

DETAILED PATIENT LABELING
Jencycla™
(norethindrone tablets USP, 0.35 mg)
Rx Only

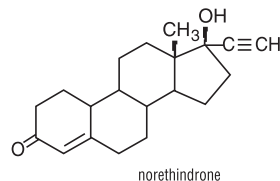
This product (like all oral contraceptives) is used to prevent pregnancy. It does not protect against HIV infection (AIDS) or other sexually transmitted diseases.

DESCRIPTION

Jencycla™ Tablets

Each tablet contains 0.35 mg norethindrone. Inactive ingredients include D&C yellow No. 10, FD&C blue No. 1, lactose anhydrous, magnesium stearate, povidone and sodium starch glycolate.

The chemical name of norethindrone is 17-hydroxy-19-nor-17 α -pregn-4-en-20-yn-3-one. It has a molecular formula of C₂₀H₂₆O₂ and a molecular weight of 298.4. It has the following structural formula:



Jencycla meets USP Dissolution Test 2.

INTRODUCTION

This leaflet is about birth control pills that contain one hormone, a progestin. Please read this leaflet before you begin to take your pills. It is meant to be used along with talking with your healthcare professional.

Progestin-only pills are often called “POPs” or “the minipill.” POPs have less progestin than the combined birth control pill (or “the pill”) which contains both an estrogen and a progestin.

HOW EFFECTIVE ARE POPs?

About 1 in 200 POP users will get pregnant in the first year if they all take POPs perfectly (that is, on time, every day). About 1 in 20 “typical” POP users (including women who are late taking pills or miss pills) gets pregnant in the first year of use. Table 2 will help you compare the efficacy of different methods.

Table 2: Percentage of Women Experiencing an Unintended Pregnancy During the First Year of Typical Use and the First Year of Perfect Use of Contraception and the Percentage Continuing Use at the End of the First Year. United States.

Method (1)	% of Women Experiencing an Unintended Pregnancy within the First Year of Use		% of Women Continuing Use at One Year ³ (4)
	Typical Use ¹ (2)	Perfect Use ² (3)	
Chance ⁴	85	85	
Spermicides ⁵	26	6	40
Periodic abstinence	25		63
Calendar		9	
Ovulation Method		3	
Sympto-Thermal ⁶		2	
Post-Ovulation		1	

Cap ⁷			
Parous Women	40	26	42
Nulliparous Women	20	9	56
Sponge			
Parous Women	40	20	42
Nulliparous Women	20	9	56
Diaphragm ⁷	20	6	56
Withdrawal	19	4	
Condom ⁸			
Female (Reality [®])	21	5	56
Male	14	3	61
Pill	5		71
Progestin Only		0.5	
Combined		0.1	
IUD			
Progesterone T	2.0	1.5	81
Copper T380A	0.8	0.6	78
LNg 20	0.1	0.1	81
Depo-Provera [®]	0.3	0.3	70
Norplant [®] and Norplant-2 [®]	0.05	0.05	88
Female Sterilization	0.5	0.5	100
Male Sterilization	0.15	0.10	100

Adapted from Hatcher et al, 1998, Ref. # 1.

Emergency Contraceptive Pills: Treatment initiated within 72 hours after unprotected intercourse reduces the risk of pregnancy by at least 75%.⁹
 Lactational Amenorrhea Method: LAM is highly effective, temporary method of contraception.¹⁰

Source: Trussell J, Contraceptive efficacy. In Hatcher RA, Trussell J, Stewart F, Cates W, Stewart GK, Kowal D, Guest F, Contraceptive Technology: Seventeenth Revised Edition. New York NY: Irvington Publishers, 1998.

¹ Among *typical* couples who initiate use of a method (not necessarily for the first time), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason.

² Among couples who initiate use of a method (not necessarily for the first time) and who use it *perfectly* (both consistently and correctly), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason.

³ Among couples attempting to avoid pregnancy, the percentage who continue to use a method for one year.

⁴ The percents becoming pregnant in columns (2) and (3) are based on data from populations where contraception is not used and from women who cease using contraception in order to become pregnant. Among such populations, about 89% become pregnant within one year. This estimate was lowered slightly (to 85%) to represent the percent who would become pregnant within one year among women now relying on reversible methods of contraception if they abandoned contraception altogether.

⁵ Foams, creams, gels, vaginal suppositories, and vaginal film.

⁶ Cervical mucus (ovulation) method supplemented by calendar in the pre-ovulatory and basal body temperature in the post-ovulatory phases.

⁷ With spermicidal cream or jelly.

⁸ Without spermicides.

⁹ The treatment schedule is one dose within 72 hours after unprotected intercourse, and a second dose 12 hours after the first dose. The Food and Drug Administration has declared the following brands of oral contraceptives to be safe and effective for emergency contraception: Ovral[®] (1 dose is 2 white pills), Alesse[®] (1 dose is 5 pink pills), Nordette[®] or Levlen[®] (1 dose is 2 light-orange pills), Lo/Ovral[®] (1 dose is 4 white pills), Triphasil[®] or Tri-Levlen[®] (1 dose is 4 yellow pills).

¹⁰ However, to maintain effective protection against pregnancy, another method of contraception must be used as soon as menstruation resumes, the frequency or duration of breastfeeds is reduced, bottle feeds are introduced, or the baby reaches six months of age.

Jencycla Tablets have not been studied for and are not indicated for use in emergency contraception.

HOW DO POPs WORK?

POPs can prevent pregnancy in different ways including:

- They make the cervical mucus at the entrance to the womb (the uterus) too thick for the sperm to get through to the egg.
- They prevent ovulation (release of the egg from the ovary) in about half of the cycles.
- They also affect other hormones, the fallopian tubes and the lining of the uterus.

YOU SHOULD NOT TAKE POPs

- If there is any chance you may be pregnant.
- If you have breast cancer.
- If you have bleeding between your periods that has not been diagnosed.
- If you are taking certain drugs for epilepsy (seizures) or for TB. (See “Using POPs with Other Medicines” below.)
- If you are hypersensitive, or allergic, to any component of this product.
- If you have liver tumors, either benign or cancerous.
- If you have acute liver disease.

RISKS OF TAKING POPs

Cigarette smoking greatly increases the possibility of suffering heart attacks and strokes. Women who use oral contraceptives are strongly advised not to smoke.

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 healthcare professional immediately.

Ectopic Pregnancy

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

Ovarian Cysts

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

Cancer of the Reproductive Organs and Breasts

Some studies in women who use combined oral contraceptives that contain both estrogen and a 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 insufficient data to determine whether the use of POPs similarly increases this risk.

A meta-analysis of 54 studies found a small increase in the frequency of having breast cancer diagnosed for women who were currently using combined oral contraceptives or had used them within the past ten years. This increase in the frequency of breast cancer diagnosis, within ten years of stopping use, was generally accounted for by cancers localized to the breast. There was no increase in the frequency of having breast cancer diagnosed ten or more years after cessation of use.

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 POPs increases the risk of developing cancer of the cervix.



TEMPLE Packaging Pvt. Ltd. 28476001 Email:-temple@bom4.vsnl.net.in			
Customer: Lupin Limited		Location: Indore	
Product Code & Name: 225088 Jencycla (norethindrone tab USP) Med Guide (Insert-Fr)			
SAP Code: xxxxxxxxxxxx		File No: xxxxx	
Version No.: 10		Date: 04.04.2013	
Open Size: 320 x 270 mm		Barcode: 225088	
Folding Size: 65 x 100 mm		Pharma code: xxxxx	
Colours: 1 (Black)		Perforation: No	
Substrate: 60 gsm Maplitho		Gluing: No	
Artwork Sr. No.: xxx			
Artwork Status: in process			
Note - This approval will be considered for final printing. Please recheck for corrections indicated earlier, in this proof also.			
Prepared by :	Checked by:	Approved by:	
<i>shaji</i>			
Customer Approval			
Checked by:		Approved by:	
Packaging Dvmpnt.	Production	Regulatory Affairs	Quality Assurance

Liver Tumors

In rare cases, combined oral contraceptives can cause benign but dangerous liver tumors. These benign liver tumors can rupture and cause fatal internal bleeding. In addition, some studies report an increased risk of developing liver cancer among women who use combined oral contraceptives. However, liver cancers are rare. There is insufficient data to determine whether POPs increase the risk of liver tumors.

Diabetic Women

Diabetic women taking POPs do not generally require changes in the amount of insulin they are taking. However, your healthcare professional may monitor you more closely under these conditions.

SEXUALLY TRANSMITTED DISEASES (STDs)

WARNING: POPs do not protect against getting or giving someone HIV (AIDS) or any other STD, such as chlamydia, gonorrhea, genital warts or herpes.

SIDE EFFECTS

Irregular Bleeding:

The most common side effect of POPs is a change in menstrual bleeding. Your periods may be either early or late, and you may have some spotting between periods. Taking pills late or missing pills can result in some spotting or bleeding.

Other Side Effects:

Less common side effects include headaches, tender breasts, nausea and dizziness. Weight gain, acne and extra hair on your face and body have been reported, but are rare.

If you are concerned about any of these side effects, check with your healthcare professional.

USING POPs WITH OTHER MEDICINES

Before taking a POP, inform your healthcare professional of any other medication, including over-the-counter medicine, that you may be taking. These medicines can make POPs less effective:

Medicines for seizures such as:

- Phenytoin (Dilantin®)
- Carbamazepine (Tegretol)
- Phenobarbital

Medicine for TB:

- Rifampin (Rifampicin)

Before you begin taking any new medicines be sure your healthcare professional knows you are taking a progestin-only birth control pill.

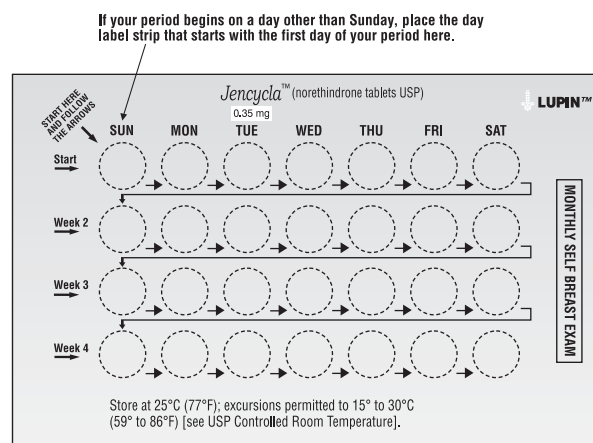
HOW TO TAKE POPs

IMPORTANT POINTS TO REMEMBER

- POPs must be taken at the same time every day, so choose a time and then take the pill at that same time every day. Every time you take a pill late, and especially if you miss a pill, you are more likely to get pregnant.
- Start the next pack the day after the last pack is finished. There is no break between packs. Always have your next pack of pills ready.
- You may have some menstrual spotting between periods. Do not stop taking your pills if this happens.
- If you vomit soon after taking a pill, use a backup method (such as a condom and/or a spermicide) for 48 hours.
- If you want to stop taking POPs, you can do so at any time, but, if you remain sexually active and don't wish to become pregnant, be certain to use another birth control method.
- If you are not sure about how to take POPs, ask your healthcare professional.

STARTING POPs

- It's best to take your first POP on the first day of your menstrual period.
- If you decide to take your first POP on another day, use a backup method (such as a condom and/or a spermicide) every time you have sex during the next 48 hours.
- If you have had a miscarriage or an abortion, you can start POPs the next day.
- Find:
 - Where on the pack to start taking pills,
 - In what order to take the pills (follow the arrows), and
 - The week numbers as shown in the picture below:



IF YOU ARE LATE OR MISS TAKING YOUR POPs

- If you are more than 3 hours late or you miss one or more POPs:
 - 1) **TAKE** a missed pill as soon as you remember that you missed it,
 - 2) **THEN** go back to taking POPs 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 POPs and use a backup method until you can talk to your healthcare professional.

IF YOU ARE BREASTFEEDING

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

IF YOU ARE SWITCHING PILLS

- If you are switching from the combined pills to POPs, take the first POP the day after you finish the last active combined pill. 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 POPs, but this is normal and to be expected.
- If you are switching from POPs to the combined pills, take the first active combined pill on the first day of your period, even if your POPs pack is not finished.
- If you switch to another brand of POPs, start the new brand anytime.
- If you are breastfeeding, 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.

PREGNANCY WHILE ON THE PILL

If you think you are pregnant, contact your healthcare professional. Even though research has shown that POPs do not cause harm to the unborn baby, it is always best not to take any drugs or medicines that you don't need when you are pregnant.

You should get a pregnancy test:

- If your period is late and you took one or more pills late or missed taking them and had sex without a backup method.
- Anytime it has been more than 45 days since the beginning of your last period.

WILL POPs AFFECT YOUR ABILITY TO GET PREGNANT LATER?

If you want to become pregnant, simply stop taking POPs. POPs will not delay your ability to get pregnant.

BREASTFEEDING

If you are breastfeeding, POPs should not affect the quality or amount of your breast milk or the health of your nursing baby. However, isolated cases of decreased milk production have been reported.

OVERDOSE

No serious problems have been reported when many pills were taken by accident, even by a small child, so there is usually no reason to treat an overdose.

OTHER QUESTIONS OR CONCERNS

If you have any questions or concerns, check with your healthcare professional. You can also ask for the more detailed "Professional Labeling" written for doctors and other healthcare professionals.

HOW TO STORE YOUR POPs

Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F).

Keep out of reach of children.

Jencycla™ is a trademark of Lupin Pharmaceuticals, Inc.

The other brands listed are trademarks of their respective owners and are not trademarks of Lupin Pharmaceuticals, Inc. The makers of these brands are not affiliated with and do not endorse Lupin Pharmaceuticals, Inc. or its products.

Distributed by:

Lupin Pharmaceuticals, Inc.
Baltimore, Maryland 21202
United States

Manufactured by:

Lupin Limited
Pithampur (M.P.) - 454 775
INDIA

April 2013

ID#: 225088

TEMPLE Packaging Pvt. Ltd. 28476001 Email:-temple@bom4.vsnl.net.in	
Customer: Lupin Limited	Location: Indore
Product Code & Name: 225088 Jencycla (norethindrone tab USP) Med Guide (Insert-Bk)	
SAP Code: xxxxxxxxxxxx	File No: xxxxx
Version No.: 10	Date: 04.04.2013
Open Size: 320 x 270 mm	Barcode: 225088
Folding Size: 65 x 100 mm	Pharma code: xxxxx
Colours: 1 (Black)	Perforation: No
Substrate: 60 gsm Maplitho	Gluing: No
Artwork Sr. No.: xxx	
Artwork Status: in process	
Note - This approval will be considered for final printing. Please recheck for corrections indicated earlier, in this proof also.	
Prepared by : <i>shaji</i>	Checked by: Approved by:
Customer Approval	
Checked by:	Approved by:
Packaging Dvmp.	Production Regulatory Affairs Quality Assurance