

HERVOTE

(Drospirenone & Ethinylestradiol Tablets)

COMPOSITION

Each film coated tablet contains :

Drospirenone U.S.P. 3 mg

Ethinylestradiol I.P. 0.03 mg

Colours : Yellow Oxide of Iron and Titanium Dioxide I.P.

HERVOTE (like all oral contraceptives) is intended to prevent pregnancy. It does not protect against HIV infection (AIDS) and other sexually transmitted diseases. Please consult your doctor or healthcare provider before you start taking the pill.

INTRODUCTION

HERVOTE is an oral contraceptive pill. 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 less than 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. However, forgetting to take pills considerably increases the chances of pregnancy.

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 the information you will need to make this decision. 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 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 revisits. You should also follow your healthcare provider's advice with regard to regular check-ups while you are on the pill.

INSTRUCTIONS

Important points to remember Before you start taking your pills

- 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 1-3 packs of pills. If you do have spotting or light bleeding or feel sick to your stomach, do not stop taking the pill. The problem will usually go away. If it does not 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. A back up method of non hormonal contraception must be used if you are not sure about the pills you have missed.
- If you have vomiting or diarrhea, or if you take some medicines, including some antibiotics and some herbal products such as St. John's Wort, your pills may not work as well. Use a back-up method (such as condoms or spermicides) 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.

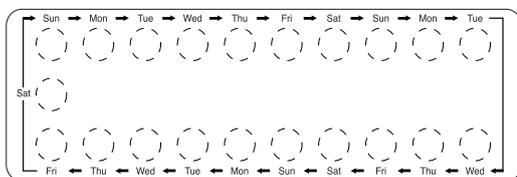
BEFORE YOU START TAKING YOUR PILLS

- 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 has 21 pills:

The HERVOTE pill pack has 21 pills to be taken for three weeks, followed by 7 pill free days.

3. Also Find:

- where on the pack to start taking pills,
- in what order to take the pills (follow the → arrows)
- the day wise marking is shown in the diagram below :



4) Be sure you have ready at all times:

- Another kind of Birth Control (such as condoms or spermicides) to use as a back-up in case you miss pills.
- An Extra, full pill pack
- When to start the first pack of pills

HOW TO START TAKING PILL

Day 1 start (Day of menstrual cycle):

- Take the first pill of the first pack during the first 24 hours of your period (first day of 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.

Starting pill from the day other than the first day of menstrual cycle:

If you start taking the pill from the day other than the first day of menstrual cycle, use another method of birth control (such as condoms) as a back-up method if you have sex any time from the day you start your first pack until the next 7 days.

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: Start the next pack on the day after your last pill free day. This means after consuming 21 pills there will be 7 pill free days to allow your menstrual cycle to start. After the 7th pill free day you must start another pack on the very next day even if your menstrual cycle is going on or has not started yet.

WHAT TO DO IF YOU MISS PILLS

If you **MISS 1** pill:

- Take it as soon as you remember. Take the next pill at your regular time. This means you may take two pills in one day.
- You do not need to use a back-up birth control method if you have sex.

If you **MISS 2** pills in a row in **WEEK 1 OR WEEK 2** of your pack:

- Take two pills on the day you remember and two pills the next day.
- Then take one 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 or spermicides) as a back-up for those 7 days.

If you **MISS 2** pills in a row in the **3RD WEEK**:

- THROW OUT** the rest of the pill pack and start a new pack that same day.
- You may not have your period this month but this is expected. However, if you miss period two months in a row, call your doctor or healthcare provider because you might be pregnant.
- You **MAY BECOME PREGNANT** if you have had sex in the 7 days after you miss pills. You **MUST** use another birth control method (such as condoms or spermicides) as a back-up for those 7 days.

If you **MISS 3 OR MORE** pills in a row (during the first 3 weeks):

- THROW OUT** the rest of the pill pack and start a new pack that same day.
- You may not have your period this month but this is expected. However, if you miss your period two 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 or spermicides) as a back-up for those 7 days.

FINALLY, IF STILL YOU ARE NOT SURE WHAT TO DO ABOUT THE PILLS YOU HAVE MISSED: use a **BACK-UP METHOD** (such as condoms or spermicides) anytime you have sex.

KEEP TAKING ONE PILL EACH DAY until you can reach your doctor or healthcare provider.

PRECAUTIONS

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

Cigarette smoking increases the risk of serious adverse effects on the heart and blood vessels 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 should not smoke. You should not take the pill if you have history of kidney or severe liver diseases. Drospirenone may increase potassium level in body hence HERVOTE should not be taken if you have heart, kidney or renal diseases.

The risk of developing certain serious diseases that can be life threatening or may cause temporary or permanent disability or death increases in the women having high blood pressure, diabetes, clotting disorders, stroke, and cancer of the breast or sex organs, jaundice, malignant or benign liver tumors.

STORAGE

Store in a dry & dark place at a temperature not exceeding 25°C.

Keep out of reach of children

PRESENTATION

HERVOTE is available as blister strip of 21 tablets.



Marketed by :

TORRENT PHARMACEUTICALS LTD.
Intrad-382 721, Dist. Mehsana, INDIA.

Manufactured by :

SYNOKEM PHARMACEUTICALS LTD.
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