

METRINELLE 2MG TABLET

Dienogest 2mg

What is in this leaflet?

1. What METRINELLE is used for
2. How METRINELLE works
3. Before you use METRINELLE
4. How to use METRINELLE
5. While you are using it
6. Side Effects
7. Storage and Disposal of METRINELLE
8. Product Description
9. Manufacturer
10. Product Registration Holder
11. Date of revision
12. Serial number

1. What METRINELLE is used for

METRINELLE is a preparation for the treatment of endometriosis (painful symptoms due to displaced tissue of the lining of the womb).

METRINELLE contains a hormone, the progestogen dienogest.

2. How METRINELLE works

Dienogest is a nortestosterone derivative with no androgenic but rather an antiandrogenic activity of approximately one third of that of cyproterone acetate. Dienogest binds to the progesterone receptor of the human uterus with only 10% of the relative affinity of progesterone.

Despite its low affinity to the progesterone receptor, dienogest has a strong progestogenic effect in vivo.

Dienogest has no significant androgenic, mineralocorticoid or glucocorticoid activity in

vivo. Dienogest acts on endometriosis by reducing the endogenous production of oestradiol and thereby suppresses the trophic effects of estradiol on both the eutopic and ectopic endometrium.

When given continuously, dienogest leads to a hypoestrogenic, hypergestagenic endocrine environment causing initial decidualization of endometrial tissue followed by atrophy of endometriotic lesions.

3. Before you use METRINELLE

When you must not use it

Do not use METRINELLE:

- If you are allergic (hypersensitive) to dienogest or any other ingredients of METRINELLE
- If you have active venous thromboembolic disorder
- If you have arterial and cardiovascular disease, past or present (e.g., myocardial infarction, cerebrovascular accident, ischemic heart disease)
- If you have diabetes mellitus with vascular involvement
- If you have presence or history of severe hepatic disease as long as liver function values have not returned to normal
- If you have presence or history of liver tumours (benign or malignant)
- If you have known or suspected sex hormone-dependant malignancies
- If you have undiagnosed vaginal bleeding

If you think this may apply to you, do not use until you have checked with your doctor.

Pregnancy and lactation:

There is only limited information about the safety of METRINELLE in pregnant women. Do not take METRINELLE if you are pregnant, trying to get pregnant or think you may be pregnant without checking with your doctor.

It is not known whether the ingredients of METRINELLE can pass into breast milk. Do not take METRINELLE if you are breastfeeding without checking with your doctor. Ask your doctor or pharmacist for advice before taking any medicine.

Before you start to use it

Talk to your doctor or pharmacist before taking METRINELLE tablets if you have or previously had any of the following conditions:

- Diabetes
- Migraine
- Vaginal or uterine bleeding
- Venous thromboembolic disorder
- Heart disease
- Liver disease or liver tumour
- Blood pressure
- Breast cancer
- Ovarian cancer
- Osteoporosis
- Depression
- Chloasma gravidarum

Taking other medications

Tell your doctor or pharmacist if you're taking any other medicines, if you've taken any recently, or if you start taking new ones. This includes medicines you bought without a prescription.

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Dienogest 2mg

4. How to use METRINELLE

How much to use

Always use METRINELLE exactly as your doctor has told you to. Check with your doctor or pharmacist if you are not sure.

When to use it

Use as directed by your doctor or pharmacist.

How long to use it

Continue taking METRINELLE for as long as your doctor recommends.

If you forget to use it

Take the tablet as soon as you remember and carry on taking the tablets at the normal times. Consult your doctor or pharmacist on what you should do if you missed a dose.

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 have taken too much of this medicine. Do this even if there are no signs of discomfort. You may need urgent medical attention.

5. While you are using it

Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists

and pharmacists treating you that you are taking METRINELLE.

Tell your doctor immediately if you become pregnant while taking this medication.

Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give METRINELLE to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

Driving and using machines:

No effect on the ability to drive or use machines has been seen with METRINELLE.

6. Side effects

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

Tell your doctor/pharmacist/nurse immediately or as soon as possible and stop using METRINELLE if any of the following happens.

The following side effects have been observed during treatment with METRINELLE:

- Changes in bleeding pattern, such as spotting, irregular bleeding or amenorrhea
- Headache
- Breast discomfort
- Depressed mood
- Acne
- Anemia
- Weight increase

- Weight decrease
- Increased appetite
- Depression
- Anxiety
- Mood swings
- Migraine
- Dry eye
- Tinnitus
- Autonomic nervous system imbalance
- disturbance in attention
- Unspecific circulatory system disorder
- Palpitations
- Hypotension
- Dyspnoea
- Nausea
- Abdominal pain
- Flatulence
- Abdominal distension
- Vomiting
- Diarrhoea
- Constipation
- Abdominal discomfort
- Gastrointestinal inflammation
- Gingivitis
- Acne alopecia
- Dry skin
- Hyperhidrosis
- Pruritus
- Hirsutism
- Onychoclasia
- Dandruff dermatitis
- Abnormal hair growth
- Photosensitivity reaction
- Pigmentation disorder
- Back pain
- Bone pain
- Muscle spasms pain in extremity
- Heaviness in extremities
- Urinary tract infection
- Breast discomfort
- Ovarian cyst
- Hot flushes
- Uterine/ vaginal bleeding including spotting
- Vaginal candidiasis
- Vulvovaginal dryness
- Genital discharge
- Pelvic pain

METRINELLE 2MG TABLET

Dienogest 2mg

- Atrophic vulvovaginitis breast mass
- Fibrocystic
- Breast disease
- Breast induration
- Asthenic conditions irritability
- Oedema

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

7. Storage and Disposal of METRINELLE

Storage:

Store below 30°C in the outer box to protect from light. Keep out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the packaging or blister after “Do not use after” or “EXP.” The expiry date refers to the last day of that month.

Disposal:

Do not throw away any medicine 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:

METRINELLE tablets are white, round, biconvex and plain, with a diameter of 5 mm approximately and thickness about 3 mm.

They may be available in

boxes of 28, 84 or 168 tablets; Not all pack sizes may be marketed.

Ingredients:

METRINELLE tablet contains Active ingredient: Dienogest 2mg

The other ingredients: Lactose monohydrate, Maize starch, Povidone K-30, Magnesium stearate.

MAL number

9. Manufacturer

Laboratorios Leon Farma, S.A.
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10. Product Registration Holder

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11. Date of revision

4 May 2025

12. Serial number

NPRA (R2) 24/106