

CONSUMER INFORMATION

**PrJENCYCLA
Norethindrone Tablets, USP**

This leaflet is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about **JENCYCLA**. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

- prevention of pregnancy

What it does:

JENCYCLA Tablets are progestin-only pills (POP) which contain a low dosage of norethindrone without the addition of an estrogen agent. It has been shown to be effective in preventing pregnancy when taken as prescribed by your doctor. Pregnancy is always more risky than taking birth control pills, except in smokers older than age 35.

Progestin-only birth control pills work in different ways including:

1. They prevent ovulation (release of the egg from the ovary) in about half of the cycles.
2. They change the mucus produced by the cervix. This slows the movement of the sperm through the mucus and through the uterus (womb).
3. They also affect other hormones, the fallopian tubes and the lining of the uterus.

Effectiveness of birth control pills:

The progestin-only pill is slightly less effective than combination birth control pills. The typical failure rate is estimated to be closer to 5 percent, due to late or missed pills.

Combination birth control pills are more than 99 percent effective in preventing pregnancy when:

- the pill is **TAKEN AS DIRECTED**, and
- the amount of estrogen is 20 micrograms or more.

A 99 percent effectiveness rate means that if 100 women used birth control pills for one year, one woman in the group would get pregnant.

The chance of becoming pregnant increases with incorrect use.

Other ways to prevent pregnancy:

Other methods of birth control are available to you. They are usually less effective than birth control pills. When used properly, however, other methods of birth control are effective enough for many women.

The following table gives reported pregnancy rates for various forms of birth control, including no birth control. The reported

rates represent the number of women out of 100 who would become pregnant in one year.

Reported pregnancies per 100 women per year:

Combination pill	less than 1 to 2
Intrauterine device (IUD)	less than 1 to 6
Progestin-only pill ^H	1 to 5
Condom with spermicidal foam or gel	1 to 6
Condom	2 to 12
Diaphragm with spermicidal foam or gel	3 to 18
Spermicide	3 to 21
Sponge with spermicide	3 to 28
Cervical cap with spermicide	5 to 18
Periodic abstinence (rhythm), all types	2 to 20
No birth control	60 to 85

^HAbout 1 in 200 progestin-only pill users will get pregnant in the first year if they all take progestin-only pills perfectly (that is, on time, every day). About 1 in 20 “typical” progestin-only pill users (including women who are late taking pills or miss pills) gets pregnant in the first year of use.

Pregnancy rates vary widely because people differ in how carefully and regularly they use each method. (This does not apply to IUDs since they are implanted in the uterus.). Regular users may achieve pregnancy rates in the lower ranges. Others may expect pregnancy rates more in the middle ranges.

The effective use of birth control methods other than birth control pills and IUDs requires more effort than taking a single pill every day. It is an effort that many couples undertake successfully.

When it should not be used:

The progestin-only pill is not suitable for every woman. In a small number of women, serious side effects may occur. Your doctor can advise you if you have any conditions that would pose a risk to you. The use of the birth control pill should always be supervised by your doctor.

You should not use JENCYCLA if you have or have had any of the following conditions:

- unusual vaginal bleeding that has not yet been diagnosed;
- smoker and over age 35;
- known or suspected cancer of the breast;
- liver tumours either benign or cancerous;
- acute liver disease;
- if you are taking certain drugs for epilepsy (seizures) or for tuberculosis (see **INTERACTIONS WITH THIS MEDICATION**);
- you are pregnant or if pregnancy is suspected; and/or
- allergic reaction to norethindrone or to any of the other ingredients in JENCYCLA (see **What the nonmedicinal ingredients are**).

What the medicinal ingredient is:

Norethindrone

What the nonmedicinal ingredients are:

D&C Yellow No.10 Aluminium Lake, FD&C Blue No.1 Aluminium Lake, lactose anhydrous, magnesium stearate, povidone K30 and sodium starch glycolate.

What dosage forms it comes in:

JENCYCLA (norethindrone) Tablets are available in a 28-day regimen.

28-day Package contains: 28 GREEN tablets each containing 0.35 mg norethindrone.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Cigarette smoking increases the risk of serious adverse effects on the heart and blood vessels. This risk increases with age and becomes significant in hormonal contraceptive users older than 35 years of age. Women should not smoke.

Birth control pills DO NOT PROTECT against sexually transmitted infections (STIs), including HIV/AIDS.

For protection against STIs, it is advisable to use latex or polyurethane condoms IN COMBINATION WITH the birth control pills.

There are also conditions that your doctor will want to watch closely or that might cause your doctor to recommend a method of contraception other than birth control pills.

BEFORE you use JENCYCVLA talk to your doctor or pharmacist if the following apply to you:

- breast disease (e.g., breast lumps) or a family history of breast cancer
- diabetes
- cigarette smoking
- migraine headaches
- depression
- fibroid tumours of the uterus
- pregnant or breast-feeding
- plan for forthcoming surgery.

You should also inform your doctor about a family history of blood clots, heart attacks or strokes.

If you see a different doctor, inform him or her that you are using JENCYCLA.

Tell your doctor if you are scheduled for any laboratory tests since certain blood tests may be affected by hormonal contraceptives.

Also tell your doctor if you are scheduled for **MAJOR** surgery. You should consult your doctor about stopping the use of JENCYCLA four weeks before surgery and not using JENCYCLA for a time period after surgery or during bed rest.

JENCYCLA should be used only under the supervision of a

doctor, with regular follow-up to identify side effects associated with its use. Your visits may include a blood pressure check, a breast exam, an abdominal exam and a pelvic exam, including a Pap smear. Visit your doctor three months or sooner after the initial examination. Afterward, visit your doctor at least once a year.

Use JENCYCLA only on the advice of your doctor and carefully follow all directions given to you. You must use the birth control pill exactly as prescribed. Otherwise, you may become pregnant. If you and your doctor decide that, for you, the benefits of JENCYCLA outweigh the risks, you should be aware of the following risks:

THE RISKS OF USING JENCYCLA

1. Ectopic Pregnancy

An ectopic pregnancy is a pregnancy outside the womb. Because progestin-only pills protect against pregnancy, the chance of having a pregnancy outside the womb is very low. If you do get pregnant while taking progestin-only pills, you have a slightly higher chance that the pregnancy will be ectopic than do users of some other birth control methods.

2. Ovarian Cysts

These cysts are small sacs of fluid in the ovary. They are more common among progestin-only pill users than among users of most other birth control methods. They usually disappear without treatment and rarely cause problems.

WARNING: If you have sudden or severe pain in your lower abdomen or stomach area, you may have an ectopic pregnancy or an ovarian cyst. If this happens, you should contact your doctor or clinic immediately.

3. Breast Cancer

Some studies in women who use combined oral contraceptives that contain both estrogen and progestin have reported an increase in the risk of developing breast cancer, particularly at a younger age and apparently related to duration of use. There is data to determine that the use of progestin-only pills may also increase this risk.

In progestin-only pill (POP) users, the older the age at stopping, the more breast cancers are diagnosed.

The most significant risk factors for breast cancer are increasing age and a strong history of breast cancer in the family (mother or sister). Other established risk factors include obesity, never having children, and having your first full-term pregnancy at a late age.

Some women who use birth control pills may be at increased risk of developing breast cancer before menopause which occurs around age 50. These women may be long-term users of birth control pills (more than eight years) or women who start using birth control pills at an early age. In a few women, the use of birth control pills may accelerate the growth of an existing but undiagnosed breast cancer. Early diagnosis, however, can reduce

the effect of breast cancer on a woman's life expectancy. The potential risks related to birth control pills seem to be small; however, a yearly breast examination by a doctor is recommended for all women.

ASK YOUR DOCTOR FOR ADVICE AND INSTRUCTIONS ON REGULAR SELF-EXAMINATION OF YOUR BREASTS.

4. Cervical Cancer

Some studies have found an increase in the incidence of cancer of the cervix in women who use oral contraceptives. However, this finding may be related to factors other than the use of oral contraceptives and there is insufficient data to determine whether the use of progestin-only pills increases the risk of developing cancer of the cervix.

5. Liver Tumours

In rare cases, combined oral contraceptives can cause benign liver tumours. These benign liver tumours can rupture and cause fatal internal bleeding. In addition, a possible but not definite association has been found with combined oral contraceptives and liver cancers in studies in which a few women who developed these very rare cancers were found to have used combined oral contraceptives for long periods of time. There is insufficient data to determine whether progestin-only pills increase the risk of liver tumours.

6. Diabetic Women

Diabetic women taking progestin-only pills generally require changes in the amount of insulin they are taking. However, your physician may monitor you more closely under these conditions.

7. Use During Pregnancy

Birth control pills should never be taken if you think you are pregnant. They will not prevent the pregnancy from continuing. There is no evidence, however, that the progestin-only pill can damage a developing child. You should check with your doctor about risks to your unborn child from any medication taken during pregnancy.

8. Use After Pregnancy, Miscarriage or An Abortion

Your doctor will advise you of the appropriate time to start the use of JENCYCLA after childbirth, miscarriage, or therapeutic abortion.

9. Pregnancy After Stopping JENCYCLA

You will have a menstrual period when you stop taking JENCYCLA. You should delay pregnancy until another menstrual period occurs within four to six weeks. Contact your doctor for recommendations on alternative methods of contraception during this time.

10. Use While Breast-feeding

In most women, progestin-only contraceptives, such as JENCYCLA, do not affect the quantity and quality of breast milk or length of lactation. However, isolated postmarketing cases of decreased milk production have been reported. Studies with various orally administered progestin-only contraceptives have shown that small amounts of progestins pass into the breast milk of nursing mothers resulting in detectable steroid levels in infant

plasma.

No adverse effects have been found on the health, growth or development of the infant.

INTERACTIONS WITH THIS MEDICATION

Certain drugs may interact with birth control pills to make them less effective in preventing pregnancy or cause an increase in breakthrough bleeding. You may also need to use a nonhormonal method of contraception during any cycle in which you take drugs that can make oral contraceptives less effective.

Drugs that may interact with JENCYCLA include:

- drugs used for the treatment of epilepsy (e.g., primidone, phenytoin, carbamazepine, rufinamide);
- drugs used for the treatment of tuberculosis (e.g., rifampin, rifabutin);
- drugs used for HIV/AIDS (e.g., nelfinavir, ritonavir-boosted protease inhibitors, darunavir, (fos)amprenavir, lopinavir, nevirapine);
- (fos)aprepitant (drug used for nausea);
- bosentan (drug used for pulmonary hypertension);
- antifungals (griseofulvin);
- the herbal remedy St. John's wort (primarily used for the treatment of depressive moods); and
- sedatives and hypnotics (e.g., benzodiazepines, barbiturates, chloral hydrate, glutethimide, meprobamate).

The pill may also interfere with the working of other drugs.

Please inform your doctor and pharmacist if you are taking or have recently taken any other drugs or herbal products, even those without a prescription. Also tell any other doctor or dentist who prescribes another drug (or the dispensing pharmacist) that you use JENCYCLA. They can tell you if you need to use an additional method of contraception and if so, for how long.

This is not a complete list of possible drug interactions with JENCYCLA. Talk to your doctor for more information about drug interactions.

PROPER USE OF THIS MEDICATION

HOW TO TAKE JENCYCLA (PROGESTIN-ONLY PILLS):

1. READ THESE DIRECTIONS

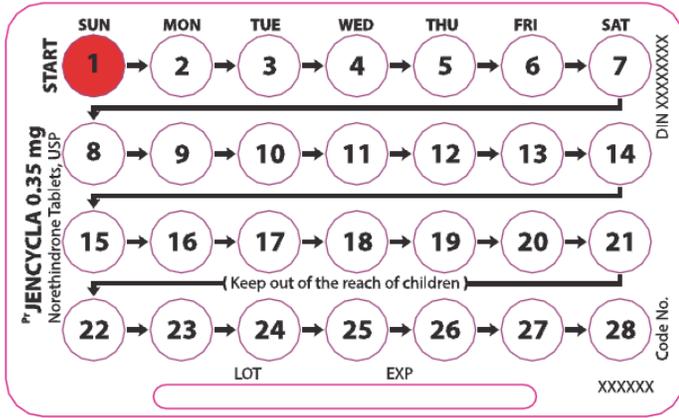
- before you start taking your pills, and
- any time you are not sure what to do.

2. LOOK AT YOUR PILL PACK

28-PILL PACK: 28 active pills (with a hormone) taken daily for 28 days.

ALSO CHECK: the pill pack for instructions on 1) where to start and 2) direction to take pills.

28-Day Package



3. You may wish to use a second method of birth control (e.g., latex or polyurethane condoms and spermicidal foam or gel) for the first seven days of the first cycle of pill use. This will provide a backup in case pills are forgotten while you are getting used to taking them.
4. When receiving any medical treatment, be sure to tell your doctor that you are using birth control pills.
5. **MANY WOMEN HAVE SPOTTING OR LIGHT BLEEDING, OR MAY FEEL SICK TO THEIR STOMACH DURING THE FIRST THREE MONTHS ON THE PILL.** If you do feel sick, do not stop taking the pill. The problem will usually go away. If it does not go away, check with your doctor or clinic. The most common side effect of progestin-only pills is a change in menstrual bleeding. Your period may be either late or early and you may have some spotting.
6. **MISSING PILLS ALSO CAN CAUSE SOME SPOTTING OR LIGHT BLEEDING,** even if you make up the missed pills. You also could feel a little sick to your stomach on the days you take two pills to make up for missed pills.
7. **IF YOU MISS PILLS AT ANY TIME, YOU COULD GET PREGNANT. THE GREATEST RISKS FOR PREGNANCY ARE:**
 - when you start a pack late, or
 - if you are more than 3 hours late or you miss one or more progestin-only pills.
8. **ALWAYS BE SURE YOU HAVE READY:**
 - **ANOTHER KIND OF BIRTH CONTROL** (such as latex or polyurethane condoms and spermicidal foam or gel) to use as a backup in case you miss pills, and
 - **AN EXTRA, FULL PACK OF PILLS.**
9. **IF YOU EXPERIENCE VOMITING OR DIARRHEA, OR IF YOU TAKE CERTAIN**

MEDICINES, your pills may not work as well. Use a backup method, such as latex or polyurethane condoms and spermicidal foam or gel, until you can check with your doctor or clinic.

10. **IF YOU FORGET MORE THAN ONE PILL TWO MONTHS IN A ROW,** talk to your doctor or clinic about how to make pill-taking easier or about using another method of birth control.
11. **THERE IS NO NEED TO STOP TAKING BIRTH CONTROL PILLS FOR A REST PERIOD.**
12. **IF YOUR QUESTIONS ARE NOT ANSWERED HERE, CALL YOUR DOCTOR OR CLINIC.**

WHEN TO START THE FIRST PACK OF PILLS

BE SURE TO READ THESE INSTRUCTIONS:

- before you start taking your pills, and
- any time you are not sure what to do.

YOUR JENCYCLA TABLETS ARE IN A 28-DAY PILL PACKAGE. With this type of birth control pill, you take 28 pills which contain only one hormone, a progestin.

STARTING PROGESTIN-ONLY PILLS

1. **THE FIRST DAY OF YOUR MENSTRUAL PERIOD (BLEEDING) IS DAY 1 OF YOUR CYCLE.** With JENCYCLA Tablets, it is best to start your first package of progestin-only pills on the first day of your menstrual period (Day 1)^H. Then you simply continue taking one tablet every single day until your package is empty. Without missing a day, start taking JENCYCLA Tablets from your new package.

^H If you decide to take your first progestin-only pill on another day, use an additional method of birth control (such as latex or polyurethane condoms and spermicidal foam or gel) every time you have sex during the next 48 hours.

2. If you have had a miscarriage or an abortion, you can start progestin-only pills the next day.
3. Take one pill at the same time every day for 28 days. Begin a new pack the next day, **NOT MISSING ANY DAYS ON THE PILLS.** Your period should occur during the last seven days of using that pill pack. JENCYCLA Tablets are taken every day, even when you are having some menstrual bleeding.

INSTRUCTIONS FOR USING YOUR PACKAGE. FOLLOW THESE INSTRUCTIONS CAREFULLY:

1. **For Day 1 start:** Label the package by selecting the day label that starts with Day 1 of your menstrual period (the first day of menstruation is Day 1). For example, if your first day of menstruation is Tuesday, attach the day label that begins with **TUE** in the space provided.

OR

For Sunday start: No day label is required. The Package is printed for a Sunday start. (The first Sunday **after** your period begins, or, if your period starts on Sunday, start that **same day**.)

2. Place the day label on the dispenser over the printed days of the week. Having the Package labelled with the days of the week will help remind you to take your pill every day.

3. To begin taking your pills, start with the pill inside the red circle (where you see the word **START**). This pill should correspond to the day of the week that you are taking your first pill. To remove the pill, push through the back of the Package.

4. On the following day, take the next pill in the same row, always proceeding from left to right (→). Each row will always begin on the same day of the week.

IF YOU ARE BREAST-FEEDING

1. If you are fully breast-feeding (not giving your baby any food or formula), you may start taking your pills 6 weeks after delivery.
2. If you are partially breast-feeding (giving your baby some food or formula), you should start taking your pills 3 weeks after delivery.

IF YOU ARE SWITCHING PILLS

1. If you are switching from the combined pills to progestin-only pills, and you were on a 21-Day regimen, take the first progestin-only pill the day after you finish the last active combined pill. If you have been on a 28- Day regimen, do not take any of the 7 inactive pills from the combined pill pack. You should know that many women have irregular periods after switching to progestin-only pills, but this is normal and to be expected.
2. If you are switching from progestin-only pills to the combined pills, take the first active combined pill on the first day of your period, even if your progestin-only pill pack is not finished.
3. If you are breast-feeding, you can switch to another method of birth control at any time, except do not switch to the combined pills until you stop breastfeeding or at least until 6 months after delivery.

WHAT TO DO DURING THE MONTH

1. TAKE A PILL AT THE SAME TIME EVERY DAY UNTIL THE PACK IS EMPTY. Progestin-only pills must be taken at the same time every day since its action is time dependent. Every time you take a pill late, and especially if you miss a pill, you are more likely to get pregnant.

- Try to associate taking your pill with some regular activity such as eating a meal or going to bed.

- Do not skip pills even if you have bleeding between monthly periods or feel sick to your stomach (nausea).
- Do not skip pills even if you do not have sex very often.

2. WHEN YOU FINISH A PACK OF 28 PILLS

- Start the next pack **ON THE NEXT DAY**. Take one pill every day. Do not wait any days between packs.

Overdose:

Symptoms of overdose may include nausea, vomiting or vaginal bleeding. Available information from cases of accidental ingestion of oral contraceptives by children indicates no serious effects.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

WHAT TO DO IF YOU MISS PILLS

IF YOU ARE MORE THAN 3 HOURS LATE OR MISS TAKING YOUR PROGESTIN-ONLY PILLS

1. Take a missed pill as soon as you remember you missed it.
2. Then go back to taking progestin-only pills at your regular time.
3. But be sure to use a backup method (such as a condom and/or a spermicide) every time you have sex for the next 48 hours.

If you are not sure what to do about the pills you have missed, keep taking progestin-only pills and use a backup method until you can talk to your doctor or clinic.

Always be sure you have on hand:

- a backup method of birth control (such as latex or polyurethane condoms and spermicidal foam or gel) in case you miss pills, and
- an extra, full pack of pills.

IF YOU FORGET MORE THAN ONE PILL TWO MONTHS IN A ROW, TALK TO YOUR DOCTOR OR CLINIC about ways to make pill-taking easier or about using another method of birth control.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Some users of birth control pills have side effects. The most common side effect of progestin-only pills is a change in menstrual bleeding. Your periods may be either early or late. You may have some spotting between periods or you may not have a period. Taking pills late or missing pills can result in some spotting or bleeding.

Less common side effects of progestin-only pills include headaches, tender breasts, nausea, vomiting, tiredness, weight gain, dizziness, acne, extra hair on your face or body, loss of hair, rash, abdominal pain, yellowing of the skin or eyes (jaundice), and tubal pregnancy.

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This leaflet was prepared by Sandoz Canada Inc.

Last revised: August 12, 2016

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist	Stop taking drug and call your doctor or pharmacist
Common	Abnormal vaginal bleeding	✓	
Uncommon	Sudden or severe pain in lower abdomen	✓	
	Allergic reaction		✓

HOW TO STORE IT

Store in original packaging, between 15°C - 30°C. Keep out of the reach of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found by contacting the sponsor, Sandoz Canada Inc., at:

1-800-361-3062

or by written request at:
145 Jules-Léger