

MINIPIL 20

Film-coated Tablets

Levonogestrel 0.10mg / Ethinylestradiol 0.02mg

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1. WHAT MINIPIL 20 IS USED FOR

MINIPIL 20 is a combined oral contraceptive (COC) pill that is used to prevent pregnancy. It is also used to treat mild to moderate acne in postmenarchal and premenopausal women who can accept contraception.

2. HOW MINIPIL 20 WORKS

The hormones in the pill help in preventing pregnancy by maintaining a constant level of hormones in the body.

3. BEFORE YOU USE MINIPIL 20

When you must not use it

Do not take **MINIPIL 20** if you have or have had:

- Formation of blood clots in veins in any part of the body
- Liver malignancies
- Known or suspected breast cancer
- Disorders of lipid metabolism

- Irregular heartbeat or disorder of the valves of the heart
- Sickle-cell anemia
- Diabetes with blood vessels abnormalities
- Undiagnosed vaginal bleeding
- Known or suspected pregnancy
- Stroke or heart-related disorder
- Uncontrolled blood pressure
- Blood coagulation disorder
- Migraine
- Disorder of the pancreas with severe hypertriglyceridemia
- Hypersensitivity to the active substances levonorgestrel, ethinylestradiol or to any of the excipients in **MINIPIL 20** tablets.

Do not use **MINIPIL 20** if you have Hepatitis C and are taking the medicinal products containing ombitasvir / paritaprevir / ritonavir and dasabuvir.

Before you start to use it

Tell your doctor if:

- you have allergies
- you smoke
- any other medical conditions

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

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 (eg. barbiturates, primidone, phenytoin, topiramate and lamotrigine)
- medicines used to treat HIV (eg. ritonavir, indinavir and some other protease inhibitors)
- antibiotics/antifungals (eg. griseofulvin, fluconazole, ampicillin, troleandomycin and other penicillins, tetracyclines)
- immunosuppressant medications (eg. cyclosporins)
- other drugs such as phenylbutazone, dexamethasone, modafinil, paracetamol, theophylline, corticosteroids and flunarizine
- herbal medicines (eg. St John's Wort)
- health supplements (eg. ascorbic acid)

These medicines/foods may be affected by **MINIPIL 20** or may affect how well it works. Please consult your prescriber.

Do not use **MINIPIL 20** 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.

4. HOW TO USE MINIPIL 20

How much to use it

One tablet is to be taken daily for 21 consecutive days, followed by a 7-day tablet-free interval. Each subsequent pack is started on the day after the tablet-free interval. A withdrawal bleed usually starts on days 2 – 3, after the last active tablet, and may not have finished before the next pack is started.

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

Your physician should decide on whether its use should be discontinued.

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:

- The last missed tablet should be taken as soon as it is remembered, which may result in the user taking two tablets on the same day.
- Subsequent tablets should be taken at the usual time. A non-hormonal back-up method of birth control must be used for the next 7 days.

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

If you use too much (overdose)

Symptoms of **MINIPIL 20** overdose in adults and children may include nausea, vomiting,

breast tenderness, dizziness, abdominal pain, drowsiness, fatigue; withdrawal bleeding may occur in females. There is no specific antidote and further treatment of overdose, if necessary, is directed to the symptoms.

5. WHILE YOU ARE USING IT

Things you must do

While you are using **MINIPIL 20** you should see your doctor regularly at least twice a year.

Things you must not do

Avoid smoking.

If you are pregnant, you must not take **MINIPIL 20**. If you become pregnant while taking **MINIPIL 20** you must stop immediately and contact your doctor.

If you are breastfeeding, you are not advised to take **MINIPIL 20**.

Things to be careful of

If you experience any unusual symptoms when you are taking **MINIPIL 20**, please consult your healthcare professionals immediately.

6. SIDE EFFECTS

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.

- Vaginal infection
- Mood changes
- Headache
- Nervousness
- Dizziness
- Nausea & vomiting
- Abdominal pain
- Acne
- Breakthrough bleeding/spotting
- Breast changes
- Painful periods
- Changes in menstrual flow
- Absence of periods

- Changes in vaginal discharge
- Fluid retention
- Weight changes

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

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 [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

7. STORAGE AND DISPOSAL OF MINIPIL 20

Keep out of the sight and reach of children.

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

Do not use **MINIPIL 20** after the expiry date. The Expiry date refers to the last day of that month.

8. PRODUCT DESCRIPTION

What it looks like

MINIPIL 20 comes in a box containing 1 blister pack of 21 active film-coated tablets. Each film-coated tablet is pink and round.

Ingredients

Each tablet contains 0.10 mg of levonorgestrel and 0.02 mg of ethinylestradiol.

The other ingredients (excipients) are anhydrous lactose, povidone K-30 (E1201), magnesium stearate (E572) and opadry II pink [polyvinyl alcohol, talc (E553b), titanium dioxide (E171), polyethylene glycol 3350, red aluminium lake (E129), lecithin (E322), iron oxide red (E172) and blue aluminium lake (E1329)].

Product Registration Number

MAL14035051ACZ

**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
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10. DATE OF REVISION

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