PATIENT INFORMATION LEAFLET

PRE-EKLAMOL MAGNESIUM SULPHATE 40 g/1000 ml Solution for I.V. Infusion
Intrevenous administration.
Sterile

- ***Active substance:*** Each 1000 ml solution contains 40 g magnesium sulphate heptahydrate.
- ***Excipients:*** Sodium chloride, water for injection.

Before using this medicine, read all of this PATIENT INFORMATION LEAFLET carefully. Because, this leaflet includes important information for you.

- *Keep this PATIENT INFORMATION 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. Do not pass it on to others.*
- *During the use of this medicine, tell that you are using this medicine when you go to a doctor or hospital.*
- *Follow these instructions exactly as written. Do not use **higher or lower** dose other*

The following subjects are covered herein:

1. What is PRE-EKLAMOL and what it is used for?

- PRE-EKLAMOL is marketed in polypropylene bags containing 40 g of magnesium sulphate heptahydrate in every 1000 ml solution.

The bags contain a colorless and clear solution. Magnesium sulphate being in the group of mineral supplements is used in the following cases:

- Treatment and prevention of eclampsia (loss of consciousness, starting with contractions, and resulting in coma pregnancy intoxication), which is an advanced stage of pre-eclampsia having symptoms of increased blood pressure during pregnancy, overhydration of the feet and body.

2. Before you are given PRE-EKLAMOL

DO NOT USE PRE-EKLAMOL under the following circumstances

If:

• Heart problems,

• Severe renal failure,

• In case of hypersensitivity to magnesium sulphate or magnesium sulphate salts, you should not use this medicine

USE PRE-EKLAMOL with CAUTION

If;

• If you are pregnant, plan to become pregnant or if you are breastfeeding,

• If you have a kidney failure or are suspected of having a kidney failure,

• If you are suffering from myasthenia gravis (a muscle disease that causes muscle weakness), use this medicine carefully.

Please consult your doctor if these warnings are valid for you, even at any time in the past.

Using PRE-EKLAMOL with food and beverages

It does not interact with food and beverages due to the route of administration.

Pregnancy

Please consult your physician or pharmacist before taking the drug.

If PRE-EKLAMOL Magnesium Sulphate 4 g/100 ml I.V. solution for infusion is administered to pregnant women for 5-7 days, it may lead to congenital anomalies. In case of more than 5-7 days; hypocalcemia (calcium deficiency in the blood), skeletal mineral deficiency, osteopenia (beginning of bone resorption) and other skeletal disorders can be observed. Continuous application to prevent premature birth is not an approved treatment. It should not be used during pregnancy unless required.

If you realize that you are pregnant during your treatment, immediately consult your physician or pharmacist.

Lactation
Please consult your physician or pharmacist before taking the drug.
It is not known whether this drug is excreted in breast milk. Do not use PRE-EKLAMOL while breastfeeding unless it is determined as necessary by your doctor.

Ability to drive and use machines
PRE-EKLAMOL has no known effect on vehicle and machine use.

Vital information regarding some of the excipients contained in PRE-EKLAMOL
It does not contain any auxiliary substances that require special precautions.

Use in combination with other drugs
The use of PRE-EKLAMOL with the following drugs may be damaging:
• Digitalis glycosides used in heart disease (eg digoxin, digidin),
• Muscle relaxants used in anesthesia (use with magnesium sulphate may increase the effect of such drugs),
• High doses of opioid (eg morphine), barbiturate (eg, amylobarbitone) or hypnotic drugs (eg nitrazepam) (use with magnesium sulphate may cause slow and / or shallow breathing),
• Calcium channel blockers such as nifedipine or nimodipine (use with magnesium sulphate may cause problems in muscle functions),
• Aminoglycoside antibiotics (eg streptomycin) may increase the neuromuscular blocking effect of parenteral magnesium.
• Following the administration of drug or drug groups such as aminoglycosides, cyclosporine, digitalis, alcohol, amphotericin B, diuretics, cisplatin, drug-induced magnesium renal loss is observed.
• It may be damaging to use it with any other drug, including non-prescription drugs.
• Since the absorption of drugs containing levothyroxine is disrupted when taken together with PRE-EKLAMOL, two drugs should be taken at least 2 hours apart.

If you are currently taking or recently took any prescribed or over-the-counter drugs, please inform your physician or pharmacist.

3. How you will be given PRE-EKLAMOL?
Since PRE-EKLAMOL will be administered by your doctor or a health care provider, the following section is for your doctor or healthcare professional.

Instructions regarding correct use and dosage/administration frequency:

MAGNESIUM SULPHATE REGIME AND TRACKING: The most preferred regimen for magnesium sulphate; Administration of 4-6 g IV loading dosage in 15-20 minutes, followed by 2 g of continuous infusion per hour. The therapeutic dose of magnesium sulphate is 3.95 to 6.90 mEq/L, and serum magnesium levels should be monitored every six hours. Magnesium sulphate Myasthenia Gravis (a disease that weakens muscle strength) is dangerous because it can trigger severe myasthenic crisis in patients. On the other hand, use

of magnesium sulphate together with calcium channel blockers may lead to low blood pressure.
Magnesium sulphate is generally continued to be administered for 24 hours after birth, but we do not have high-quality data to determine the time of discontinuation of the drug. For women with mild pre-eclampsia (toxemia of pregnancy), 12 hours may be sufficient, while anticonvulsant therapy should be continued for 24-48 hours in women with severe pre-eclampsia and eclampsia (toxemia of pregnancy).

To prevent involuntary contractions (convulsions) in toxemia of pregnancy; After administering 4 g/ 100 ml IV solution for infusion in 15-20 minutes, 12 to 15 drops per minute are given in the form of 40 g / 1000 ml IV solution for infusion.

Pre-term birth; Initial dose: IV 4-6 g Magnesium Sulphate (32-48 mEq magnesium) is given by IV infusion in 20-30 minutes. Maintenance dose: 1-3 g of magnesium sulphate per hour (8-24 mEq of magnesium) is given until the uterine contractions stop. Dosage limits for adults: Up to 40 g magnesium sulphate (320 mEq magnesium) per day.
Parenteral medicinal products should be examined carefully for the presence of particles before use and should not be applied in case of color change before application.

Method of administration:
PRE-EKLAMOL is administered I.V. (intravenous) path.
The concentration of magnesium sulphate solutions to be used via intravenous infusion should be less than 20%, i.v. injection rate should not exceed 150 mg magnesium sulphate per minute. However, it may be necessary to increase this speed in severe pregnancy toxemia seizures.

Different age groups:
Use in elderly:
No special dose adjustment is required, provided there is no renal failure.

Special use cases:
Renal failure:
It should not be used in patients with severe renal failure.

Hepatic failure:
No data is available.

If you are under the impression that the effect PRE-EKLAMOL is too strong or weak, consult your physician or pharmacist.

If you have taken more PRE-EKLAMOL than you should have:

Since your medicine will be administered by a healthcare provider, it is not expected to use more PRE-EKLAMOL than you should use. However, if you think you are overdosed, you should inform your healthcare staff as soon as possible.

Excessive magnesium intake results in sudden drop in blood pressure (hypotension) and paralysis of the respiratory system. Loss of patellar reflex (knee cap reflex) is one of the symptoms of magnesium poisoning. If it is used more than necessary, artificial respiration should be performed until the calcium salt is injected. IV Calcium (5-10 mEq) can be used as an antagonist.
Treatment: Respiration is supported by I.V. administration of 10-20 ml of 10% calcium gluconate solution. If renal function is normal, appropriate fluids should be given to facilitate magnesium excretion from the body. Dialysis may be necessary in patients with renal failure or severe hypermagnesemia.

If you have used PRE-EKLAMOL more than you should have or more than prescribed, consult a physician or a pharmacist.

If you forget to take PRE-EKLAMOL

Since your medicine will be administered by a healthcare professional, the dose you should use is not expected to be forgotten. However, if you think that the dose should not be given to you, you should inform the health personnel.

Do not double-dose to make up for forgotten doses.

Possible effects once PRE-EKLAMOL treatment is concluded
No adverse effects are expected when treatment is terminated.

4. Possible side effects

Like all medicines, PRE-EKLAMOL may have side effects in people who are sensitive to the substances contained in its ingredient.
• Respiratory depression (slow and / or shallow breathing)
• Circulation collapse (disorder)
• Reduced blood pressure
• Irregular heartbeat or slow heart rate
• Heart attack
• Decrease in blood calcium levels (This may cause tingling or muscle twitching.)
• Loss of knee reflex
• Reduced body temperature
• Flushing and sweating

If you notice any side effect not mentioned in this leaflet, please inform your doctor or pharmacist.

5. How to store PRE-EKLAMOL

Keep PRE-EKLAMOL out of the sight and reach of children, and in its original packaging.

Store at room temperature under 25ºC.

Use in accordance with expiration dates.

Do not throw away any expired or unused medicines! Give to the collection system determined by the Ministry of Environment and Urbanization.

Do not use the PRE-EKLAMOL after the expiration date in the package.

Marketıng Authorısation Holder and Manufacturer:

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