

URGENT: DRUG RECALL

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

September 3, 2025

Dear Pharmacy, Wholesale and Retail Customer:

This is to inform you that Glenmark is initiating a voluntary recall 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	20230733	3 X 28 tablet pack	October 2025

The recall to the retail level of the above-identified Desogestrel and Ethinyl Estradiol Tablets USP 0.15 mg/ 0.02 mg and Ethinyl Estradiol Tablets USP 0.01 mg (Viorele) batch have been initiated due to failure results were 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, wherein the Impurity D, Specified Impurity at RRT 0.70, Any unknown impurity and Total impurities results are found to be OOS in Desogestrel and Ethinyl Estradiol Tablets USP 0.15 mg/ 0.02 mg against the specification of Not more than 1.0%, Not more than 1.00%, and Not more than 3.50% respectively.

To date, Glenmark has not received any reports of adverse events related to this recall. 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.

Glenmark
A new way for a new world

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 February 08, 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 Product recall. Your notification to

your retail customers may be enhanced by including a copy of this recall notification letter. Again,

this recall should be carried out to the retail level only. Because this is not a consumer level recall,

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

Recall 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 recall return please contact Inmar at (877) 839-9416.

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

This recall 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 Digitally signed by thomas.callaghan@glenmarkphar lenmarkpharma.com Date: 2025.09.03 12:23:46 -04'00'

Thomas Callaghan

Executive Director - Regulatory Affairs, North America

US Agent for Glenmark Pharmaceuticals Limited

Enclosure(s):

Product Labels

Recall 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)





gm 20.0 gm 21.0 92U, sJaldeT lotatile let lette goes O.0 (gm 10.0 92U, sJaldeT lotbested lynids 3 bns **VIORELE®** 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 promised See package insert for full prescribing information. Store at 20°C to 25°C (68°F to 77°F) [see U5P Controlled Room Temperaturek NOTE: THIS Manufactured by: Glenmark Pharmaceuticals Limited Colvale-Bardez, Goa 403513, India PACKAGE IS NOT CHILD MESISTANT. KEFFTHIS AND ALL GO/DRUGS/785 MEDICATION OUT Manufactured for: OF THE REACH OF Glenmark Pharmaceuticals Inc., USA. Mahwah, NJ 07430 CHILDREN.

Questions? 1 (888) 721-7115

www.glenmarkpharma-us.com

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

glenmark

(gm

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

each containing 28 tablets

NDC 68462-318-29

VIORELE

(Desogestrel and Ethinyl Estradiol

Tablets, USP 0.15 mg/0.02 mg and

Ethinyl Estradiol Tablets, USP 0.01 mg)

glenmark

3 Blisters

Regimen

28 day

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

6 **Glenmark**

VIOREL

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



Carole Capella Digitally signed by Carole Date: 2021.08.23 1427-55.

Digitally signed by Kristin Kristin DiStefano Diskefano Dete: 2021:08.23 15:11:48

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REMARKS:

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LOCATION:

PACK:

COUNTRY: USA

PHARMACODE

ITEM CODE:

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G GLENMARK PHARMACEUTICALS LTD.

PRODUCT NAME:

DATE: 20-08-2021

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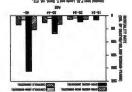


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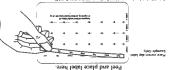
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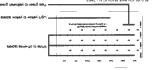
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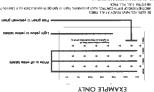
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28 Pill Pack

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Patient Package Insert Brief Summary

VIDRELE® (Desogestref 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 macking (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.

not protest 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 quills. The yighcal failure rate of large missers of pill users is less than 5% per year when women who miss pills are included from most women, oral contraceptives are also free of sensor or unplassant side effects. However, forgetting to take pills considerably increases the chances of pregnancy for the majority of women, oral contraceptives can be less rately but there are some women who are at high risk of developing orrans serious diseases that can be liftle threatening or may cause temporary or permanent disability. The risks associated with laking and contraceptives can be increase significantly if you.

- have high blood pressure, diabetes, high cholesteri
- 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

Most side effects of the pill are not serious. The most common such effects Most side effects of the pill are not serious. The most common such effects are nausea, vomiting, bleeding between menstrual periods, weight gain, breas tenderness, headache, and difficulty wearing contact lenses. These side effects especially nausea and vomiting, may subside within the first three months of use.

- especially nausea and vomiting, may subside within the first three months of use. The senious side effects of the full locur very infrequently, specially 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 (thrombophlealits) or lungs (pulmonary embolism) stoppage or rupture of a blood vessel in the brain (stroke), blockage of blood vessels in the heart (heart attack or anging actority or other organs of the body. As memoniad 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 this veen rarer.
- the pill is thus even rarer.

 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

The symptoms associated with these serious side effects are discussed in the detailed intelligence with your supply of pills. Notify your detoor or healthcare provider if you notice any unusual physical disturbances while taking the all. In addition, drugs such as framping as well as some antoonvolsants and some antibiotics may decrease oral contraceptive effectiveness.

There may be slight increases in the risk of breast cancer among currient users of hommonal birth control pills with longer drustion 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.

than the use of oral contraceptives. Taking the fill provides some important non-contraceptive benefits. These include less panful menstruation, less menstrual blood loss and anema, fewer pelvic infections, and fewer cancers of the owary and the hinny of the uterus. Be sure to discuss any merical conditions you may have with your doctor or healthcare provider. Your doctor or healthcare provider will take a medical and tamily history, before prescribing oral contraceptives and will examine you. The physical examination may be deleged to another time if you request it and your doctor or healthcare provider believes that it is a pood medical practice to postpore it You should be reexamined believes that it is a pood medical practice to postpore it you should be reexamined. believes that it is good making practice by ospicite. It is disting to be considered 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 protect against transmission of HIV (AIDS) and other sexually transmitted is such as chiamydia, genital herpes, genital warts, gonorrhea, hepatitis 8, and syphilis.

INSTRUCTIONS TO PATIENTS

HOW TO TAKE THE PILL

IMPORTANT POINTS TO REMEMBER BEFORE YOU START TAKING YOUR PILLS

- EXINE TO GRAIT THRESE 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
- If you miss pills you could get pregnant. This includes starting the pack late.
- The more pills you mass, the more likely you are to get pregnant. MANY WOMEN HAVES POTTING OF LIGHT BLEEDING ONE MAY FEEL SICK TO THEIR STOMACH DURING THE FIRST 1 TO 3 PACKS OF PILLS. If you feel suck to your stomach, do not story taking the pill rough of the pills. The problem will susually go away, if it doesn't go away, check with your doctor or healthcare.
- provider.
 MISSING PILLS CAN ALSO CAUSE SPOTTING DR 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
- e sick to your stomach. 'OU 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 DUESTIONS OR ARE UNSURE ABOUT THE INFORMATION IN THIS LEAFLET, call your doctor or healthcare provide

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). ALSO FIND:
- 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.

28 Pill Pack EXAMPLE ONLY

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

- 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 midright when the bleeding begins).

 Place this day label strip in the continuity.
- 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

- Take the first "active" (white to off-white) pill of the first pack during the tirst. A 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:
- MOAY START: Take the first Tactive" (white to off-white) pill of the first pack on the <u>Sunday</u> after your period <u>states</u>, even if you are still beeding. If your period begins on Sunday, start the pack that same did not Use another method of <u>binth</u> coatrol 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 DD DURING THE MONTH

1. TAKE DHE PILL AT THE SAME TIME EVERY DAY UNTIL THE PACK IS EMPTY ot skip pills even if you are spotting or bleeding betw

feel sick to your stomach (nausea). Do not skip pills even if you do not have sex very often

2. WHEN YOU SINISH A PACK OR SWITCH YOUR RRAND OF PILLS

which You Finish A PACK On SWITCH TOUR BRAND OF PILES:

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. On not wait any days. between packs

WHAT TO DO IF YOU MISS PILLS

- It 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:

 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 <u>7 days</u> 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.
- THROW OUT the rest of the purpose and state. The rest of the pack and start a new pack of pills that 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
- Too may find near you proud of an information and expected information in miss your period 2 months in a row. Call your doots or in-failtness provider because you might be prepared. Too MAY BECOMP PRECINANT if you have sex in the <u>7 flays</u> after you miss gills. You MUST use another brith control method (such as condoms, floam, or spronge) as a bekin-up method for those 7 days.
- If you MISS 3 OR MORE "active" (white to off-white) pills in a row (during the first

If you are a Day 1 Starter: THROW OUT the rest of the pill pack and start a new pack that same day.

Mourare a Sunday Starter

Meg taking 1 pill every day until Sunday.

No Sunday, THROW OUT the rest of the pack and start a new pack of pills that same day.

- same day.

 You may not have your period this month but this is expected. However, if you may not have 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 see in the 7_fags 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

you forget any of the 2 [pale green to yellowish green] or 5 [light yellow to yellow]

pils 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 Colvale-Bardez, Goa 403513, India



Glenmark

Glenmark Pharmaceuticals Inc., USA Mahwah, NJ 07430

Duestions 2 1 (888) 721-7115

April 2023

DETAILED PATIENT PACKAGE INSERT

VIORELE® (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 inlended to prevent pregnancy. It does not protect against HIV intection (AIDS) and other sexually transmitted intections.

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

DESCRIPTIONThe following oral contraceptive product contains a combination of a progestin and estrogen, the two kinds of female hormones:
Each white to oft-white tablet contains 0.15 mg (desogester), USP and 0.02 mg ethinyl estratiol. USP, Each paid green to lydowship green tablet contains in ert 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) Any woman who consides using oral contraceptives (the birth control pill of the full) should understand the benefits and nisk of using this form of borth control. This feaflet 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 decision and will also help you determine if you are at risk of developing any of the serious side decision and will so help in the little will be as effective as possible. However, this leaflet is not a replacement for a careful discussor between you and your door or neathbrace provider. You should also discuss the information provided in this leattlet with him or ner, both when you first start taking the pill and during your revisit. You should also follow your doctor's or healthcare provider's advice with repard to regular check-ups while you are on the pill.

EFFECTIVENESS OF ORAL CONTRACEPTIVES

CONTINUENCES UP UNAL CONTRACEPTIVES
Oral contraceptives or "birth control pills" or "the pill" are used to prevent preparacy and are more effective than other non-surgical methods of birth control. When they are been corrective, the chance of beening pregnant is set than 1% (1 or preparacy per 10) women per year of use) when used pertectly, without missing any pills. Typical failure rates are actually 5% per year. The chance of becoming pregnant increases with each missed pill during a mensitual cycle.

In comparation, typical failure rates for other methods of birth control during the first year of use are a follows:

if at your or bac are as renown.	
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 cigarette per day) and is quite marked in women over 55 years of age. Women who use oral contraceptives are strongly advised not to smoke.

Some women should not use the pill. For example, you 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:

- o have any or 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
- Mission of blood using his decipy and a your legs. Thest pain (angine pectors). Known or suspected trises in the decipy and the summer of the Tretiowing of the whites of the eyes or of the skin (aundice) during prepnancy or during previous use of the offi
- Liver tumor (benign or cancerous)

 Hepatitis C and are taking any drug combination containing ombitasvir/

 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 contro

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 Élevated cholesterol or triglycerides
- High blood pressure Migraine or other headaches or epilepsy Decression
- Depression Gallbladder, heart, or kidney disease

History of scanty or irregular menstrual periods

Women with any of these conditions should be checked offen 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 DT TAKING DRAL CONTRACEFTIVES

1. Risk of developing blood clobs

1. Risk of the service of the service of the service of seability. In particular,

2. cold in the leg or a crusse hromotophethis and a clid that frares to the lungs can

cause a sudden blockage of the vessel carrying blood to the lungs. The risks of these

see effects may be greater with deseogested-containing oral contraceptives such as

desogestrelethiny estratiol and ethinyl estradiol than with certain other low-dose

subless such as the service of the s

developing blood clots. You should consult your doctor or healthcare provider about stopping or all contraceptives there to flow weeks before suprey and not taking oral contraceptives from 6 to flow weeks before suprey and not taking oral contraceptives from 6 the clowery of a bally, it is advisable to wait of a tleast flour weeks after delivery if you are not breastfeeding or flour weeks after a second immester abortion. If you are breastfeeding, you should wait until you have weared your child before using the pill (see Breastfeeding on Gour weeks after a second high doce pills and may be greater with longer duration of oral contraceptive use. The risk of circularly disease in oral contraceptive uses may be higher in users of high doce pills and may be greater with longer duration of oral contraceptive use in addition, some of these increased risks may continue for an umber of years after stopping oral contraceptives. One of the contraceptive uses the stopping oral contraceptives does not increase with length of use and disappears after pill use is stopped. The risk of abnormal blood clothing increases with age in both uses and non-users of oral contraceptives. One of the contraceptive use of the stoppears after pill use is stopped. The risk of abnormal blood clothing increases with age in both uses and non-users of oral contraceptives. One of the increase with length of use and disappears after pill use is stopped. The risk of abnormal clothing. Among non-users in the same age group, about in 20,000 would be hospitablewed actly var. For oral contraceptive users in great in this been estimated that user in women between the ages of 15 and 34 the risk of default in 20,000 would be hospitablewed high var. For oral contraceptive users and about 1 in 10,000 per year for non-users in the same age or oral to the development of the pill of

2. Heart attacks and strokes

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

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

3. Gallbladder disease
Oral contraceptive users probably have a greater risk than non-users of having gallbladder disease. Although this risk may be related to pills containing high doses gallbladder or of estrogens.

or estropers

A. Uner tumor.

In race cases, oral contraceptives can cause beingin but dangerous liver tumors.

In race cases, oral contraceptives can cause that 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 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.

even rarer

5. Risk of Caner
It is not known if hommonal 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 hed in the peast do not use hormonal birth control because some breast cancers are sensitive to hommones. Some estudies have found an increase in the inodence of cancer of the centx in women who use or al contraceptives. However, this finding may be related to factors of the pease that the use of oral contraceptives. There is insufficient evidence to rule out the possibility that pills may cause auch 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 developic certain diseases which may lead to disability or feath. An estimate of the number deaths associated with different methods of birth control and pregnancy has be calculated and is shown in the following table.

CUIATED AND IS STOWN IN THE COLOWING LABOR.

NUAL NUMBER OF BIRTH-RELATED OR METHOD-RELATED DEATHS
SOCIATED WITH CONTROL OF FERTILITY PER 100,000 NON-STERILE WOMEN,
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
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**	8.0	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
Deviado obstigance*	2.5	1.0	1.6	1.7	20	2.6

3. DEV.:	Item code, Version, Consistency of Design, overprint area, Pack size. Dimensione & Layout Regulatory Text Machine Sultability			
	Machine Sultabliny			
	· · · · · · · · · · · · · · · · · · ·			
	Entire Text			
REMARKS: NA				
	F	FCPDC001/01.00		

"Deaths are method related in the above table. The 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 bill that for women aged 15 a 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 flower from 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) that he estimated risk associated with pregnancy (2810,000 women) in that age group. The suggestion that women over 40 who do not smoke should not take or all contraceptives as based on information from other, high-dose pills and on less selective use by healthy, non-amoning women over 40 years of age may outweigh the possible rosks. However, all women, aspecially older women, are cautioned to use the lowest dose pill that is effective.

WARNING SIGNALS

- 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 of in the lung).

 Pain in the call (indicating a possible of on the leg).

 Crushing chest pain or heaviness in the chest (indicating a possible heart affack).

 Sudden severe headsche or vomiting, dizziness or fainting, disturbances of vision or speech, weakness, or numbers in an arm or leg (incidating a possible stroke).

 Sudden partial or complete loss of vision (indicating a possible city in the eye).

 Breast lumps, (indicating possible breast cancer or fibrocytic disease of the breast; ask your doctor or healthcare provider to show you how to examine your breasts).
- reasts)
 evere pain or tenderness in the stomach area (indicating a possibly ruptured
 ver tumor)
- Invertumor)

 Difficulty in sleeping, weakness, lack of energy, fatigue, or change in mood (possibly indicating severe depression)

 Jaunotice or a yellowing of the skin or eyeals, accompanied frequently by fever, fatigue, loss of appetite, dark colored urne, or light colored bowel movements (indicating possible liver problems).

SIDE EFFECTS OF GRAL CONTRACEPTIVES

SIDE EFFECTS OF GRAL CONTRACEPTIVES

1. Vaginal bleeding
Irregular vaginal bleeding or spotting may occur while you are taking the pills.
Irregular bleeding may say from sight is saming between menstrual periods to breakthrough bleeding may say from sight is saming between menstrual periods to rebreakthrough bleeding occurs most often during the first few months of vall contraceptive use, but may be so 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. Pontate liesers.

Contact lenses
If you wear contact lenses and notice a change in vision or an inability to wear your lenses, contact your foctor 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

 Uner 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

1. Missed periods and use of oral contraceptives before or during early pregnancy

1. Allsaed periods and use of oral contraceptives before or during sarry pregnancy. There may be times when your may not menstrate regularly, after you have completed taking a cycle of pills. If you have taken your pills regularly, and miss one mentarrual period. Continue taking your pills for the next cycle but the sure to introvuo doctor or haalthcare provider before doing so if you have not taken the pills daily as instructed and missed a mentitrual period. or if you missed two consecutive menstrail periods, you may be pregnant. Check with your doctor or healthcare provider immediately to determine whether you are represent. Do not continue to take oral contraceptives until you are sure you are not pregnant. Do not continue to take oral contraceptives until you are sure you are not pregnant. On the continue to the contraception. There is no conclusive evidence that oral contraceptive use is associated with an increasen which decets, when taken indurentely during early pregnancy. Previously,

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 necession 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

2. While hreadfreeding.
1. While hreadfreeding.
1. You are beastfeeding, 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, nucliding velowing of their (jaundice) and breast enlargement. In addition, on all contraceptives may decrease the amount and qualify of your milk. It possible do not use oral contraceptives 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.
1. Unperiod to completely.

Leasuratury TREES
If you are scheduled for any laboratory tests tell your doctor or healthcare provider
you are taking birth control pills. Certain blood tests may be affected by birth
control pills.

4. Drug interactions

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 frainpin, drugs used for perlipsys such as bathiturates (for example, phenobactival), phenyton (Diantin' is one brand of this drug), phenythout position of personal productions of prevention of the production of t

hirth 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

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

- Bosentan Carbamazepine Felbamate Griseofulvin
- Oxcarbazepini
- Phenytoin
 Rifampin
 St. John's wort
 Topiramate
- As with all prescription products, you should notify your healthcare provider any other medicines and herbal products you are taking. You may need to us barrier contraceptive when you take drugs or products that can make birth compilis less effects.

Security transmitted infections This product (like all oral contraceptives) is intended to prevent pregnancy, does not protect against transmission of HIV (AIDS) and other sexually transmitt ns such as chiamydia, genital herpes, genital warts, gonorrhea, hepatitis

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.

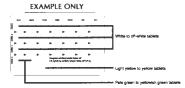
 2. THE RIGHT WAY TO TAKE THE PILL IS TO TAKE ONE PILL EVERY DAY AT THE SAME TIME
 - SAME TIME. If you miss pills you could get pregnant. This includes starting the pack late.
- If you mass pills you could get pregnant. This includes starting the pack late. The more pills you miss, the more likely you are to get pregnant. MANY WOMEN HAVE SPOTTING OR LIGHT BLEEDING, OR MAY FEEL SICK TO THEIR STOMAND UDRING THE FIRST TO 3 PACKS OF PILLS. If you test sick to your stomach, do not stop taking the pill. The problem will usually go away. If it deem't yo 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
- Ull new upsy you want with a size of the s
- your doctor or healthcare provider.
 IF YOU HAVE TROUBLE REMEMBERING TO TAKE THE PILL, talk to your doctor Ithcare provider about how to make pill-taking easier or about using another
- method of birth control.

 In You HAVE ANY OUESTIONS OR ARE UNSURE ABOUT THE INFORMATION IN THIS LEAFLE, 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 in 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
- 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.

28 Pill Pack



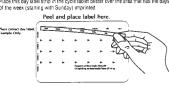
Note: If the first day of your period is a Sunday, you can skip steps #1 and #2.

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.

- M1: day label strip that starts with the first day of your period (this is the day I bleeding or spotting, even if it is almost midnight when the bleeding
- age this day label strip in the cycle tablet blister over the area that has the days of the week (starting with Sunday) imprinted



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:

1 has 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 brint poortiol 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 brint control.

WHAT TO DO DURING THE MONTH

1. TAKE ONE PILL AT THE SAME TIME EVERY DAY UNTIL THE PACK IS EMPTY. On not skip pills even if you are sporting 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 PINISH 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

WHAT TO DO IF YOU MISS PILLS

- If you MISS 1 "active" [white to of-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
- or 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.

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:

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

- Of same, since day some state of the same day of the same day
- You MUST use another birth control method (such as condo 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

- iveeks)

 If you are a Day I Starter

 THROW OUT the rest of the pill pack and start a new pack that same day

 If you are a Sounds Starter.

 Keep staining 1 pill evany day withi 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

 heresizes you munit be arechant.
- miss your period z into the preparative because you might be preparative because you might be preparative. You MAY BECOME PREGNANT if you have sex in the \underline{Idags} 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

any of the 2 (pale green to yellowish green) or 5 (light yellow to yellow) If you forget any of the 2 [pale green to yellowish gr 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

Use a BACK-UP METHOD anytime you have sex. KEEP TAKING ONE "ACTIVE" (WHITE TO OFF-WHITE) PILL EACH DAY until you can

your doctor or healthcare provider

PREDRAMCY DUE TO PILL FAILURE
The incidence of pill failure resulting in pregnancy is approximately one percent (i.e., one pregnancy per 100 women per year) if taken every day as directed, but more hypocal failure rates are about 5%. If failure does occur, the risk to the fetus is minimal

PREGNANCY AFTER STOPPING THE PILL

recuments at text STOPPING THE PLL.

There may be some delay in becoming pregnant after you stop using oral contraceptives, especially if you had irregular menstrual cycles before you used oral contraceptives. It may be divisible to postopine conception until you menstruating regularly once you have stopped taking the pill and desire pregnancy. There does not appear to be any increase in birth defects in newborn babies when pregnancy occurs soon after stopping the pill.

OVERDOSAGE

OVERHUMANUE
Serious ill effects have not been reported following ingestion of large doses of oral contraceptives by young children. Overdosage may cause nausea and withdrawal bleeding in themales. In case of overdosage, contact your doctor, healthcare provider or pharmacust. OTHER INFORMATION

OTHER MERGHANIUM

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 designed 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 your. Be sure to inform your doctor or healthcare provider if there is a family history of any of the conditions is test previously in this leaffest the sure to keep all appointments be because this is a time to determine if there are early signs of side effects of oral contraceptive use. Do not use the drug for any condition other than the one for which it was prescribed. This drug has been prescribed specifically for you; do not give it to others who may

want birth control pills

HEALTH BENEFITS FROM GRAL CONTRACEPTIVES
In addition to preventing pregnancy, use of combination oral contraceptives may
provide cerain benefits. They are
— menstrual cycles may become more regular
— blood flow during menstruation may be lighter and less iron may be lost. Therefore,
aremia due to medicalency is less likely to occur

- pain or other symptoms during menstruation may be encountered less frequently.
 ectopic (fubal) pregnancy may occur less frequently.
 non-canacrosis cysts or lumps in the brasst may occur less frequently.
 acute pelvic inflammatory disease may occur less frequently.
 oral contraceptive uses may provide some protection against developing two forms of cancer: cancer of the ovaries and cancer of the lining of the stress

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:

6 Glenmapk

Glenmark Pharmaceuticals Inc., USA Mahwah. NJ 07430

Questions? 1 (888) 721-7115

April 2023

GLENMARK PHARMACEUTICALS LTD. DATE:06 04:2023 PANTONE SHADE NO: Black PRODUCT NAME: VIORELE BSP & DPL INSERT US R2 PKG. DEV.: ITEM CODE: PE63502 VFRSION: 0423-1 PHARMACODE: NA BARCODE: 63502 COUNTRY: US PRODUCTION: Machine Sultability LOCATION: Goa DA: Embra Text fold:80x60mm PACK: REMARKS: NA ACTUAL SIZE: 390X410 MM SPECIFICATION: 60 GSM MAPLITHO PAPER FCPDC001/01.00 No Packaging Pvt. Ltd. Fort: Helvetica Condensed Sap code: 30100020087



Glenmark Pharmaceuticals Inc.

RECALL RETURN RESPONSE FORM

DESOGESTREL AND ETHINYL ESTRADIOL TABLETS USP 0.15 MG/ 0.02 MG AND ETHINYL ESTRADIOL TABLETS USP 0.01 MG (VIORELE)

3 X 28 pack (Tablets) (NDC 68462-318-29) Retail Level 9/3/2025

Please fill out this form completely. By doing so, this will acknowledge that you have read and understood the recall instructions and have taken the appropriate action. Customer Name: DEA#: DEA # is required, if it is not provided, the processing of your form will be delayed. Address: Zip: City: State: Contact Name (Please Print): Email: Telephone#: Contact Signature: Date: DEBIT MEMO# (If unsure, leave blank): Wholesaler Information if not directly purchased from Glenmark Pharmaceuticals Inc.: Wholesaler Name: DEA#: City: State: Zip: 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 recalled items. OR □ I have quarantined and listed in the box below the quantity of recalled 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 0.15 mg/ 0.02 mg and Ethinyl Estradiol Tablets USP 0.01 mg (Brand Name – Viorele)

Sr. No.	NDC	Batch Number	Pack Size	Expiry Date	Total Full/ Sealed and Partial/ Open Bottle Count
1	68462-318-29	20230733	3 X 28 tablet pack	October 2025	

If you have any questions regarding this form or product return please contact Inmar at (877) 839-9416 Office hours 9am to 5pm EST Mon thru Fri.

Please fax this form to: 1-817-868-5362 or E-mail rxrecalls@inmar.com Recall Event ID N131350 RCL206-25