bosentan*)
- - HIV/AIDS (*efavirenz*)
- St. John's Wort (or any herbal products containing *hypericum perforatum*)

Your doctor or pharmacist may advise you to use another form of contraception.

What if I have taken an emergency contraceptive (morning after pill) before starting Opill[®]?

- **Talk to a doctor or pharmacist** if you have taken an emergency contraceptive in the past 5 days.
- Opill[®] should not be used for 5 days after using the emergency contraceptive ella[®] which contains ulipristal acetate. This might reduce the ability of both Opill[®] and ella[®] to prevent pregnancy. Also, **use a condom** (or another barrier method) every time you have sex until your next period.

What if I have sudden or severe persistent pain in my lower belly mostly on one side?

Seek medical help right away.

You may have an ectopic pregnancy (*a fertilized egg implanted in the wrong place*).

While ectopic pregnancy is unlikely if you are taking Opill[®] as directed, it is a serious risk

if it occurs. Severe persistent belly pain may occur for a few reasons and should be assessed right away.

What if I become pregnant while taking Opill®?

- **Stop taking this product and talk to a doctor** if you get pregnant while taking Opill®.
- Signs that you may be pregnant might include: missed periods, tender breasts, feeling nauseous, fatigue, and/or needing to urinate urgently or more frequently.
- **Take a pregnancy test or talk to a doctor** if your period is late after missing any tablets in the last month, if you have not had a period for 2 months, or if you think you may be pregnant.

What if I get migraines while using Opill®?

If you start having migraines with aura (*headaches that start with changes in vision*) or your migraine headaches get worse, **talk to a doctor but continue taking every day**. Some women with migraine may be at increased risk of stroke.

What if I develop yellowing of skin or eyes while using Opill®?

Seek medical help right away if you develop the following rare symptoms: yellowing of the whites of your eyes or skin (*especially with fever, tiredness, loss of appetite or dark colored urine*). These may be a sign of liver problems which can be a serious medical condition.

1. What could happen to your periods while taking Opill®?

What changes in my menstrual period are normal while using Opill®?

Most changes to periods are to be expected.

Continue taking Opill® exactly as directed, even if you have the following changes in your periods:

- Your periods may be less or more frequent, shorter or longer, lighter or heavier than before you started Opill®. You may also have some spotting or bleeding between periods.
- Some women stop having periods while taking Opill®.
- **Take a pregnancy test or talk to a doctor** if your period is late after missing any tablets in the last month, if you have not had a period of 2 months, or if you think you may be pregnant. Signs that you may be pregnant are listed in section 5, under « What if I become pregnant while taking Opill.

What changes to my period are NOT expected when using Opill®?

Talk to a doctor AND continue taking this product every day if you experience any of the following:

- You repeatedly have vaginal bleeding that is brought on by sex.
- You start having menstrual periods that last more than 8 days or are unusually heavy.
- **Other questions you may have**

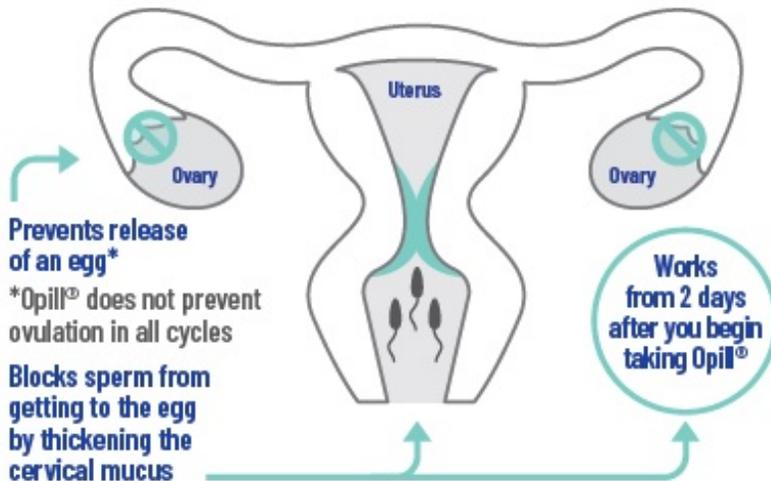
What type of oral contraceptive is Opill®?

- Opill® is a progestin-only pill (*POP*)
- Opill® contains the hormone progestin but does not contain estrogen, so it is

different than the commonly used combined oral contraceptive, which contains both estrogen and progestin.

Opill[®] works mainly by thickening your cervical mucus which helps to block sperm from getting to the egg. You must take it every day to prevent pregnancy. In addition, Opill[®] may prevent your ovaries from releasing eggs.

- Every one of the 28 tablets in your blister pack contains the active ingredient so you must take one tablet every day with no breaks.



How effective is Opill[®] at preventing pregnancy?

- As with any birth control method, Opill[®] does not prevent pregnancy all the time. Opill[®] will work best if you take it exactly as directed.
- In 8 US clinical trials, approximately 98 out of 100 sexually active women who used Opill[®] for a year did not become pregnant in that time.

What if I decide I want to get pregnant?

- If you decide you want to become pregnant, simply stop taking Opill[®]. Opill[®] will not delay your ability to get pregnant.

Is it okay to use Opill[®] if I'm breastfeeding?

- Yes. Opill[®] is safe and effective in breastfeeding women. Small amounts of progestin may pass into the breast milk; however, no adverse effects have been found on either breastfeeding performance or infant health.

What types of side effects may I expect while using Opill[®]?

- When used as directed, Opill[®] is safe and effective.
- The most common side effect is changes in menstrual periods (bleeding). See section 6.
- Less common side effects may include headaches, dizziness, nausea, increased appetite, abdominal pain, cramps or bloating.

Routine healthcare

You should continue to see your healthcare provider(s) for routine healthcare visits.

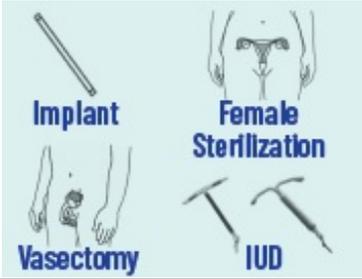
- It is important that you continue to have regular Pap smear tests (cervical screening) while taking Opill[®].
- Regular breast screening (mammography) is also recommended.
- If you are worried you may have a Sexually Transmitted Disease (STD) including HIV

(AIDS), see your healthcare provider as soon as you can. Many STDs, like HIV, have no symptoms at all. The only way to know for sure that you do not have an STD is to get tested. Only barrier methods (such as condoms) can protect you from STD.

You should tell your healthcare provider(s) that you are taking Opill[®].

Regular contraception

There are many different types of contraception available, and you should be able to find the right method for you. The different contraceptive options are listed below from the most effective to the least effective. You can ask your healthcare provider(s) for advice.

		How to make your method most effective
<p>Tier 1 More Effective Less than 1 pregnancy per 100 women in one year</p>		<p>After procedure, little or nothing to do or remember Vasectomy: Use another method for first 3 months</p>
<p>Tier 2 4-7 pregnancies per 100 women in one year</p>		<p>Injectable: Get repeat injections on time Pills: Take a pill each day Patch, ring: Keep in place, change on time</p>
<p>Tier 3 Less Effective More than 13 pregnancies per 100 women in one year</p>		<p>Condoms, sponge, withdrawal, spermicides, diaphragm: Use correctly every time you have sex Fertility awareness-based methods: Abstain or use condoms on fertile days. Newer methods (Standard Days, Natural Cycles, and Symptothermal may be easier to use and consequently more effective).</p>

ARA, Marrazzo J, Kowal D, eds. Contraceptive technology. 21sted. New York, NY: Ayer Company Publishers, Inc., 2018

More about routine healthcare and contraception

For further information on all methods of contraception or screening, go to

- <https://www.cdc.gov/reproductivehealth/contraception/index.htm>
- https://www.cdc.gov/cancer/breast/basic_info/screening.htm
- https://www.cdc.gov/cancer/cervical/basic_info/screening.htm

What if I still have questions about Opill[®]?

If you have questions or need more information, call our toll-free number: **1-877-414-6859**

Reminder card Front -

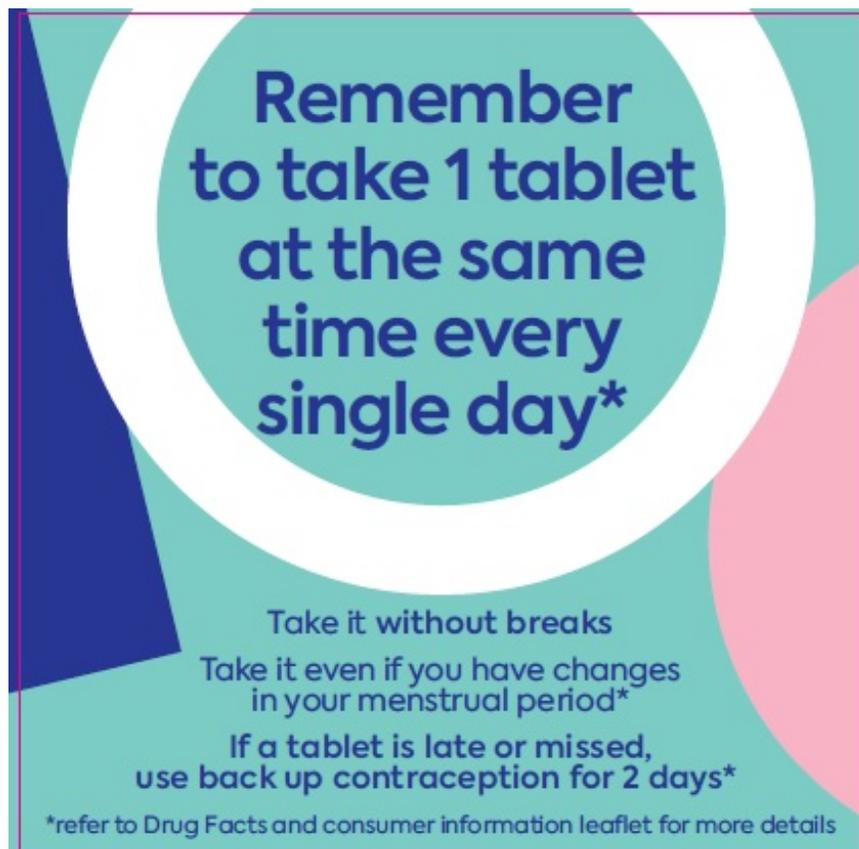
Remember to take 1 tablet at the same time every single day*

Take it **without breaks**

Take is even if you have changes in your menstrual period*

If a tablet is late or missed, use back up contraception for 2 days*

*refer to Drug Facts and consumer information leaflet for more details



Reminder card Back -

Opill[®]

Norgestrel tablets 0.075mg

I will take my pill every day at: _____AM/PM

A few tips...

- Pair the tablet-taking with a daily task
- Keep the pack visible in the same place
- Put reminders in visible places such as bathroom mirror, phone or coffee machine
- Set an alarm on your smartphone

DP30706



Package/Label Principal Display Panel

PERRIGO Selfcare [™]

FULL PRESCRIPTION STRENGTH

Contains 1 x 28 Day Supply

Opill [®]

Norgestrel tablets 0.075mg

Daily Oral Contraceptive

FDA APPROVED

28 Tablets

Take one tablet at the same time every day

DO NOT USE AS AN EMERGENCY CONTRACEPTIVE

Opill[®]
Norgestrel tablets 0.075mg
Daily Oral Contraceptive

Drug substance product of Germany.
Drug product manufactured in Ireland.

Manufactured for
Laboratoire HRA Pharma

Distributed by:
PMI Branded
Pharmaceuticals, Inc.
Allegan, MI 49010

DP30701

 FULL PRESCRIPTION STRENGTH

Contains
1
x 28 Day
Supply

Opill[®]
Norgestrel tablets 0.075mg
**Daily Oral
Contraceptive**

 **28
Tablets**

Take **one tablet** at the same time every day
DO NOT USE AS AN EMERGENCY CONTRACEPTIVE

 LOT:
EXP:


8 50054 27801 2

Opill®
 Norgestrel tablets 0.075mg
 Daily Oral
 Contraceptive

Reminder: Tips are inside the package to help you remember to take Opill® at the same time every day. Do not flush tablets. Dispose via a take-back option or see www.fda.gov/drugdisposal

Drug Facts

Active ingredient (in each tablet)
 Norgestrel 0.075 mg

Purpose
 Daily Oral Contraceptive

Use

To prevent pregnancy

Warnings

Allergy alert: Do not use if you are allergic to this product or any of its ingredients, such as FD&C yellow No. 5 (tartrazine). People allergic to aspirin often have a tartrazine allergy too. Symptoms may include hives, facial swelling, asthma (wheezing), shock, skin reddening, rash, blisters. If an allergic reaction occurs, stop use and seek medical help right away.

Sexually transmitted diseases (STDs) alert: This product does not protect against HIV/AIDS or other STDs.

Do not use

- if you **have or ever had** breast cancer
- if you are already pregnant or think you may be pregnant
- together with another birth control pill, vaginal ring, patch, implant, injection or an IUD (intra-uterine device)
- as an emergency contraceptive (morning after pill). This product does not prevent pregnancy when used after unprotected sex
- if you are male

Ask a doctor before use if

- you currently have vaginal bleeding between your periods and you have not already talked to a doctor
- you have liver problems
- you **have or ever had** any cancer

Ask a doctor or pharmacist before use if

- you are taking a prescription drug for seizures, tuberculosis, HIV/AIDS, pulmonary hypertension
- you are taking a supplement containing St John's Wort (an herbal ingredient)
- if you have taken ulipristal acetate (an emergency contraceptive, or morning after pill) in the past 5 days

See the enclosed leaflet for a detailed list of medicines that may interact with this product. ▶

LIFT FLAP

Drug Facts (continued)

When using this product

- you are likely to experience changes in your menstrual periods, such as irregular periods, spotting or bleeding between your periods, or you may stop having periods. To prevent pregnancy, keep taking the product.
- you may experience headaches, dizziness, nausea, increased appetite, abdominal pain, cramps or bloating
- talk to a doctor (but continue taking every day) if
 - you have repeated vaginal bleeding brought on by sex
 - you start having periods that last more than 8 days or are unusually heavy
 - you start having migraines with aura (headaches that start with changes in vision) or your migraine headaches get worse
- take a pregnancy test or talk to a doctor if
 - your period is late after missing any tablets in the last month
 - you have not had a period for 2 months or think you may be pregnant

Seek medical help right away if

- you have sudden or severe persistent pain in your lower belly mostly on one side (you could have an ectopic pregnancy)
- you develop yellowing of your skin or whites of your eyes especially with fever, tiredness, loss of appetite or dark colored urine

Stop use and ask a doctor if

- you become pregnant

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- take 1 tablet **at the same time every day**
 - this product will work best to prevent pregnancy when taken exactly as directed
 - you can start on any day of the month
 - use a condom (or another barrier method) every time you have sex during the first 2 days of use (48 hours) after you start your first pack of this product, because it takes 2 days for this product to start working

See the enclosed leaflet for more information on how to switch from another contraceptive method. ▶

Drug Facts (continued)

Directions (continued)

- **never skip your daily tablet**
 - to prevent pregnancy, take this product every day, even when you bleed or have spotting
 - when you finish this pack, start the next one the following day without a break
- **if you are more than 3 hours late taking your tablet or miss taking your tablet on 1 or more days:**
 - take 1 tablet immediately, as soon as you remember that you missed it
 - then go back to taking your daily tablet at your usual time
 - use a condom (or another barrier method) every time you have sex during the next 2 days (48 hours), because it takes 2 days for this product to start working again
- **if you vomit for any reason or have severe diarrhea within 4 hours of taking your daily tablet,** use a condom (or another barrier method) every time you have sex for the next 2 days (48 hours), because the medicine may not have been fully absorbed
- you should continue to see your healthcare provider(s) for routine healthcare visits

When to use a condom (or another barrier method)

- every time you have sex for the next 2 days (48 hours):
 - after you start your first pack of this product
 - if you take a tablet more than 3 hours late or miss a tablet on 1 or more days
 - if you vomit or have a severe diarrhea within 4 hours of taking a tablet

Other information

- contains FD&C yellow No.5 (tartrazine) as a color additive
- **read the instructions, warnings and enclosed product leaflet before use**
- as with any birth control method, this product does not prevent pregnancy all the time
- this product will work best if you take it exactly as directed
- store between 20°-25°C (68°-77°F)
- do not flush tablets. Dispose via a take-back option or see www.fda.gov/drugdisposal

Inactive ingredients

cellulose, FD&C Yellow No. 5, lactose, magnesium stearate, polacrillin potassium

Questions or comments?

Call 1-877-414-6859

Scan the QR code to
access an online version
of the Consumer
Information Leaflet
enclosed in this pack.



NDC 0113-8101-01

TAMPER EVIDENT:
Do not use if carton
is opened or if foil
blister is broken

Oral use only

OPILL

norgestrel tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67296-1938(NDC:0113-8101)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NORGESTREL (UNII: 3J8Q1747Z2) (NORGESTREL - UNII:3J8Q1747Z2)	NORGESTREL	0.075 mg

Inactive Ingredients

Ingredient Name	Strength
POLACRILIN POTASSIUM (UNII: 0BZ5A00FQU)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics

Color	yellow	Score	no score
Shape	ROUND	Size	5mm
Flavor		Imprint Code	NG;75
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67296-1938-2	1 in 1 CARTON	03/04/2024	
1		28 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA017031	03/04/2024	

Labeler - Redpharm Drug (828374897)**Establishment**

Name	Address	ID/FEI	Business Operations
Redpharm Drug		828374897	repack(67296-1938)