

# NOVYNETTE TABLET

Ethinylestradiol/Desogestrel (0.02 mg/0.15 mg)

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## What Novynette is used for

Oral contraception.

## How Novynette works

Novynette works by inhibition of ovulation and changes in the cervical secretion to prevent pregnancy.

## Before you use Novynette

### - When you must not use it

Do not take Novynette if you have any of the conditions listed below:

- if you have (or have ever had) a blood clot in a blood vessel of your legs, your lungs or other organs;
- if you know you have a disorder affecting your blood clotting – for instance, protein C deficiency, protein S deficiency, antithrombin-III deficiency, Factor V Leiden or antiphospholipid antibodies;
- if you need an operation and you are off your feet for a long time;
- if you have ever had a heart attack or a stroke;
- if you have (or have ever had) angina pectoris (a condition that causes severe chest pain and may be a first sign of a heart attack) or temporary stroke symptoms;
- if you have any of the following diseases that may increase your risk of a clot in the arteries:
  - severe diabetes with blood vessel damage
  - very high blood pressure
  - a very high level of fat in the blood (cholesterol or triglycerides)
  - a condition known as hyperhomocysteinaemia;
  - if you have (or have ever had) 'migraine with aura';
- if you have (or have ever had) or if you are suspected of having breast cancer or cancer of the genital organs;

- if you have (or have ever had) a liver disease and your liver function is still not normal.
- if you have (or have ever had) a tumour in the liver;
- if you have unexplained bleeding from your vagina;
- if you have a condition characterised by the overgrowth of the lining of the womb (endometrial hyperplasia);
- if you have inflammation of the pancreas or history of inflammation of the pancreas associated with severe elevated fat levels in the blood;
- if you are allergic to desogestrel or ethinylestradiol, or any of the other ingredients of this medicine.
- if you have Hepatitis C and are taking the medicinal products containing ombitasvir / paritaprevir / ritonavir, dasabuvir, glecaprevir / pibrentasvir or sofosbuvir / velpatasvir / voxilaprevir (these products may cause increases in liver function blood test results (increase in ALT liver enzyme)). Novynette can be restarted 2 weeks after you stop this medication.
- if you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing contact a doctor immediately. Products containing estrogens may cause or worsen the symptoms of hereditary and acquired angioedema;
- if you have systemic lupus erythematosus (SLE – a disease affecting your natural defence system);
- if you have haemolytic uraemic syndrome (HUS - a disorder of blood clotting causing failure of the kidneys);
- gallstones;
- if you have gestational herpes (skin rash with blisters during pregnancy);
- if you have Sydenham's chorea (a disease of the nerves in which uncontrolled movements of the body occur);
- if you have recurrent attack of severe swelling underneath the skin.

## Pregnancy and lactation

Do not take Novynette if you are pregnant, trying to get pregnant or think you may be pregnant. If you get pregnant while taking Novynette, stop taking it immediately and contact your doctor.

Do not take Novynette if you are breast-feeding.

### - Before you start use it

Before the use of the tablet, your doctor will ask you some questions about your personal health history and that of your close relatives, will carry out comprehensive medical and gynecological examination and will exclude pregnancy.

Novynette, like other hormonal contraceptives, does not protect against HIV infection (AIDS) or any other sexually transmitted disease.

## Warnings and precautions

*Tell your doctor if any of the following conditions apply to you or gets worse while you are using Novynette:*

## Blood clots

Using a combined hormonal contraceptive such as Novynette increases your risk of developing a blood clot compared with not using one. In rare cases a blood clot can block blood vessels and cause serious problems.

*It is important to remember that the overall risk of a harmful blood clot due to Novynette is small.*

**Seek urgent medical attention if you notice possible signs of a blood clot** that may mean you are suffering from a blood clot in the leg (i.e. deep vein thrombosis), a blood clot in the lung (i.e. pulmonary embolism), a heart attack or a stroke.

## How to recognise a blood clot

### Symptoms of blood clots can include:

#### Deep vein thrombosis:

- unusual unilateral leg pain and/or swelling

#### Pulmonary embolism:

- sudden breathlessness or rapid breathing
- sudden onset of coughing
- sharp chest pain which may increase with deep breathing

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## Blood clot in the eye:

- sudden, partial or total loss of vision

## Heart attack:

- chest discomfort, pressure, squeezing pain below the breastbone, sometimes radiating to the back, jaw, throat, arm and stomach
- rapid or irregular heartbeats
- anxiety, shortness of breath
- fullness, indigestion or choking feeling

## Stroke:

- sudden weakness or numbness of the face, arm or leg, especially on one side of the body;
- sudden confusion, trouble speaking or understanding
- loss of consciousness

## Blood clots blocking other blood vessels:

- swelling and slight blue discolouration of an extremity.

## Factors that increase your risk of a blood clot in blood vessels

- as you get older (particularly above about 35 years);
- smoking (women over 35 years should be strongly advised not to smoke if they wish to use a combined oral contraceptive (COC))
- obesity (body mass index (BMI) over 30 kg/m<sup>2</sup>);
- a positive family history (if one of your immediate family has had a stroke, heart attack or blood clot in the leg, lung or other organ at a young age);
- prolonged immobilisation, major surgery, any surgery on the legs, or major trauma;
- high blood pressure;
- migraine;
- if you, or someone in your immediate family, have a high level of fat in the blood (cholesterol or triglycerides);
- if you just gave birth;
- if you have a problem with your heart (valve disorder, disturbance of the rhythm called atrial fibrillation);
- if you have sickle cell anaemia (an inherited disease of the red blood cells);
- if you have chronic inflammatory bowel disease;
- if you have diabetes.

## Novynette and tumours

Breast cancer has been observed slightly more often in women using combined pills, but it is not known whether this is caused by the treatment. For example it may be that more tumours are detected in women on combined pills because they are examined by their doctor more often. The occurrence of breast tumours becomes gradually less after stopping the combination hormonal contraceptives. It is important to regularly check your breasts and you should contact your doctor if you feel any lump.

In rare cases, benign liver tumours, and in even fewer cases malignant liver tumours have been reported in pill users. Contact your doctor immediately if you have unusual severe abdominal pain.

## Psychiatric disorders

Some women using hormonal contraceptives including Novynette have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

## Laboratory tests

In case of blood sampling you should tell your doctor or lab assistant that you are taking an oral contraceptive, because the preparation may affect the results of certain laboratory tests.

## Regular check-ups

Once you have started taking Novynette, your doctor will see you again for regular check-ups or if you have any problem you can see your doctor at any time.

## Children and adolescents

The safety and efficacy of Novynette in adolescents below 18 years have not yet been established. No data are available.

## Novynette contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

## Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy from a pharmacy, supermarket or health food shop without a prescription.

Do not use Novynette if you have Hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir. Your doctor will prescribe another type of contraceptive if you are treated with these medicinal products. Some medicines can have an influence on the blood levels of Novynette and can make it *less effective in preventing pregnancy* or can cause unexpected bleeding such as medicines used for:

- epilepsy (e.g. barbiturates, carbamazepine, phenytoin, primidone, felbamate, oxcarbazepine, topiramate);
- tuberculosis (e.g. rifampicin);
- HIV and hepatitis C virus infections (e.g. nevirapin, efavirenz) or other infections (e.g. griseofulvin);
- increase of blood pressure in the lung (bosentan);
- the herbal remedy St. John's wort (*Hypericum perforatum*).

The following medicines increase the blood levels of Novynette causing side effects:

- etoricoxib (used to treat inflammation and pain of the joints),
- itraconazole, ketoconazole, fluconazole (used to treat fungal infections);
- diltiazem (used to treat certain heart diseases and high blood pressure);
- antibiotics such as clarithromycin, erythromycin.

Novynette may *influence the effect* of other medicines, e.g.:

- ciclosporin (to prevent transplant rejection);
- lamotrigine (used for the treatment of epilepsy);
- theophylline (used to treat breathing problems);
- tizanidine (used for the treatment of muscle spasm),
- levothyroxine (used for the treatment of thyroid hormone deficiency).

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If you have diabetes, your doctor will monitor your condition carefully during the whole treatment with Novynette

## How to use Novynette

### - How much to use

Carefully follow all directions given to you by your doctor and pharmacist. Swallow each pill whole, with water. One tablet should be taken once a day, preferably always at the same time, starting on the first day of the monthly period for 21 days. This is followed by a tablet-free period of 7 days, during which a menstruation-like bleeding occurs. Intake of the next 21 tablets should be started on the 8th day, even if bleeding has not stopped.

*When no hormonal contraceptive has been used in the past month*

- Wait for your period to begin. The first tablet should be taken on the first day of your period.
- If your period has already begun, you can start taking your pills on day 2 to 5 of the menstrual cycle, irrespectively of the fact whether bleeding has stopped or not. In this case additional contraceptive precautions must be taken for the first 7 days of using the pill during the first cycle.

*When changing from another combined hormonal contraceptive (combined oral contraceptive pill, vaginal ring, or transdermal patch)*

You can start taking Novynette the day after you take the last tablet from your present pill pack (this means no tablet-free break). If your present pill pack also contains inactive tablets you can start Novynette on the day after taking the last active tablet (if you are not sure which this is, ask your doctor or pharmacist). You can also start later, but never later than the day following the tablet-free break of your present pill (or the day after the last inactive tablet of your present pill). In case you use a vaginal ring or transdermal patch, start taking Novynette preferably on the day of removal, or at the latest when the next application would have been due.

*Changing to Novynette from a progestogen-only pill (POP, or minipill)*

You can stop taking pills only containing progestogen any time, and start taking Novynette the next day at the usual time. But be sure to use additional prevention (such as condoms or spermicides) during intercourse in the first 7 days, during which you take the pills.

*Changing to Novynette from a progestogen-only injection, an implant or a progestogen-releasing intrauterine system (IUS)*

You can start to take Novynette on the day that your next injection is due, or on the day that your implant or intrauterine system is removed. However, you should use additional method of contraception (such as condoms or spermicides) during intercourse in the first 7 days, during which you take the pills.

## Starting after childbirth

Administration of the first tablet to non-breastfeeding mothers may be given at 21-28 days after delivery, and no additional contraceptive precautions are required. If intercourse has taken place, Novynette tablet should not be started until the first day of the first menstrual period. If Novynette tablet is started more than 28 days after delivery, then additional contraceptive precautions are required for the first 7 days.

## After a miscarriage or abortion

After a miscarriage or abortion, your doctor should advise you about taking the medicine.

You can start using Novynette immediately after a miscarriage or abortion. In this case you do not need extra contraceptive precautions.

## What to do if you have a stomach upset

If you vomited or had diarrhoea within 3-4 hours after taking the pill, the active substances in the pill may not be fully absorbed into your body. After vomiting or diarrhoea, take another tablet from another pack as soon as possible. If possible, take it within 12 hours of when you normally take your pill. If this is not possible or 12 hours

have passed, follow the advice given under 'If you forget to use it'.

## What to do if you want to delay or to shift your period

*If you want to delay your period* you should continue the next pack of Novynette, after taking the last tablet in the current pack, without a pill-free interval. You can take as many pills from this next pack as you want, until the end of the second blister pack.

*If you want to shift your period* to another day of the week, other than the one in which period usually occurs in the currently used regimen week, you may shorten (but never lengthen) the forthcoming pill-free interval by as many days as you like. The shorter the pill-free interval, the greater the possibility that you will not have a withdrawal bleeding, and that you may have breakthrough bleeding or spotting during the tablet use from the second pack.

### - When to use it

Use as directed by your doctor or pharmacist.

### - How long to use it

Take Novynette for the duration as your doctor recommends. You can stop taking Novynette whenever you want. If you do not want to become pregnant, ask your doctor for advice about other reliable methods of birth control. If you want to become pregnant, stop taking Novynette and wait for a menstrual period before trying to become pregnant. You will be able to calculate the expected delivery date more easily.

### - If you forget to use it

#### **If one pill is 12 hours late or less**

You are still protected against pregnancy if you take the late pill as soon as you remember, and keep taking your next pills at the usual time. This may mean taking two pills in one day.

#### **If you are more than 12 hours late in taking a pill,**

your protection against pregnancy might be reduced so you must use extra contraceptive precautions.

#### **If you have missed more than one**

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## **pill, ask your doctor for advice.**

### - If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. There have been no reports of serious deleterious effects from overdose. Symptoms that may occur in this case are: nausea, vomiting and, in young girls, slight vaginal bleeding.

## **While you are using it**

### - Things you must do

Tell all the doctors, dentists and pharmacists that are treating you that you are taking Novynette.

### - Things you must not do

Do not take any new medicines without consulting your doctor or pharmacist.

### - Things to be careful of

If intermenstrual bleeding occurs, the taking of the pill should be continued.

These bleedings usually stop spontaneously. If intermenstrual bleeding persists or occur repeatedly, a gynaecological examination should be carried out to exclude organic lesions. If no withdrawal bleeding occurs during the 7 pill-free days, therapy should be stopped until pregnancy is excluded.

If you have a tendency to chloasma, avoid exposure to the sun or ultraviolet radiation whilst taking combined hormonal contraceptives.

### *Driving and using machines*

Novynette has no influence on the ability in driving or using machines.

## **Side effects**

Like all medicines, Novynette can cause side effects although not everybody gets them.

In the first part of the treatment period a large part of the women may expect to get side effects such as breast tenderness, malaise and spot bleeding. However, these side effects are usually temporary and disappear after 2-4

months.

## **Very common** side effects

- irregular menstruation

## **Common** side effects:

- depressed mood, change in mood, nervousness
- headache
- dizziness
- feeling sick, abdominal pain
- acne
- breast pain, breast tenderness, absence of menstruation, painful menstruation, symptoms which women can experience in the weeks before their period such as: tiredness or trouble sleeping, bloating pain
- increase of body weight

## **Uncommon** side effects:

- fluid retention (swelling)
- decreased sexual desire
- migraine
- impaired hearing (otosclerosis)
- high blood pressure
- vomiting, diarrhoea
- skin rash, hives
- breast enlargement

## **Rare** side effects:

- hypersensitivity reactions
- increased sexual desire
- contact lens intolerance
- skin disorders erythema nodosum (characterized by painful reddish skin nodules), erythema multiforme (characterized by rash with target-shaped reddening or sores), brown patches on the skin, on the face or body (chloasma)
- vaginal discharge, breast discharge
- decrease of body weight
- harmful blood clots in blood vessels. The chance of having a blood clot may be higher if you have any other conditions that increase this risk (see section "Before you use Novynette" for more information on the conditions that increase risk for blood clots and the symptoms of a blood clot.

## **Not known** (frequency cannot be estimated from the available data):

- exacerbation of symptoms of hereditary and acquired angioedema.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

## **Storage and Disposal of Novynette**

### - Storage

Keep out of the reach and sight of children.

Store below 30°C. Protect from light and moisture.

Do not store any medicine in the bathroom, or near a sink, or on a window sill.

Do not leave it in the car especially on hot days. Heat and dampness can destroy medicines.

Do not use your medicine after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

### - Disposal

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required.

These measures will help to protect the environment.

## **Product Description**

### - What it looks like

Slightly yellow, round shaped, biconvex film-coated tablets of 6 mm diameter, with P9 sign on one side and RG sign on other side.

### - Ingredients

- Active ingredients  
Ethinylestradiol/Desogestrel

### - Inactive ingredients

Tablet core: potato starch; stearic acid; alpha-tocopherol; lactose monohydrate; magnesium stearate; silica colloidal anhydrous; povidone K 30; quinoline yellow (E 104);

Tablet coating: hypromellose; Macrogol 6000; propylene glycol.

### - MAL number

MAL05072014AZ

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**Manufacturer**

Gedeon Richter Plc.

H - 1103, Budapest

Gyömrői út 19-21 Hungary

**Product Registration Holder**

Pahang Pharmacy Sdn. Bhd

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5 ½ Mile off Jalan Meru,

41050 Klang, Selangor, Malaysia

**Date of revision**

11/04/2023

**Serial Number**

NPRA(R4/1)090323/00021