

## CLINICAL UPDATE

<b>Brand Name</b>	Lyleq™
<b>Generic Name</b>	norethindrone
<b>Drug Manufacturer</b>	Afaxys Pharma, LLC

### Clinical Update

#### TYPE OF CLINICAL UPDATE

New brand

#### FDA APPROVAL DATE

N/A

#### LAUNCH DATE

FDB Addition Date – 1/8/2021

#### REVIEW DESIGNATION

N/A

#### TYPE OF REVIEW

Abbreviated New Drug Approval (ANDA): 207304

#### DISPENSING RESTRICTIONS

N/A

### Overview

#### INDICATION(S) FOR USE

Progestin-only oral contraceptives are indicated for the prevention of pregnancy.

#### MECHANISMS OF ACTION

Lyleq™ progestin-only oral contraceptives prevent conception by suppressing ovulation in approximately half of users, thickening the cervical mucus to inhibit sperm penetration, lowering the mid-cycle LH and FSH peaks, slowing the movement of the ovum through the fallopian tubes, and altering the endometrium.

#### DOSAGE FORM(S) AND STRENGTH(S)

Tablet: 0.35 mg

#### DOSE & ADMINISTRATION

**Routine Contraception:** Take 0.35 mg (1 tablet) PO once daily at the same time of day as indicated by the pack, without interruption. Administration is continuous, with no interruption between pill packs. The interval between doses should not exceed 24 hours; missed doses greatly increase the risk of pregnancy.

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### EFFICACY

If used perfectly, the first-year failure rate for progestin-only oral contraceptives is 0.5%. However, the typical failure rate is estimated to be closer to 5%, due to late or omitted pills. The following table lists the pregnancy rates for users of all major methods of contraception.

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 <sup>3</sup> (4)
	Typical Use <sup>1</sup> (2)	Perfect Use <sup>2</sup> (3)	
Chance <sup>4</sup>	85	85	
Spermicides <sup>5</sup>	26	6	40
Periodic abstinence	25		63
Calendar		9	
Ovulation Method		3	
Sympto-Thermal <sup>6</sup>		2	
Post-Ovulation		1	
Cap <sup>7</sup>			
Parous Women	40	26	42
Nulliparous Women	20	9	56
Sponge			
Parous Women	40	20	42
Nulliparous Women	20	9	56
Diaphragm <sup>7</sup>	20	6	56
Withdrawal	19	4	
Condom <sup>8</sup>			
Female (Reality)	21	5	56
Male	14	3	61
Pill	5		71
Progestin only		0.5	
Combined		0.1	
IUDs			
Progesterone T	2	1.5	81
Copper T380A	0.8	0.6	78
LNg20	0.1	0.1	81
Depo-Provera <sup>®</sup>	0.3	0.3	70
Levonorgestrel Implants (Norplant <sup>®</sup> )	0.05	0.05	88
Female Sterilization	0.5	0.5	100
Male Sterilization	0.15	0.1	100

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