

DRUG MARKET WITHDRAWAL

**DESOGESTREL AND ETHINYL ESTRADIOL TABLETS USP 0.15 MG/ 0.02 MG AND
ETHINYL ESTRADIOL TABLETS USP 0.01 MG (VIORELE)
28 X 3 pack (Tablets)
(NDC 68462-318-29)**

September 2, 2025

Dear Pharmacy, Wholesale and Retail Customer:

This is to inform you that Glenmark is initiating a Market Withdrawal at the Retail level involving the following prescription product:

Desogestrel and Ethinyl Estradiol Tablets USP 0.15 mg/ 0.02 mg and Ethinyl Estradiol Tablets USP 0.01 mg (Brand Name – Viorele)

Sr. No.	NDC	Batch Number	Pack Size	Expiry Date
1	68462-318-29	20240086	3 X 28 tablet pack	January 2026
2	68462-318-29	20240128	3 X 28 tablet pack	February 2026

Glenmark is initiating a market withdrawal at the **Retail level** for the above-identified batches of Desogestrel and Ethinyl Estradiol Tablets USP 0.15 mg/ 0.02 mg and Ethinyl Estradiol Tablets USP 0.01 mg (Viorele) due to failure results reported for the Related Substances (By HPLC) test for commercial annual stability batch # 20230733 at the long-term (25°C/60% RH) 18 month time stability interval. Recall is being initiated for batch # 20230733 separately.

Glenmark filed Prior Approval Supplement (PAS) and received the approval on April 25, 2024, to change the drug product formula to control the degradation of 'Impurity D' and 'Total impurities' since the product is sensitive to peroxide degradation (Oxygen). The revised manufacturing formulation is implemented from July 2024. All the batches manufactured post July 2024 are manufactured using the revised formulation.

As of today, three (3) batches of Viorele tablets are in the market and within shelf life that have been manufactured before the implementation of the revised formulation. Out of these 3 batches, subject OOS batch # 20230733 was charged as the annual stability batch for the year 2023. As part of the impact assessment, reserve sample of the other two (2) batches were tested for Related Substances (By HPLC), and the results comply as per the specification.

Hence, as an abundance of caution, Glenmark is initiating a market withdrawal of both these batches # 20240086 (Expiry – January 2026) and # 20240128 (Expiry - February 2026) that are within shelf life, and manufactured before the implementation of the revised formulation.

To date, Glenmark has not received any reports of adverse events related to this subjected batches. The health hazard assessment concluded that the observed OOS results in related substance test are not considered a clinically significant risk to patient health and safety.

Please see the details of product batches listed in the above table and refer to the enclosed product labels for ease in identifying the product.

Please examine your inventory, and if you have any inventory available for the batches specified in the above table, you should quarantine such product immediately and not dispense any further product from these lots. Glenmark Pharmaceuticals Inc., USA, initiated shipment of this product on April 16, 2024.

In addition, if you are a wholesaler/ distributor who has further distributed this product, please identify those retail customers and notify them at once of this market withdrawal. Your notification to your retail customers may be enhanced by including a copy of this market withdrawal notification letter. Again, this market withdrawal should be carried out to the retail level only. Because this is not a consumer-level market withdrawal, notice to the consumer level is not required.

Glenmark is requesting the batches specified in the above table to be returned to Inmar Rx Solutions (address below) using the Postage Paid Product Return label that was provided in your Market Withdrawal Return Packet.

Inmar Rx Solutions
3845 Grand Lakes Way
Grand Prairie, TX 75050

Please complete and return the enclosed response form preferably within 72 hours of receipt of this notification. Please either fax your response to 817-868-5362 or email to Rxrecalls@Inmar.com.

If you have any questions regarding your market withdrawal return please contact Inmar at **877-837-7681**.

Inmar office hours are Monday through Friday, from 9 am to 5 pm EST.

This market withdrawal is being made with the knowledge of the Food and Drug Administration.

Thank you for your cooperation,

Sincerely,

GLENMARK PHARMACEUTICALS INC., USA

thomas.callaghan@g
lenmarkpharma.com

Digitally signed by
thomas.callaghan@glenmarkpha
rma.com
Date: 2025.09.02 11:30:22 -04'00'

Thomas Callaghan

Executive Director - Regulatory Affairs, North America

US Agent for Glenmark Pharmaceuticals Limited

Enclosure(s):

Product Labels

Market Withdrawal Return Response Form

Product label:

Desogestrel and Ethinyl Estradiol Tablets USP 0.15 mg/ 0.02 mg and Ethinyl Estradiol Tablets USP 0.01 mg (Brand Name – Viorele)



SAME SIZE ARTWORKS
CRT SIZE : 155 MM X 45 MM X 95 MM

UNVARNISHED AREA
95 mm x 20 mm
FOR (G) & EXP

(Desogestrel and Ethinyl Estradiol Tablets, USP 0.15 mg/0.02 mg and Ethinyl Estradiol Tablets, USP 0.01 mg)

Each white to off-white tablet contains 0.15 mg desogestrel, USP and 0.02 mg ethinyl estradiol, USP. Each pale green to yellowish green tablet contains inert ingredients and each light yellow to yellow tablet contains 0.01 mg ethinyl estradiol, USP.

IMPORTANT: Each pouch contains Detailed Patient Labeling and Brief Patient Labeling. Both should be included with each package dispensed to the patient.

Usual Dosage: One tablet daily as prescribed. See package insert for full prescribing information.

Store at 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature].

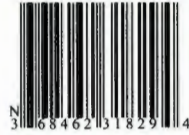
Manufactured by:
Glenmark Pharmaceuticals Limited
Colvale-Barder, Goa 403513, India

GO/DRUGS/785

Manufactured for:
Glenmark Pharmaceuticals Inc., USA,
Mahwah, NJ 07430

08/21

NOTE: THIS PACKAGE IS NOT CHILD RESISTANT. KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN.



Questions? 1 (888) 721-7115
www.glenmarkpharma-us.com

glenmark

VIORELE®
(Desogestrel and Ethinyl Estradiol Tablets, USP
0.15 mg/0.02 mg and Ethinyl Estradiol Tablets, USP 0.01 mg)

NDC 68462-318-29

**28 day
Regimen**

VIORELE®
(Desogestrel and Ethinyl Estradiol
Tablets, USP 0.15 mg/0.02 mg and
Ethinyl Estradiol Tablets, USP 0.01 mg)

3 Blisters
each containing 28 tablets

Rx only
This product (like all oral contraceptive) is intended to prevent pregnancy. It does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

glenmark

VIORELE®
(Desogestrel and Ethinyl Estradiol Tablets, USP 0.15 mg/0.02 mg and Ethinyl Estradiol Tablets, USP 0.01 mg)

glenmark

VIORELE®
(Desogestrel and Ethinyl Estradiol Tablets, USP
0.15 mg/0.02 mg and Ethinyl Estradiol Tablets, USP 0.01 mg)

DATE: 20-08-2021
VERSION: 06

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May Breedlove
Digitally signed by May Breedlove
Date: 2021.08.23 13:32:33 -04'00'

Carole Capella
Digitally signed by Carole Capella
Date: 2021.08.23 14:27:55 -04'00'

Kristin DiStefano
Digitally signed by Kristin DiStefano
Date: 2021.08.23 15:11:48 -04'00'

VIOREL[®] (Desogestrel and Ethinyl Estradiol Tablets, USP 0.15 mg/0.02 mg and Ethinyl Estradiol Tablets, USP 0.01 mg)



Patient Package Insert Brief Summary

VIOREL[®] (Desogestrel and Ethinyl Estradiol Tablets, USP 0.15 mg/0.02 mg and Ethinyl Estradiol Tablets, USP 0.01 mg)

Cigarette smoking increases the risk of serious cardiovascular side effects from oral contraceptive use. This risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use oral contraceptives are strongly advised not to smoke.

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

Oral contraceptives, also known as "birth control pills" or "the pill", are taken to prevent pregnancy, and when taken correctly, have a failure rate of about 1% per year when used without missing any pills. The typical failure rate of large numbers of pill users is less than 5% per year when women who miss pills are included. For most women, oral contraceptives are also free of serious or unpleasant side effects. However, forgetting to take pills considerably increases the chances of pregnancy.

For the majority of women, oral contraceptives can be taken safely. But there are some women who are at high risk of developing certain serious diseases that can be life-threatening or may cause temporary or permanent disability. The risks associated with taking oral contraceptives increase significantly if you:

- smoke
- have high blood pressure, diabetes, high cholesterol
- have or have had clotting disorders, heart attack, stroke, angina pectoris, cancer of the breast, jaundice, or malignant or benign liver tumors.

Although cardiovascular disease risks may be increased with oral contraceptive use after age 40 in healthy, non-smoking women (even with the newer low-dose formulations), there are also greater potential health risks associated with pregnancy in older women.

You should not take the pill if you suspect you are pregnant or have unexplained vaginal bleeding.

Most side effects of the pill are not serious. The most common such effects are nausea, vomiting, bleeding between menstrual periods, weight gain, breast tenderness, headache, and difficulty wearing contact lenses. These side effects, especially nausea and vomiting, may subside within the first three months of use. The serious side effects of the pill occur very infrequently, especially if you are in good health and are young. However, you should know that the following medical conditions have been associated with or made worse by the pill:

1. Blood clots in the legs (thrombophlebitis) or lungs (pulmonary embolism), stroke or rupture of a blood vessel in the brain (stroke), blockage of blood vessels in the heart (heart attack or angina pectoris) or other organs of the body. As mentioned above, smoking increases the risk of heart attacks and strokes, and subsequent serious medical consequences.
2. Liver tumors, which may rupture and cause severe bleeding. A possible but not definite association has been found with the pill and liver cancer. However, liver cancers are extremely rare. The chance of developing liver cancer from using the pill is thus even rarer.
3. High blood pressure, although blood pressure usually returns to normal when the pill is stopped.

The symptoms associated with these serious side effects are discussed in the detailed leaflet given to you with your supply of pills. Notify your doctor or healthcare provider if you notice any unusual physical disturbances while taking the pill. In addition, drugs such as rifampin, as well as some anticonvulsants and some antibiotics may decrease oral contraceptive effectiveness.

There may be slight increases in the risk of breast cancer among current users of hormonal birth control pills with longer duration of use of 8 years or more. 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.

Taking the pill provides some important non-contraceptive benefits. These include less painful menstruation, less menstrual blood loss and anemia, fewer pelvic infections, and fewer cancers of the ovary and the lining of the uterus. Be sure to discuss any medical condition you may have with your doctor or healthcare provider. Your doctor or healthcare provider will take a medical and family history before prescribing oral contraceptives and will examine you. The physical examination may be delayed to another time if you request it and your doctor or healthcare provider believes that it is a good medical practice to postpone it. You should be reexamined at least once a year while taking oral contraceptives. The detailed patient information leaflet gives you further information which you should read and discuss with your doctor or healthcare provider.

This product (like all oral contraceptives) is intended to prevent pregnancy. It does not protect against transmission of HIV (AIDS) and other sexually transmitted infections such as chlamydia, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis.

INSTRUCTIONS TO PATIENTS

HOW TO TAKE THE PILL

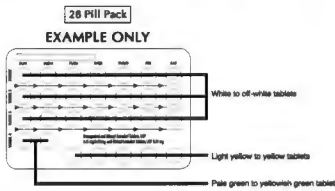
IMPORTANT POINTS TO REMEMBER

BEFORE YOU START TAKING YOUR PILLS:

1. BE SURE TO READ THESE DIRECTIONS: Before you start taking your pills. Anytime you are not sure what to do.
2. THE RIGHT WAY TO TAKE THE PILL IS TO TAKE ONE PILL EVERY DAY AT THE SAME TIME. If you miss pills you could get pregnant. This includes starting the pack late. The more pills you miss, the more likely you are to get pregnant.
3. MANY WOMEN HAVE SPOTTING OR LIGHT BLEEDING, OR MAY FEEL SICK TO THEIR STOMACH DURING THE FIRST 1 TO 3 PACKS OF PILLS. If you feel sick to your stomach, do not stop taking the pill. The problem will usually go away. If it doesn't go away, check with your doctor or healthcare provider.
4. MISSING PILLS CAN ALSO CAUSE SPOTTING OR LIGHT BLEEDING, even when you make up these missed pills. On the days you take 2 pills to make up for missed pills, you could also feel a little sick to your stomach.
5. IF YOU HAVE VOMITING OR DIARRHEA, for any reason, or IF YOU TAKE SOME MEDICINES, including some antibiotics, your pills may not work as well. Use a back-up method (such as condoms, foam, or sponge) until you check with your doctor or healthcare provider.
6. IF YOU HAVE TROUBLE REMEMBERING TO TAKE THE PILL, talk to your doctor or healthcare provider about how to make pill-taking easier or about using another method of birth control.
7. IF YOU HAVE ANY QUESTIONS OR ARE UNSURE ABOUT THE INFORMATION IN THIS LEAFLET, call your doctor or healthcare provider.

BEFORE YOU START TAKING YOUR PILLS

1. DECIDE WHAT TIME OF DAY YOU WANT TO TAKE YOUR PILL. It is important to take it at about the same time every day.
2. LOOK AT YOUR PILL PACK. IT WILL HAVE 28 PILLS. This 28-pill pack has 26 "active" (white to off-white and light yellow to yellow) pills (with hormones) and 2 "inactive" (pale green to yellowish green) pills (without hormones).
3. ALSO FIND:
 - 1) where on the pack to start taking the pills,
 - 2) in what order to take the pills (follow the arrows) and
 - 3) the week numbers as shown in the picture below.



4. BE SURE YOU HAVE READY AT ALL TIMES: ANOTHER KIND OF BIRTH CONTROL (such as condoms, foam, or sponge) to use as a back-up in case you miss pills.

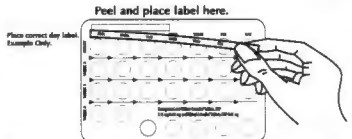
AN EXTRA, FULL PILL PACK

WHEN TO START THE FIRST PACK OF PILLS

You have a choice of which day to start taking your first pack of pills. Decide with your doctor or healthcare provider which is the best day for you. Pick a time of day which will be easy to remember.

DAY 1 START:

1. Pick the day label strip that starts with the first day of your period (this is the day you start bleeding or spotting, even if it is almost midnight when the bleeding begins).
2. Place this day label strip in the cycle tablet blister over the area that has the days of the week (starting with Sunday) imprinted.



Note: If the first day of your period is a Sunday, you can skip steps #1 and #2.

3. Take the first "active" (white to off-white) pill of the first pack during the first 24 hours of your period.
4. You will not need to use a back-up method of birth control, since you are starting the pill at the beginning of your period.

SUNDAY START:

1. Take the first "active" (white to off-white) pill of the first pack on the Sunday after your period starts, even if you are still bleeding. If your period begins on Sunday, start the pack that same day.
2. Use another method of birth control as a back-up method if you have sex anytime from the Sunday you start your first pack until the next Sunday (7 days). Condoms, foam, or the sponge are good back-up methods of birth control.

WHAT TO DO DURING THE MONTH

1. TAKE ONE PILL AT THE SAME TIME EVERY DAY UNTIL THE PACK IS EMPTY. Do not skip pills even if you are spotting or bleeding between monthly periods or feel sick to your stomach (nausea).
2. You will not need to use a back-up method of birth control, since you are starting the pill at the beginning of your period.

2. WHEN YOU FINISH A PACK OR SWITCH YOUR BRAND OF PILLS: 21 pills: Wait 7 days to start the next pack. You will probably have your period during that week. Be sure that no more than 7 days pass between 21-day packs. 28 pills: Start the next pack on the day after your last pill. Do not wait any days between packs.

WHAT TO DO IF YOU MISS PILLS

- If you MISS 1 "active" (white to off-white) pill:
1. Take it as soon as you remember. Take the next pill at your regular time. This means you take 2 pills in 1 day.
 2. You do not need to use a back-up birth control method if you have sex.
- If you MISS 2 "active" (white to off-white) pills in a row in WEEK 1 OR WEEK 2 of your pack:
1. Take 2 pills on the day you remember and 2 pills the next day.
 2. Then take 1 pill a day until you finish the pack.
 3. You MAY BECOME PREGNANT if you have sex in the 7 days after you miss pills. You MUST use another birth control method (such as condoms, foam, or sponge) as a back-up method for those 7 days.
- If you MISS 2 "active" (white to off-white) pills in a row in WEEK 3:
1. If you are a Day 1 Starter: THROW OUT the rest of the pill pack and start a new pack that same day. If you are a Sunday Starter: Keep taking 1 pill every day until Sunday. On Sunday, THROW OUT the rest of the pack and start a new pack of pills that same day.
 2. You may not have your period this month but this is expected. However, if you miss your period 2 months in a row, call your doctor or healthcare provider because you might be pregnant.
 3. You MAY BECOME PREGNANT if you have sex in the 7 days after you miss pills. You MUST use another birth control method (such as condoms, foam, or sponge) as a back-up method for those 7 days.
- If you MISS 3 OR MORE "active" (white to off-white) pills in a row (during the first 3 weeks):

1. If you are a Day 1 Starter: THROW OUT the rest of the pill pack and start a new pack that same day. If you are a Sunday Starter: Keep taking 1 pill every day until Sunday. On Sunday, THROW OUT the rest of the pack and start a new pack of pills that same day.
2. You may not have your period this month but this is expected. However, if you miss your period 2 months in a row, call your doctor or healthcare provider because you might be pregnant.
3. You MAY BECOME PREGNANT if you have sex in the 7 days after you miss pills. You MUST use another birth control method (such as condoms, foam, or sponge) as a back-up method for those 7 days.

A REMINDER FOR THOSE ON 28-DAY PACKS

If you forget any of the 2 (pale green to yellowish green) or 5 (light yellow to yellow) pills in Week 4, THROW AWAY the pills you missed. Keep taking 1 pill each day until the pack is empty. You do not need a back-up method.

FINALLY, IF YOU ARE STILL NOT SURE WHAT TO DO ABOUT THE PILLS YOU HAVE MISSED: USE A BACK-UP METHOD anytime you have sex. KEEP TAKING ONE "ACTIVE" (WHITE TO OFF-WHITE) PILL EACH DAY until you can reach your doctor or healthcare provider.

Manufactured by:
Glenmark Pharmaceuticals Limited
Covalde-Bardex, Goa 403513, India

Manufactured for:

glenmark
Glenmark Pharmaceuticals Inc., USA
Mahwah, NJ 07430

Questions? 1 (888) 721-7115
www.glenmarkpharma-usa.com

April 2023

DETAILED PATIENT PACKAGE INSERT

VIOREL[®] (Desogestrel and Ethinyl Estradiol Tablets, USP 0.15 mg/0.02 mg and Ethinyl Estradiol Tablets, USP 0.01 mg)

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

Rx only

PLEASE NOTE: This labeling is revised from time to time as important new medical information becomes available. Therefore, please review this labeling carefully.

DESCRIPTION

The following oral contraceptive product contains a combination of a progestin and estrogen, the two kinds of female hormones:
Each white to off-white tablet contains 0.15 mg desogestrel, USP and 0.02 mg ethinyl estradiol, USP. Each pale green to yellowish green tablet contains inert ingredients and each light yellow to yellow tablet contains 0.01 mg ethinyl estradiol, USP.

INTRODUCTION

Any woman who considers using oral contraceptives (the birth control pill or the pill) should understand the benefits and risks of using this form of birth control. This leaflet will give you much of the information you will need to make this decision and will also help you determine if you are at risk of developing any of the serious side effects of the pill. It will tell you how to use the pill properly so that it will be as effective as possible. However, this leaflet is not a replacement for a careful discussion between you and your doctor or healthcare provider. You should discuss the information provided in this leaflet with him or her, both when you first start taking the pill and during your visits. You should also follow your doctor's or your healthcare provider's advice with regard to regular check-ups while you are on the pill.

EFFECTIVENESS OF ORAL CONTRACEPTIVES

Oral contraceptives or "birth control pills" or "the pill" are used to prevent pregnancy and are more effective than other non-surgical methods of birth control. When they are taken correctly, the chance of becoming pregnant is less than 1% (1 pregnancy per 100 women per year of use) when used perfectly, without missing any pills. Typical failure rates are actually 5% per year. The chance of becoming pregnant increases with each missed pill during a menstrual cycle. In comparison, typical failure rates for other methods of birth control during the first year of use are as follows:

Implants (2 or 6 capsules): <1%	Male sterilization: <1%
Injection: <1%	Cervical Cap with spermicides: 20 to 40%
IUD: <1 to 2%	Condom alone (male): 14%
Diaphragm with spermicides: 20%	Condom alone (female): 21%
Spermicides alone: 26%	Periodic abstinence: 25%
Vaginal sponge: 20 to 40%	Withdrawal: 19%
Female sterilization: <1%	No methods: 85%

WHO SHOULD NOT TAKE ORAL CONTRACEPTIVES

Cigarette smoking increases the risk of serious cardiovascular side effects from oral contraceptive use. This risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use oral contraceptives are strongly advised not to smoke.

Some women who use oral contraceptives should not take the pill if you are pregnant or think you may be pregnant. You should also not use the pill if you have any of the following conditions:

- A history of heart attack or stroke
- Blood clots in the legs (thrombophlebitis), lungs (pulmonary embolism), or eyes
- A history of blood clots in the deep veins of your legs
- Chest pain (angina pectoris)
- Known or suspected breast cancer
- Unexplained vaginal bleeding (until a diagnosis is reached by your doctor)
- Yellowing of the whites of the eyes or of the skin (jaundice) during pregnancy or during previous use of the pill
- Liver tumor (benign or cancerous)
- Hepatitis C and are taking any drug combination containing ombitasvir/

paritaprevir/ritonavir, with or without dasabuvir. This may increase levels of the liver enzyme "alanine aminotransferase" (ALT) in the blood.

Tell your doctor or healthcare provider if you have ever had any of these conditions. Your doctor or healthcare provider can recommend another method of birth control.

OTHER CONSIDERATIONS BEFORE TAKING ORAL CONTRACEPTIVES

Tell your doctor or healthcare provider if you have:

- Breast nodules, fibrocystic disease of the breast, an abnormal breast x-ray or mammogram
- Diabetes
- Elevated cholesterol or triglycerides
- High blood pressure
- Migraine or other headaches or epilepsy
- Depression
- Gallbladder, heart, or kidney disease
- History of scanty or irregular menstrual periods.

Women with any of these conditions should be checked often by their doctor or healthcare provider if they choose to use oral contraceptives.

Also, be sure to inform your doctor or healthcare provider if you smoke or are on any medications.

RISKS OF TAKING ORAL CONTRACEPTIVES

1. Risk of developing blood clots

Blood clots and blockage of blood vessels are one of the most serious side effects of taking oral contraceptives and can cause death or serious disability. In particular, a clot in the leg can cause thrombophlebitis and a clot that travels to the lungs can cause a sudden blockage of the vessel carrying blood to the lungs. The risks of these side effects may be greater with desogestrel-containing oral contraceptives such as desogestrel/ethinyl estradiol and ethinyl estradiol than with certain other low-dose pills. Rarely, clots occur in the blood vessels of the eye and may cause blindness, double vision, or impaired vision.

If you take oral contraceptives and need elective surgery, need to stay in bed for a prolonged illness or have recently delivered a baby, you may be at risk of developing blood clots. You should consult your doctor or healthcare provider about stopping oral contraceptives three to four weeks before surgery and not taking oral contraceptives for two weeks after surgery or during bed rest. You should also not take oral contraceptives soon after delivery of a baby. It is advisable to wait for at least four weeks after delivery if you are not breastfeeding or four weeks after a second trimester abortion. If you are breastfeeding, you should wait until you have weaned your child before using the pill (see Breastfeeding in GENERAL PRECAUTIONS).

The risk of circulatory disease in oral contraceptive users may be higher in users of high dose pills and may be greater with longer duration of oral contraceptive use. In addition, some of these increased risks may continue for a number of years after stopping oral contraceptives. The risk of venous thromboembolic disease associated with oral contraceptives does not increase with length of use and disappears after pill use is stopped. The risk of abnormal blood clotting increases with age in both users and non-users of oral contraceptives, but the increased risk from the oral contraceptive appears to be present at all ages. For women aged 20 to 44 it is estimated that about 1 in 2000 using oral contraceptives will be hospitalized each year because of abnormal clotting. Among non-users in the same age group, about 1 in 20,000 would be hospitalized each year. For oral contraceptive users in general, it has been estimated that in women between the ages of 15 and 34 the risk of death due to a circulatory disorder is about 1 in 12,000 per year, whereas for non-users the rate is about 1 in 50,000 per year. In the age group 35 to 44, the risk is estimated to be about 1 in 2,500 per year for oral contraceptive users and about 1 in 10,000 per year for non-users.

2. Heart attacks and strokes

Oral contraceptives may increase the tendency to develop strokes (stoppage or rupture of blood vessels in the brain) and angina pectoris and heart attacks (blockage of blood vessels in the heart). Any of these conditions can cause death or serious disability.

Smoking greatly increases the possibility of suffering heart attacks and strokes. Furthermore, smoking and the use of oral contraceptives greatly increase the chances of developing and dying of heart disease.

3. Gallbladder disease

Oral contraceptives users probably have a greater risk than non-users of having gallbladder disease, although this risk may be related to pills containing high doses of estrogens.

4. Liver tumors

In rare cases, oral contraceptives can cause benign but dangerous liver tumors. These benign liver tumors can rupture and cause fatal internal bleeding. In addition, a possible but not definite association has been found with the pill and liver cancers in two studies, in which a few women who developed these very rare liver cancers were found to have used oral contraceptives for long periods. However, liver cancers are extremely rare. The chance of developing liver cancer from using the pill is thus even rarer.

5. Risk of Cancer

It is not known if hormonal birth control pills cause breast cancer. Some studies, but not all, suggest that there could be a slight increase in the risk of breast cancer among current users with longer duration of use.

If you have breast cancer now, or have had it in the past, do not use hormonal birth control because some breast cancers are sensitive to hormones. 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. There is insufficient evidence to rule out the possibility that pills may cause such cancers.

ESTIMATED RISK OF DEATH FROM A BIRTH CONTROL METHOD OR PREGNANCY
All methods of birth control and pregnancy are associated with a risk of developing certain diseases which may lead to disability or death. An estimate of the number of deaths associated with different methods of birth control and pregnancy has been calculated and is shown in the following table.

ANNUAL NUMBER OF BIRTH-RELATED OR METHOD-RELATED DEATHS ASSOCIATED WITH CONTROL OF FERTILITY PER 100,000 NON-STERILE WOMEN, BY FERTILITY CONTROL METHOD ACCORDING TO AGE

Method of control and outcome	15 to 19	20 to 24	25 to 29	30 to 34	35 to 39	40 to 44
No fertility control methods*	7	7.4	9.1	14.8	25.7	28.2
Oral contraceptives non-smoker**	0.3	0.5	0.9	1.9	13.8	31.6
Oral contraceptives smoker**	2.2	3.4	6.6	13.5	51.1	117.2
IUD***	0.8	0.8	1	1	1.4	1.4
Condom*	1.1	1.6	0.7	0.2	0.3	0.4
Diaphragm/spermicide*	1.9	1.2	1.2	1.3	2.2	2.8
Periodic abstinence*	2.5	1.6	1.6	1.7	2.9	3.6

GLENMARK PHARMACEUTICALS LTD.		DATE: 06.04.2023	PANTONE SHADE NO: Black
PRODUCT NAME: VIOREL BSP & DPL INSERT US R2		PKG. DEV.:	Item code, Version, Consistency of Design, Equipment used, Pack Size, Dimensions & Layout
ITEM CODE: PE63502	VERSION: 0423-1	RA	Regulatory Test
PHARMACODE: NA	BARCODE: 63502	PRODUCTION:	Machine Suitability
COUNTRY: US		QA:	Erros Test
LOCATION: Goa		REMARKS: NA	
PACK: fold: 80x60mm			
ACTUAL SIZE: 390X410 MM			
SPECIFICATION: 60 GSM LAPLITHO PAPER			FCPCD001/01.00

- * Deaths are birth related
** Deaths are method related

In the above table, the risk of death from any birth control method is less than the risk of childbirth, except for oral contraceptive users over the age of 35 who smoke and pill users over the age of 40 even if they do not smoke. It can be seen in the table that for women aged 15 to 39, the risk of death was highest with pregnancy (7 to 26 deaths per 100,000 women, depending on age). Among pill users who do not smoke, the risk of death is always lower than that associated with pregnancy for any age group, although over the age of 40, the risk increases to 32 deaths per 100,000 women, compared to 28 associated with pregnancy at that age. However, for pill users who smoke and are over the age of 35, the estimated number of deaths exceeds those for other methods of birth control. If a woman is over the age of 40 and smokes, her estimated risk of death is four times higher (117/100,000 women) than the estimated risk associated with pregnancy (28/100,000 women) in that age group. The suggestion that women over 40 who do not smoke should not take oral contraceptives is based on information from older, high-dose pills and on less selective use of pills than is practiced today. An Advisory Committee of the FDA discussed this issue in 1989 and recommended that the benefits of oral contraceptive use by healthy, non-smoking women over 40 years of age may outweigh the possible risks. However, all women, especially older women, are cautioned to use the lowest dose pill that is effective.

WARNING SIGNALS

If any of these adverse effects occur while you are taking oral contraceptives, call your doctor or healthcare provider immediately:

- Sharp chest pain, coughing of blood, or sudden shortness of breath (indicating a possible clot in the lung)
- Pain in the calf (indicating a possible clot in the leg)
- Crushing chest pain or heaviness in the chest (indicating a possible heart attack)
- Sudden severe headache or vomiting, dizziness or fainting, disturbances of vision or speech, weakness, or numbness in an arm or leg (indicating a possible stroke)
- Sudden partial or complete loss of vision (indicating a possible clot in the eye)
- Breast lumps (indicating possible breast cancer or fibrocystic disease of the breast; ask your doctor or healthcare provider to show you how to examine your breasts)
- Severe pain or tenderness in the stomach area (indicating a possibly ruptured liver tumor)
- Difficulty in sleeping, weakness, lack of energy, fatigue, or change in mood (possibly indicating severe depression)
- Jaundice or a yellowing of the skin or eyeballs, accompanied frequently by fever, fatigue, loss of appetite, dark colored urine, or light colored bowel movements (indicating possible liver problems)

SIDE EFFECTS OF ORAL CONTRACEPTIVES

1. Vaginal bleeding

Irregular vaginal bleeding or spotting may occur while you are taking the pills. Irregular bleeding may vary from slight staining between menstrual periods to breakthrough bleeding which is a flow much like a regular period. Irregular bleeding occurs most often during the first few months of oral contraceptive use, but may also occur after you have been taking the pill for some time. Such bleeding may be temporary and usually does not indicate any serious problems. It is important to continue taking your pills on schedule. If the bleeding occurs in more than one cycle or lasts for more than a few days, talk to your doctor or healthcare provider.

2. Contact lenses

If you wear contact lenses and notice a change in vision or an inability to wear your lenses, contact your doctor or healthcare provider.

3. Fluid retention

Oral contraceptives may cause edema (fluid retention) with swelling of the fingers or ankles and may raise your blood pressure. If you experience fluid retention, contact your doctor or healthcare provider.

4. Melasma

A spotty darkening of the skin is possible, particularly of the face.

5. Other side effects

Other side effects may include nausea and vomiting, change in appetite, headache, nervousness, depression, dizziness, loss of scalp hair, rash, and vaginal infections. If any of these side effects bother you, call your doctor or healthcare provider.

GENERAL PRECAUTIONS

1. Missed periods and use of oral contraceptives before or during early pregnancy
There may be times when you may not menstruate regularly after you have completed taking a cycle of pills. If you have taken your pills regularly and miss one menstrual period, continue taking your pills for the next cycle but be sure to inform your doctor or healthcare provider before doing so. If you have not taken the pills daily as instructed and missed a menstrual period, or if you missed two consecutive menstrual periods, you may be pregnant. Check with your doctor or healthcare provider immediately to determine whether you are pregnant. Do not continue to take oral contraceptives until you are sure you are not pregnant, but continue to use another method of contraception.

There is no conclusive evidence that oral contraceptive use is associated with an increase in birth defects, when taken inadvertently during early pregnancy. Previously, a few studies had reported that oral contraceptives might be associated with birth defects, but these studies have not been confirmed. Nevertheless, oral contraceptives or any other drugs should not be used during pregnancy unless clearly necessary and prescribed by your doctor or healthcare provider. You should check with your doctor or healthcare provider about risks to your unborn child of any medication taken during pregnancy.

2. While breastfeeding

If you are breastfeeding, consult your doctor or healthcare provider before starting oral contraceptives. Some of the drug will be passed on to the child in the milk. A few adverse effects on the child have been reported, including yellowing of the skin (jaundice) and breast enlargement. In addition, oral contraceptives may decrease the amount and quality of your milk. If possible, do not use oral contraceptives while breastfeeding. While breastfeeding, you should use another method of contraception since breastfeeding provides only partial protection from becoming pregnant and this partial protection decreases significantly as you breastfeed for longer periods of time. You should consider starting oral contraceptives only after you have weaned your child completely.

3. Laboratory tests

If you are having birth control pills, certain blood tests may be affected by birth control pills.

4. Drug interactions

Certain drugs may interact with birth control pills to make them less effective in preventing pregnancy or cause an increase in breakthrough bleeding. Such drugs include rifampin, drugs used for epilepsy such as barbiturates (for example, phenobarbital), phenytoin (Dilantin® is one brand of this drug), phenylbutazone (Butazolidin® is one brand), and possibly certain antibiotics. You may need to use additional contraception when you take drugs which can make oral contraceptives

less effective.

Birth control pills may interact with lamotrigine, an anticonvulsant used for epilepsy. This may increase the risk of seizures, so your physician may need to adjust the dose of lamotrigine.

Some medicines may make birth control pill less effective, including:

- Barbiturates
- Bosentan
- Carbamazepine
- Felbamate
- Gnasefulvin
- Oxcarbazepine
- Phenytoin
- Rifampin
- St. John's wort
- Topiramate

As with all prescription products, you should notify your healthcare provider of any other medicines and herbal products you are taking. You may need to use a barrier contraceptive when you take drugs or products that can make birth control pills less effective.

5. Sexually transmitted infections

This product (like all oral contraceptives) is intended to prevent pregnancy. It does not protect against transmission of HIV (AIDS) and other sexually transmitted infections such as chlamydia, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis.

HOW TO TAKE THE PILL

IMPORTANT POINTS TO REMEMBER

BEFORE YOU START TAKING YOUR PILLS:

- BE SURE TO READ THESE DIRECTIONS. Before you start taking your pills, anytime you are not sure what to do.
- THE RIGHT WAY TO TAKE THE PILL IS TO TAKE ONE PILL EVERY DAY AT THE SAME TIME.

If you miss pills you could get pregnant. This includes starting the pack late. The more pills you miss, the more likely you are to get pregnant.

MANY WOMEN HAVE SPOTTING OR LIGHT BLEEDING, OR MAY FEEL SICK TO THEIR STOMACH DURING THE FIRST 1 TO 3 PACKS OF PILLS.

If you feel sick to your stomach, do not stop taking the pill. The problem will usually go away. If it doesn't go away, check with your doctor or healthcare provider.

MISSING PILLS CAN ALSO CAUSE SPOTTING OR LIGHT BLEEDING, even when you make up these missed pills.

On the days you take 2 pills to make up for missed pills, you could also feel a little sick to your stomach.

IF YOU HAVE VOMITING OR DIARRHEA, for any reason, or IF YOU TAKE SOME MEDICINES, including some antibiotics, your pills may not work as well.

Use a back-up method (such as condoms, foam, or sponge) until you check with your doctor or healthcare provider.

IF YOU HAVE TROUBLE REMEMBERING TO TAKE THE PILL, talk to your doctor or healthcare provider about how to make pill-taking easier or about using another method of birth control.

IF YOU HAVE ANY QUESTIONS OR ARE UNSURE ABOUT THE INFORMATION IN THIS LEAFLET, call your doctor or healthcare provider.

BEFORE YOU START TAKING YOUR PILLS

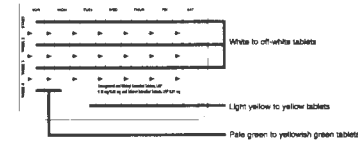
- DECIDE WHAT TIME OF DAY YOU WANT TO TAKE YOUR PILL. It is important to take it at about the same time every day.
- LOOK AT YOUR PILL PACK. IT WILL HAVE 28 PILLS.

This **28-pill pack** has 26 "active" (white to off-white and light yellow to yellow) pills (with hormones) and 2 "inactive" (pale green to yellowish green) pills (without hormones).

3. ALSO FIND:

- where on the pack to start taking the pills;
- in what order to take the pills (follow the arrows) and
- the week numbers as shown in the picture below.

28 Pill Pack
EXAMPLE ONLY



Note: If the first day of your period is a Sunday, you can skip steps #1 and #2.

- BE SURE YOU HAVE READY AT ALL TIMES. ANOTHER KIND OF BIRTH CONTROL (such as condoms, foam, or sponge) to use as a back-up in case you miss pills.

AN EXTRA, FULL PILL PACK.

WHEN TO START THE FIRST PACK OF PILLS

You have a choice of which day to start taking your first pack of pills. Decide with your doctor or healthcare provider which is the best day for you. Pick a time of day which will be easy to remember.

DAY 1 START:

- Pick the day label strip that starts with the first day of your period (this is the day you start bleeding or spotting, even if it is almost midnight when the bleeding begins).
- Place this day label strip in the cycle tablet blister over the area that has the days of the week (starting with Sunday) imprinted.



Peel and place label here.

- Take the first "active" (white to off-white) pill of the first pack during the first 24 hours of your period.

- You will not need to use a back-up method of birth control, since you are starting the pill at the beginning of your period.

SUNDAY START:

- Take the first "active" (white to off-white) pill of the first pack on the Sunday after your period starts, even if you are still bleeding. If your period begins on Sunday, start the pack that same day.

- Use another method of birth control as a back-up method if you have sex anytime from the Sunday you start your first pack until the next Sunday (7 days). Condoms, foam, or the sponge are good back-up methods of birth control.

WHAT TO DO DURING THE MONTH

- TAKE ONE PILL AT THE SAME TIME EVERY DAY UNTIL THE PACK IS EMPTY.** Do not skip pills even if you are spotting or bleeding between monthly periods or feel sick to your stomach (nausea). Do not skip pills even if you do not have sex very often.

- WHEN YOU FINISH A PACK OR SWITCH YOUR BRAND OF PILLS:** 21 pills: Wait 7 days to start the next pack. You will probably have your period during that week. Be sure that no more than 7 days pass between 21-day packs.

- 28 pills: Start the next pack on the day after your last pill. Do not wait any days between packs.

WHAT TO DO IF YOU MISS PILLS

- If you **MISS 1 "active"** (white to off-white) pill:
 - Take it as soon as you remember. Take the next pill at your regular time. This means you take 2 pills in 1 day.
 - You do not need to use a back-up birth control method if you have sex.

- If you **MISS 2 "active"** (white to off-white) pills in a row in **WEEK 1 OR WEEK 2** of your pack:
 - Take 2 pills on the day you remember and 2 pills the next day.
 - Then take 1 pill a day until you finish the pack.
 - You **MAY BECOME PREGNANT** if you have sex in the **7 days** after you miss pills.

You **MUST** use another birth control method (such as condoms, foam, or sponge) as a back-up method for those 7 days.

- If you **MISS 2 "active"** (white to off-white) pills in a row in **WEEK 3**:
 - If you are a **Day 1 Starter**: THROW OUT the rest of the pill pack and start a new pack that same day.

- If you are a **Sunday Starter**: Keep taking 1 pill every day until Sunday. On Sunday, THROW OUT the rest of the pack and start a new pack of pills that same day.

- You may not have your period this month but this is expected. However, if you miss your period 2 months in a row, call your doctor or healthcare provider because you might be pregnant.

- You **MAY BECOME PREGNANT** if you have sex in the **7 days** after you miss pills. You **MUST** use another birth control method (such as condoms, foam, or sponge) as a back-up method for those 7 days.

- If you **MISS 3 OR MORE "active"** (white to off-white) pills in a row (during the first 3 weeks):
 - If you are a **Day 1 Starter**: THROW OUT the rest of the pill pack and start a new pack that same day.

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- pain or other symptoms during menstruation may be encountered less frequently
- ectopic (tubal) pregnancy may occur less frequently
- non-cancerous cysts or lumps in the breast may occur less frequently
- acute pelvic inflammatory disease may occur less frequently
- oral contraceptive use may provide some protection against developing two forms of cancer: cancer of the ovaries and cancer of the lining of the uterus

If you want more information about birth control pills, ask your doctor, healthcare provider, or pharmacist. They have a more technical leaflet called the Prescribing Information which you may wish to read.

Manufactured by:
Glenmark Pharmaceuticals Limited
Colvale-Bardez, Goa 403513, India

Manufactured for:

glenmark
Glenmark Pharmaceuticals Inc., USA
Mahwah, NJ 07430

Questions? 1 (888) 721-7115
www.glenmarkpharma-us.com

MARKET WITHDRAWAL RETURN RESPONSE FORM**DESOGESTREL AND ETHINYL ESTRADIOL TABLETS USP 0.15 MG/ 0.02 MG AND ETHINYL
ESTRADIOL TABLETS USP 0.01 MG (VIORELE)****28 X 3 pack (Tablets)****(NDC 68462-318-29)****Retail Level****9/2/2025**

Please fill out this form completely. By doing so, this will acknowledge that you have read and understand the withdrawal instructions and have taken the appropriate action.

Customer Name:	DEA#:
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DEA # is required, if it is not provided, the processing of your form will be delayed.

Address:

City:	State:	Zip:
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Contact Name (Please Print):

Telephone#:	Email:
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Contact Signature:	Date:
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DEBIT MEMO# (If unsure, leave blank):

Wholesaler Information if not directly purchased from Glenmark Pharmaceuticals Inc.:

Wholesaler Name:	DEA#:
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City:	State:	Zip:
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I have checked my stock and communicated to my customers at the appropriate level:

☐ I confirm that all locations that received the impacted products have been notified to the Retail level
_____ (Initial and date)

☐ I do not have any stock of the market withdrawn items. **OR**

☐ I have quarantined and listed in the box below the quantity of market withdrawn units and I will be returning to Inmar, as soon as possible. Upon receipt of this Response Form, Inmar, will issue return authorization label(s)

Please indicate the # of needed box labels _____

**Desogestrel and Ethinyl Estradiol Tablets USP 0.15mg/ 0.02mg and Ethinyl Estradiol Tablets USP 0.01mg
(Brand Name – Viorele)**

Sr. No.	NDC	Batch Number	Pack Size	Expiry Date	Total Full/ Sealed and Partial/ Open Bottle Count
1	68462-318-29	20240086	3 X 28 tablet pack	January 2026	
2	68462-318-29	20240128	3 X 28 tablet pack	February 2026	

If you have any questions regarding this form or product return please contact Inmar at (877) 837-7681 Office hours 9am to 5pm EST Mon thru Fri.

Please fax this form to: 1-817-868-5362 or E-mail rxrecalls@inmar.com

Market Withdrawal Event ID N131351 RCL207-25