

DIENILLE 2MG / 0.03MG FILM COATED TABLETS

Dienogest 2mg / Ethinylloestradiol 0.03mg

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1. WHAT DIENILLE IS USED FOR

DIENILLE is a combined oral contraceptive (COC) pill. It is used to prevent pregnancy. It is also used to treat mild to moderate acne in woman seeking oral contraception.

2. HOW DIENILLE WORKS

The hormones in the pill help in preventing pregnancy and treatment of moderate acne by maintaining a constant level of hormones

3. BEFORE YOU USE DIENILLE

When you must not use it

Do not take DIENILLE if you have an allergy to:

- Dienogest and/or ethinylloestradiol
- Any of the ingredients listed at the end of this leaflet

Do not take DIENILLE if you have or have had a blood clot in:

- the blood vessels of the legs (deep vein thrombosis)

- the lungs (pulmonary embolism)
- the heart
- the brain (stroke)
- other part of the body

Do not take DIENILLE if you are concerned about an increased risk of blood clots. Blood clots are rare. Very occasionally blood clots may cause serious permanent disabilities, or may even be fatal.

Do not take DIENILLE if you are concerned about an increased risk of blood clot because of age and smoking. The risk of blood clots increase as you age. Smoking too increases the risk of blood clots. You should stop smoking when you are taking the Pill, especially if you are older than 35 years old.

Do not take DIENILLE if you have or have had:

- angina (chest pain)
- mini-stroke (transient ischaemic attack)
- migraine, accompanied with visual symptoms, speech disability, or weakness or numbness in any part of the body
- diabetes mellitus with blood vessel damage
- pancreatitis (inflammation of the pancreas)
- severe liver disease
- cancer that may grow under influence of sex hormones
- liver tumour
- unexplained vaginal bleeding

Do not use DIENILLE if you have Hepatitis C and are taking the medicinal products containing ombitasvir / paritaprevir / ritonavir and dasabuvir.

If any of the above

symptoms occur, please stop the pill and consult your doctor immediately. In the meantime, please use other non-hormonal methods of contraception.

Do not take DIENILLE if you are or think you might be pregnant.

Do not give DIENILLE to a child.

If you are not sure when to commence this medication, please consult your doctor or pharmacist.

Before you start to use it

Tell your doctor if:

- you have allergies to any other medicines or preservatives
- you smoke
- any other medical conditions

Ask your doctor to check if you:

- are overweight
- have high cholesterol or triglycerides
- have liver disease
- have gall bladder disease
- have Crohn's disease or ulcerative colitis
- have systemic lupus erythematosus
- have haemolytic uraemic syndrome
- have sickle cell disease
- have a condition that occurred for the first time, or worsened during pregnancy or previous use of sex hormones
- have chloasma (yellowish-brown pigmentation patches on the skin)
- have hereditary angio-oedema (eg. swollen face, tongue and/or pharynx and/or difficulty swallowing, or hives together with difficulty in breathing)

Please inform your doctor if any of the above condition occur for the first time, or recur or worsen while taking DIENILLE.

Tell doctor if you are breastfeeding.

Taking other medicines

Inform your doctor if you are taking any other medicines including:

- medicines used to treat tuberculosis (eg. rifampicin, rifabutin)
- medicines used to treat epilepsy
- medicines used to treat HIV
- antibiotics
- antidepressants
- antacids
- blood pressure medications
- immunosuppressant medications
- herbal medicines (eg. St John's Wort)
- grapefruit

These medicines/foods may be affected by DIENILLE or may affect how well it works.

Do not use DIENILLE 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 before starting the treatment with these medicinal products.

You may need to use additional barrier contraceptive methods while you are taking any of these medications and for some time after stopping them.

4. HOW TO USE DIENILLE

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instruction given on the label or in this leaflet, please consult your doctor or pharmacist.

How much to use it

One tablet is to be taken for 21 consecutive days. Each subsequent pack is started after 7 tablet-free days. Your period usually occur within this period. Typically, it starts 2 – 3 days after the last pill and may still be present when the first tablet from the next blister pack is taken.

When to use it

Take one tablet a day at the same time, according to the sequence printed on the blister pack.

How long to use it

For contraception:

Your doctor may prescribe DIENILLE for long periods, until you no longer need or want contraception.

For the treatment of acne:

Your doctor will advise how long to take DIENILLE for the treatment of acne.

If you forgot to use it

If the forgotten pill is taken **within 12 hours**, no further precautions are needed; the product should be taken as soon as possible and further tablets should be taken at the usual time.

If the tablet is forgotten for **more than 12 hours**, contraceptive protection may be reduced. In this case, the following rules have to be applied:

- Taking the pill should not be stopped for more than 7 days
- For the proper inhibition of the hypothalamus- hypo physis-ovary system, tablets have to be taken for 7 days without interruption

Based on these, the following advice can be given for the everyday practice:

First week

You should take the last forgotten tablet, even if this means taking two tablets in one day then continue to the tablet at the normal time. Additional

contraceptive precautions should be taken for the next 7 days. However, if sexual intercourse has already proceeded in the previous 7 days, pregnancy cannot be excluded. Risk of getting pregnant is proportional to the number tablets missed and is increasing as the “missed-period” gets closer to the tablet free period.

Second week

You should take the last forgotten tablet, even if this means taking two tablets in one day and then continue to take tablet at the normal time. If she has taken the tablets regularly on the preceding 7 days, there is no need to take additional contraceptive precautions. However, if there was more than one tablet missed or you have taken the tablets regularly, additional contraceptive precautions must be taken for the next 7 days.

Third week

In this period the risk for incomplete contraception is extremely high because of the advancing tablet-free period. However, some sort of contraception can be ensured by modifying the schedule of the tablets. By using the next protocols, there is no need to take additional contraceptive precautions, given that the woman has taken the tablets regularly on the preceding 7 days. If not, the first protocol should be selected and additional contraceptive precautions must be taken for the next 7 days.

For further information, please refer to product insert or consult your healthcare professionals.

If you use too much (overdose)

The acute oral toxicity of dienogest and ethinylestradiol is small. When a considerable amount of DIENILLE has been taken by a small child, the possibility of the development of toxic symptoms is small.

Overdose may cause nausea, vomiting and, in young girls, withdrawal bleeding. There is no need for special treatment. If necessary, symptomatic treatment should be applied.

5. WHILE YOU ARE USING IT

Things you must do

While you are using DIENILLE you should see your doctor regularly at least twice a year.

Contact your doctor as soon as possible if:

- you have severe pain or swelling in either of your legs, unexplained pains in the chest, breathlessness, an unusual cough, especially when you cough up blood (possibly indicating a thrombosis).
- you have a sudden, severe stomach ache or look jaundiced (possibly indicating liver problems);
- you feel a lump in your breast (possibly indicating breast cancer);
- you have a sudden or severe pain in the lower abdomen or stomach area (possibly indicating an ectopic pregnancy, this is a pregnancy outside the womb);
- you are to be immobilised or are to have surgery (consult your doctor at least four weeks in advance);
- you have unusual, heavy vaginal bleeding;
- you suspect that you are pregnant

Things you must not do

Avoid smoking as it increase the risk of thrombosis.

If you are pregnant, you must not take DIENILLE. If you become pregnant while taking DIENILLE you must stop immediately and contact your doctor.

Things to be careful of

If you experience any unusual

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symptoms when you are taking DIENILLE, please consult your healthcare professionals immediately.

6. SIDE EFFECTS

If you notice any of the following side effects and they worry you, tell your doctor or pharmacist:

- Nausea
- Stomach pain
- Changes in weight
- Headache
- Mood changes
- Breast tenderness or pain

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 calling Tel: 03-78835490, or visiting the website nptra.moh.gov.my (Public → Reporting → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

7. STORAGE AND DISPOSAL OF DIENILLE

Keep out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not store above 30°C. Keep in a cool and dry place.

Do not use DIENILLE after the expiry date which is stated on the carton after “Do not use after:” or “EXP:”. The Expiry date refers to the last day of that month.

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.

8. PRODUCT DESCRIPTION

What it looks like

White or off white, round, biconvex film-coated tablet

Ingredients

Each film-coated tablet contains Dienogest 2mg / Ethinyloestradiol 0.03mg

Tablet core

Lactose monohydrate, magnesium stearate, maize starch, povidon 30, talc

Film coating

Opaglos 2 clear, containing: sodium carboxymethyl-cellulose, glucose, maltodextrin, sodium citrate dihydrate, soy lecithin

Product Registration Number

MAL18056094AZ

9. MANUFACTURER AND PRODUCT REGISTRATION HOLDER

Manufacturer

LABORATORIOS LEON FARMA, S.A.
La Vallina s/n Poligono Industrial
Navatejera, 24193
Leon, Spain

Product Registration Holder

Eurodrug Laboratories (M) Sdn Bhd
T2-21-10, The Square,
One City,
Jalan USJ 25/1C,
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Selangor, Malaysia

10. DATE OF REVISION

13/10/2025

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