**INDICATIONS AND USAGE**

The use of oral contraceptives is associated with increased risks of several adverse medical reactions. These risks are related to the amount of estrogen and progestogen that a method delivers. The relative risk of certain adverse effects from oral-contraceptive use increases with age, while smoking interacts to increase the risk for hemorrhagic strokes. The relative risk of hemorrhagic stroke is reported to be 1.2 for non-smokers, 2.1 for light smokers, 5.8 for moderate smokers, and 14 for heavy smokers. The increase in risk of vascular disease from oral contraceptives is not related to length of use. However, a possible increase in risk of mortality with age for oral-contraceptive users was not discerned in a recent large study.

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A complete medical history and physical examination should be taken prior to the initiation of a contraceptive regimen. In the event of breakthrough bleeding or spotting, consideration should be given to whether the symptoms are due to the method of contraception or to a co-existing medical condition. It is recommended that LEVLEN® 21 Tablets be taken at the same time each day. During the first cycle of medication, the patient should be instructed to begin LEVLEN® 21 Tablets on the first day of menstruation. Also during the first cycle, the patient should be instructed to continue taking one tablet daily for 21 consecutive days. The 7 days of placebo should be taken at the end of cycle 1 and throughout the time the tablet is discontinued. This schedule is repeated for the entire duration of use.

**ADVERSE REACTIONS**

**I. DRUG-RELATED RISKS OF ORAL CONTRACEPTIVES**

A. Vascular Disease

The relative risk of developing venous thromboembolic disease associated with oral contraceptive use varies with the estrogen and progestin combination. The relative risk of developing venous thromboembolic disease associated with oral contraceptive use varies with the estrogen and progestin combination. The relative risk of developing venous thromboembolic disease associated with oral contraceptive use varies with the estrogen and progestin combination. The relative risk of developing venous thromboembolic disease associated with oral contraceptive use varies with the estrogen and progestin combination.

B. Cancer

An increased risk of the following serious adverse reactions has been demonstrated in postmenopausal women: endometrial cancer, breast cancer, and retinal vascular lesions. The risk was not demonstrated in other age groups. In another study in Great Britain which included 7,740 deaths, a possible increase in risk of mortality with age for oral-contraceptive users was not discerned. The relative risk of developing colorectal cancer is reported to be 1.2 for non-smokers, 2.1 for light smokers, 5.8 for moderate smokers, and 14 for heavy smokers.

C. Other Adverse Reactions

**A. CONTRAINDICATIONS AND PRECAUTIONS**

Contraindications are as follows: Known or suspected carcinoma of the breast; cerebral-vascular or coronary-artery disease; known or suspected liver tumors; undiagnosed abnormal genital bleeding; known or suspected thrombophlebitis or thromboembolic disease due to oral contraceptives; known or suspected pregnancy; hemorrhage or extrusion of the intrauterine device; women in whom use of an oral contraceptive is known to be hazardous to the mother or fetus; women who are being treated for peptic ulcer; women with a history of migraines, particularly if complicated by visual disturbances or nausea or vomiting; women who have had chronic dysmenorrhea; women with a history of gallbladder disease or gallstones; women who have had a stroke or thromboembolic disease; women who have a personal or family history of diabetes mellitus; or women who have a history of jaundice associated with oral contraceptives.

**II. INDICATIONS AND USAGE**

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is day one.) Withdrawal bleeding usually occurs within 3 days following the and then 7 pink inert tablets for twenty-eight (28) consecutive days, begin- 

...tablets on the next day after ingestion of the last pink tablet, regardless of 

...course, following the same schedule. She begins taking her light-orange 

...there are some women who are at high risk of developing certain serious 

...References furnished upon request.

In the nonlactating mother, LEVLEN® 28 Tablets may be initiated post-

...misses one or more pink tablets, she is still protected against pregnancy 

...It the patient has adhered to the prescribed regimen and misses two 

...of birth control. This leaflet will give you much of the information you will 

INTRODUCTION

...happens to less than 1% when used perfectly, without missing any pills. Typical 

...advice with regard to regular check-ups while you are on the pill.

WHO SHOULD NOT TAKE ORAL CONTRACEPTIVES

...who use oral contraceptives should not smoke.

...Periodic abstinence 20%

...Condom alone 12%

...IUD 6%

...In packages of:

...NDC 50419-021, 21 active, light-orange tablets marked “B” on one side 

...21 round tablets as follows:

...how to use the pill properly so that it will be as effective as possible. How-

...it the patient has adhered to the prescribed regimen and misses two 

...advice with regard to regular check-ups while you are on the pill.

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