For current labeling information, please visit https://www.fda.gov/drugsatfda

This label may not be the latest approved by FDA.

Reference ID: 5207533

Inactive ingredients

Drug Facts (continued)

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

Information Leaflet enclosed in this pack.

®

Oral use only

NDC 73302-789-01

Take Norgestrel tablets 0.075mg

EXP: LOT:

Contraceptive

This label may not be the latest approved by FDA. For current labeling information, please visit https://www.fda.gov/drugsatfda

®

Drug product manufactured in Ireland.

Laboratoire HRA Pharma

Manufactured for

Allegan, MI 49010

PMI Branded

Tablets

1 28

DP30701

Information Leaflet enclosed in this pack.

®

Oral use only

NDC 73302-789-01

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EXP: LOT:

Contraceptive

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Allegan, MI 49010

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Information Leaflet enclosed in this pack.
Drug Facts

Full Prescribing Information

Oral only

For current labeling information, please visit https://www.fda.gov/drugsatfda

Reference ID: 5207533

Full Prescribing Information

Norgestrel tablets 0.075mg

Components:
- Norgestrel
- FD&C Yellow No. 5
- Lactose
- Magnesium stearate
- Polacrilin potassium

Full Prescribing Information

For current labeling information, please visit https://www.fda.gov/drugsatfda

Reference ID: 5207533

Full Prescribing Information

Oral only

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Reference ID: 5207533

Full Prescribing Information

Oral only
Daily Oral Contraceptive

Norgestrel tablets 0.075mg

This product does not prevent pregnancy all the time as with any birth control method.

To prevent pregnancy, take this product every day, even when you bleed or have spotting.

Take 1 tablet immediately, as soon as you remember that you missed it.

When you finish this pack, start the next one the following day without a break.

This product will work best to prevent pregnancy when taken exactly as directed.

Before you start using this product, your doctor should tell you about all the ways this product can help you stay healthy.

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

Reminders are inside the package to help you.
<table>
<thead>
<tr>
<th>SUN</th>
<th>MON</th>
<th>TUE</th>
<th>WED</th>
<th>THU</th>
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<td>If a tablet is late or missed, use back up contraception for 2 days</td>
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<tr>
<td>Refer to Drug Facts Label for more details</td>
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<td>Store between 20°-25°C (68°-77°F) PAA209687</td>
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For current labeling information, please visit https://www.fda.gov/drugsatfda.

This label may not be the latest approved by FDA.

Reference ID: 5207533
What could happen to your period when taking Opill®?

- You start having menstrual periods that last more than 8 days.
- You repeatedly have vaginal bleeding that is brought on by sex.
- Your periods may be heavier or are unusually heavy.
- You may also have some spotting or bleeding between periods.
- Your period may be 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.
- Signs that you may be pregnant are listed in section 5, under "What if I become pregnant while taking Opill."
- Every one of the 28 tablets in your blister pack contains the active ingredient Norgestrel tablets 0.075mg.
- Opill® contains the hormone progestin but does not contain estrogen, so it is not a combined oral contraceptive (POP).
- Blocks sperm from getting to the egg.
- Prevents release of eggs (ovulation) in all cycles.
- 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.
- Yes. Opill® is safe and effective in breastfeeding women.
- If you decide you want to become pregnant, simply stop taking Opill®.
- Most changes to periods are to be expected.
- Routine contraception methods are listed below from the most effective to the least effective. You can ask your healthcare provider(s) for advice.
- 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 Tier 1: Male sterilization; Tier 2: Female sterilization, injecting hormones, taking pills; Tier 3: Male or female condoms, spermicides, diaphragm:

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What type of oral contraceptive is Opill®?

- It is a non-oral contraceptive used for birth control but a combined oral contraceptive (POP).
- It contains the hormone progestin but does not contain estrogen, so it is not a combined oral contraceptive (POP).
- The hormone progestin prevent pregnancy by stopping or thinning the lining of the uterus so that the egg cannot implant, or by changing the lining so that the egg cannot implant.
- Every one of the 28 tablets in your blister pack contains the active ingredient Norgestrel tablets 0.075mg.
- You may use it to use Opill® to prevent pregnancy.
- You must take it every day to prevent pregnancy. In addition, Opill® may prevent your ovaries from releasing eggs.
- It is a non-oral contraceptive used for birth control but a combined oral contraceptive (POP).

What if I don’t want to get pregnant?

- Regular contraception methods are listed below from the most effective to the least effective. You can ask your healthcare provider(s) for advice.
- 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 Tier 1: Male sterilization; Tier 2: Female sterilization, injecting hormones, taking pills; Tier 3: Male or female condoms, spermicides, diaphragm:

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What are the benefits of using Opill®?

- It is a non-oral contraceptive used for birth control but a combined oral contraceptive (POP).
- It contains the hormone progestin but does not contain estrogen, so it is not a combined oral contraceptive (POP).
- Yes. Opill® is safe and effective in breastfeeding women.
- If you decide you want to become pregnant, simply stop taking Opill®.

What can I expect while using Opill®?

- You may be able to find the right method for you. The different contraceptive options are Tier 1: Male sterilization; Tier 2: Female sterilization, injecting hormones, taking pills; Tier 3: Male or female condoms, spermicides, diaphragm:

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What type of side effects may I expect while using Opill®?

- You may be able to find the right method for you. The different contraceptive options are Tier 1: Male sterilization; Tier 2: Female sterilization, injecting hormones, taking pills; Tier 3: Male or female condoms, spermicides, diaphragm:

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How effective is Opill® at preventing pregnancy?

- It is a non-oral contraceptive used for birth control but a combined oral contraceptive (POP).
- Yes. Opill® is safe and effective in breastfeeding women.
- If you decide you want to become pregnant, simply stop taking Opill®.
- Male sterilization; Tier 2: Female sterilization, injecting hormones, taking pills; Tier 3: Male or female condoms, spermicides, diaphragm:

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What if I missed a pill while using Opill®?

- You may be able to find the right method for you. The different contraceptive options are Tier 1: Male sterilization; Tier 2: Female sterilization, injecting hormones, taking pills; Tier 3: Male or female condoms, spermicides, diaphragm:

<table>
<thead>
<tr>
<th>Method</th>
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<tbody>
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What if I still have questions about Opill®?

- You may be able to find the right method for you. The different contraceptive options are Tier 1: Male sterilization; Tier 2: Female sterilization, injecting hormones, taking pills; Tier 3: Male or female condoms, spermicides, diaphragm:

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If you have questions or need more information, call Opill® 1-877-444-6819.
Before you start...
Two things you need to know.

1 What is Opill®?
Opill® is a 21-tablet packet of a daily oral contraceptive (or birth control pill) used by women to prevent pregnancy. Opill® is a combination of ethinyl estradiol and levonorgestrel.

2 How to take Opill®?
Before you start... It takes 2 days for Opill® to start working.

Tips to help you remember

4 Tips to help you remember to take Opill® on-time

Before you start...
Two things you need to know.

3 Is Opill® right for you?
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Is Opill® right for you?
Remember to take 1 tablet at the same time every single day*

Take it without breaks
Take it 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

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

Reference ID: 5207533
This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

CHRISTINE P NGUYEN
07/13/2023 07:33:36 AM

KAREN M MURRY
07/13/2023 07:36:32 AM

Reference ID: 5207533