PACKAGE LEAFLET: INFORMATION FOR THE USER

ERGOMETRIN Lek

0.2 mg film-coated tablet

ERGOMETRINE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. WHAT ERGOMETRIN LEK IS AND WHAT IT IS USED FOR

Ergometrin Lek 0.2 mg film-coated tablets lead to muscle contractions of the uterus. Ergometrine is water soluble alkaloid that is found naturally in ergot (Secale cornutum, rye fungus). It stimulates rhythmic contractions of the uterus, increases the frequency of existing contractions, and increases the tone of the muscles of the uterus. Its effect is especially strong during pregnancy and postpartum period.

ERGOMETRIN Lek film-coated tablets are used:

• for the prevention and treatment of bleeding from the uterus after childbirth, Caesarean or abortion (miscarriage)

• to facilitate reduction of the uterus to its normal size after childbirth, when the tone of muscles is decreased

Medicine begins to Act 5-15 minutes after application.

2. BEFORE YOU TAKE ERGOMETRIN LEK

Do not use ERGOMETRIN Lek:

- If you are allergic (hypersensitive) to ergometrine, ergot alkaloids (alkaloid group of fungus) or any of the other ingredients of ERGOMETRIN Lek
- If you are pregnant or think you may be pregnant
- If there is a risk of miscarriage
- If you are pregnant and you are having problems with swelling, increased blood pressure and protein in the urine (EPH gestosis), or even convulsions (eclampsia)
- If you are in the first or second stage of labor
- If you have sepsis (blood poisoning, the presence of bacteria or other infectious organisms or their toxins in the blood or tissues)
- If you are breast-feeding
- If you have Vascular disease of limbs (an advanced disease of peripheral vessels such as progressive obliterative angiopathy)
- If you are having problems with lungs, liver or kidney problems
- If you currently treat severe heart disease
- If you have heart problems due to lack of blood flow to the heart muscle (history of pain in the chest or heart attack)
- If you have had seizures due to transient problems of blood circulation in the brain (transient ischemic attacks) or stroke
- If you have severe injury of cardiac mitral valve (severe mitral stenosis)
- If you are taking medicines that constrict blood vessels (such as adrenaline, dopamine, propranolol)
- If you are taking antiviral medicines (such as saquinavir)
- If you are taking systemic antifungals (antifungal medicines, such as ketoconazole)
- If you are taking antidepressants (such as fluoxetine)
- If you are taking antimicrobial medicines (such as macrolides, tetracyclines, metronidazole)
- If you are taking Leukotriene Receptor Antagonists (such as zileuton, medicine to treat asthma)

Take special care with ERGOMETRIN Lek:

- If you have high blood pressure
- If you have Porphyria (a disorder of metabolism of proteins)

Anesthesia should be avoided.
Do not smoke while taking ERGOMETRIN Lek.
Effects of ERGOMETRIN Lek are reduced if you have hypocalcaemia (low calcium levels).
With multiple childbirth, you shouldn't take ERGOMETRIN Lek until after the birth of the last child.
Do not take ERGOMETRIN Lek longer than 7 days.

Taking other medicines

Please tell your doctor or pharmacist if you are using or have recently used any other medicine.
This includes medicines that can be purchased without a prescription.

- concomitant use with halothane (a general anesthetic) reduces the effects to uterus Ergometrin Lek
- you should wait at least 24 hours after discontinuation of the use of Ergometrine to use triptane for the treatment of migraine headache (sumatriptan, zolmitriptan). If you are taking triptane, you must wait at least 6 hours prior to the application of ERGOMETRIN Lek.
- ERGOMETRIN Lek increases the effects of prostaglandins (medicines that stimulate uterine contraction).

Taking ERGOMETRIN Lek with food and drink
Grapefruit juice may increase the plasma concentrations of ergometrine; do not drink it while taking this medicine.

Pregnancy and breastfeeding
Ask your doctor or pharmacist for advice before using any medicine.

Pregnancy
If you are pregnant, think you are pregnant or planning a pregnancy, be sure to tell the doctor before starting the treatment.
The medicine should not be used in pregnant women.

Breast feeding
Tell your doctor if you are breast-feeding. Ergometrine passes into breast milk and may cause signs of poisoning (Ergotism) in infants. Therefore, nursing mothers should not take this medicine.

Driving and using machines
In some patients, the medicine can cause dizziness, which temporarily reduces the ability to drive and use machines.

Important information about some of the ingredients of ERGOMETRIN Lek
ERGOMETRIN Lek coated tablets contain lactose. If a doctor told you that you have intolerance to some sugars, contact him before taking this medicine.

3. HOW TO TAKE ERGOMETRIN LEK

Your doctor will decide how many tablets a day you need to take, and how long will your treatment last. You should exactly follow the doctor's instructions. You should not change the dose or stop treatment without consulting your doctor.

For the treatment of incomplete shrinking of the uterus after childbirth and slight bleeding, take 1-2 tablets every 6 to 12 hours, but not more than 8 tablets per day.
Do not take the medicine longer than 7 days.

If you have the impression that the effect of Ergometrin Lek's is too strong or too weak, contact your doctor or pharmacist.

If you take more ERGOMETRIN Lek than you should
If you take too many tablets, contact your doctor. Bring any remaining tablets with you to show them to the doctor.
Signs of acute poisoning can occur within 5 minutes after taking the medicine. They include nausea, vomiting, diarrhea and painful contractions of the uterus. The main symptoms of overdose are cramps and problems with blood circulation in extremities. Other symptoms are reduced or raised blood pressure, weak pulse, shortness of breath, loss of consciousness, cold extremities, chest pain, and increased coagulation of the blood.
Chronic intoxication (Ergotism) may occur due to long-term administration of ERGOMETRIN Lek, medicine overdose or hypersensitivity to the medicine. The signs are the same as with acute intoxication; symptomatic treatment is required.

If you forget to take ERGOMETRIN Lek
If you miss a dose, take the next dose at the usual time and continue to take the medicine as instructed by a doctor.
Do not take a double dose to make up for a forgotten dose

If you have further questions about taking this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like any other medicine, ERGOMETRIN Lek may cause side effects, although not everybody gets them.
Assessment of side effects is based on the following frequencies:

- Very common: affects more than 1 in 10 patients
- Common: affects about 1 to 10 in 100 patients
- Uncommon: occurs in 1 to 10 in 1000 patients
- Rare: affects about 1 to 10 in 10000 patients
- Very rare: affects less than 1 in 10000 patients
- Unknown: frequency cannot be estimated on the basis of the available data

You may experience the following side effects:

Common

- nausea and vomiting
- headache
- high blood pressure

Very rare

- decreased cardiac operation
- problem with heartbeats and other heart rhythm problems
- pain in the chest
- heart attack
- vertigo
- stroke
- ringing in the ears (Tinnitus)
- difficulty in breathing or shortness of breath
- abdominal pain
- diarrhea
- severe allergic reaction that causes difficulty in breathing or dizziness with possible additional difficulties (skin rash, hypotension, anaphylactic shock)
- confusion

If any of the side effects get worse or you notice side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE ERGOMETRIN LEK

Keep the medicine out of reach and sight of children.
Keep at temperature below 25 ° C, protected from light and moisture.
Shelf life: 3 years
Do not use ERGOMETRIN Lek after the expiry date stated on the box. The expiry date of the medicine refers to the last day of the 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.

6. FURTHER INFORMATION

What ERGOMETRIN Lek contains

The active substance is ergometrine.

Each tablet contains 0.2 mg of ergometrine maleate.

The other ingredients are:

Core:

butylated hydroxyanisole (E 320)
lactose monohydrate
povidone
crospovidone
corn starch
maleate acid
Stearic acid
Talc

Coating:

carnauba wax
hypromellose
macrogol 400
iron oxide, Brown (E172)

What ERGOMETRIN Lek looks like and contents of the pack

Film-coated tablets.
Dark Brown, round, biconvex, film-coated tablets.
Boxes with brown glass bottles of 20 film-coated tablets, every Tablet contains 0.2 mg of ergometrine maleate; adsorption capsules in each bottle.

Regime of dispensing

The medicine is issued to the doctor's prescription

Manufacturer

LEK farmacevtska družba d.d.,
Verovškova 57, Ljubljana, Republic of Slovenia

Manufacturer of the medicinal product

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Verovškova 57, Ljubljana, Republic of Slovenia