PACKAGE LEAFLET: INFORMATION FOR THE USER

METHYLERGOMETRIN

0.25 mg/mL oral drops, solution

METYLERGOMETRINE

• 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 Methylergometrin is and what it is used for
2. Before you take Methylergometrin
3. How to take Methylergometrin
4. Possible side effects
5. How to store Methylergometrin
6. Further information

1. WHAT METHYLERGOMETRIN IS AND WHAT IT IS USED FOR

Methylergometrin contains the active substance metylergonovin-maleate, which is a semi-synthetic derivative of ergometrine, natural alkaloids. It is intended for the prevention and treatment of bleeding from the uterus. Methylergometrin acts on the smooth muscles of the uterus, leading to rapid and sequential contraction of the muscles of the uterus, thus reducing blood loss. Methylergometrin, oral drops, solution is used in the treatment of bleeding from the uterus, caused by childbirth or abortion.

2. BEFORE YOU TAKE METHYLERGOMETRIN

Warn the doctor if you are taking other medicines, you have a chronic disease, a metabolic disorder, if you are hypersensitive to medicines or have had an allergic reaction to some of them.

DO NOT USE METHYLERGOMETRIN

You should not take Methylergometrin, oral drops if:

• you have a hypersensitivity to metylergonovin maleate and/or alkaloids or any ingredients of this medicine

- you have a severe form of hypertension (high blood pressure)
- you have preeclampsia, eclampsia (a difficult situation during pregnancy that is most common at the end of the pregnancy and during childbirth, and manifests are headache, flashing signals and glitter, buzzing sound in the ears, general weakness, swelling, very high blood pressure)
- you have angina (pain and tightness in the chest), unstable or vasospastic
- are pregnant
- you have blockage (obliteration) of blood vessels
- have septicemia (presence of bacteria in the blood)
- you have liver or kidney damage.

WARNINGS AND PRECAUTIONS

Caution should be exercised when applying the medicine to patients with mild to moderately high blood pressure (severe hypertension is a side effect), anemia or a severe form of increased functions of the thyroid gland (hyperthyroidism) because of the potential occurrence of heart complications.

TAKING METHYLERGOMETRIN WITH FOOD OR DRINKS

Taking Methylergometrin, oral drops with food or drinks does not affect the effectiveness of the medicine.

PREGNANCY AND BREASTFEEDING

Before you start taking any medication, consult your doctor or pharmacist.
If you are pregnant or think you may be pregnant, contact your doctor.
Methylergometrin should not be used during pregnancy because of their uterotonic effects (increases the rhythmic contractions of the uterine wall).
At therapeutic doses, the amount of the medicine that is excreted into human breast milk is such that it can have a toxic effect on the child. Women who are breastfeeding should not be treated for more than 3 days. Methylergometrin can reduce the secretion of breast milk. Special caution is required when administering the medicine during the period of breastfeeding.
If you have any questions, please contact your doctor.

Ability to drive and use machines

If you feel faintness and dizziness during treatment with Methylergometrin you should not operate motor vehicles and use machinery.

What you need to know about other substances contained in methylergometrin

Methylergometrin contains methyl parahydroxybenzoate which may cause allergic reactions, and rarely bronchospasm.
This medicine contains small amounts of ethanol (alcohol), less than 100 mg per dose.

TAKING OTHER MEDICINES

Please tell your doctor or pharmacist about all medicines you are taking or have recently taken, including those obtained without a prescription or herbal medicines.

In particular, tell your doctor if you are taking:

- macrolide antibiotics (e.g., erythromycin, troleandomycin, clarithromycin)-antibacterial medicines
- inhibitors of reverse transcriptase inhibitors and HIV protease inhibitors (e.g., ritonavir, indinavir, nelfinavir, delavirdine)-medicines in the treatment of HIV and AIDS.
- antifungicides (e.g., ketoconazole, itraconazole, voriconazole)-antifungal medicines
- inhibitors of the enzyme CYP 3A4 inhibitors (saquinavir, nefazodone, fluconazole, grapefruit juice, fluoxetine, fluvoxamine, zileuton and clotrimazole)
- other vasoconstrictors (triptane), sympathomimetics or alkaloids.

Simultaneous application of Methylergometrin and bromocriptine is not recommended.
For the prevention and treatment of uterine bleeding concomitant administration of two uterotonic such as Methylergometrin and oxytocin can sometimes be required. Oxytocin has a rapid effect, while Methylergometrin has longer effects.

There have been reported cases of ventricular tachycardia and fibrillation (heart rhythm disorders), as well as acute myocardial infarction and cardiac arrest, sometimes with fatal outcomes, with simultaneous administration of sulprostone and/or oxytocin and/or metylergometrine therapy of hemorrhage after childbirth due to uterine atony.

Anaesthetics, such as halothane and metoxyfluran, can reduce the effects of Methylergometrin.

3. HOW TO TAKE METHYLERGOMETRIN

Always take this medicine exactly as your doctor recommend and do not stop the treatment until your doctor tells you to do so. If you think that Methylergometrin has too weak or too strong effect on your body, consult a doctor or pharmacist.

Dosage is adjusted according to indications.

After childbirth or abortion, with incomplete restoring of the uterus to its normal size and late bleeding after childbirth, 3 x 10-15 drops per day is a recommended dose. The maximum duration of treatment is one week.

IF YOU TAKE MORE MEDICINE THAN YOU SHOULD

If you think that you have taken a higher dose of Methylergometrin than what has been recommended to you or if someone else has taken your medicine, talk to your doctor, pharmacist or go to the nearest medical facility.

Symptoms of overdose are: nausea, vomiting, abdominal pain, numbness of the extremities, elevated blood pressure, in more severe cases the drop in blood pressure, respiratory depression, a drop in body temperature, muscle spasms and muscle rigidity and coma.

Treatment is symptomatic, with careful monitoring of vital functions of breathing and heart rate.
The measures that are being taken are the following:

- the maintenance of adequate ventilation, especially if you experience seizures or coma
- correction of hypotension with appropriate medicines
- treatment of seizures with appropriate anticonvulsive medication
- treatment of peripheral Vasospasm by heating the extremities.

IF YOU FORGET TO TAKE METHYLERGOMETRIN

Never take a double dose to replace the missed dose of the medicine.
If you accidentally miss the daily dose, just take the next dose at the usual time.

WHAT HAPPENS IF YOU SUDDENLY STOP TAKING METHYLERGOMETRIN

Your doctor will advise you when to stop therapy.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Methylergometrin can cause side effects in some patients.
If any of the following side effects occur, talk to your doctor:

The most common side effects are high blood pressure, severe cases associated with epileptic seizures and headaches, as well as the drop in blood pressure.

Common: skin Exanthema (rash).

Uncommon: nausea and vomiting, chest pain and hyperhydrosis (excessive sweating).

Rare: acute myocardial infarction, arterial spasm of blood vessels (coronary and peripheral), slow or rapid heartbeat, shortness of breath, blood in the urine, the inflammation of the surface veins, leg cramps, fainting, tinnitus, clogged nose, diarrhea, sweating, palpitations (subjective palpitations), redness, abnormal taste.

Very rare: anaphylactic reactions (severe hypersensitivity reactions).

If you notice any side effects please tell your doctor or pharmacist.

5. HOW TO STORE METHYLERGOMETRIN

Keep out of reach of children!
Store up to 25 ° c.
After opening store at room temperature and use within 28 days.

SHELF LIFE
2 (two) years. It should not be used after the expiration date indicated on the package.

Unused medicine will be destroyed in accordance with the applicable regulations.

6. FURTHER INFORMATION

What Methylergometrin contains

Solution 1 mL (20 drops) contains:
0.25 mg of metilergonovin- maleate.
Other substances: methyl-parahydroxybenzoate, thiourea, glycine, ethanol 96%, glycerol, tartaric acid, purified water.

Methylergometrin, oral drops, solution is clear and colorless solution.

Regime of dispensing

The medicine is issued on doctor's prescription

Manufacturer

Hemofarm pharmaceutical products manufacturing driver Banja Luka
Novakovići have been destroyed b.b, Banja Luka, Bosnia and Herzegovina

Manufacturer of the medicinal product

Hemofarm proizvodnja farmaceutskih proizvoda d.o.o. Banja Luka
Novakovići b.b, Banja Luka, Bosnia and Herzegovina