PACKAGE LEAFLET

MYOCRON 50mg/5mL I.V. Solution for Injection, Vial

It is applied intravenously.

- ***Active substance:*** Each vial (5 ml) contains 50 mg rocuronium bromide as active substance.
- ***Excipient(s):*** Sodium acetate, sodium chloride, acetic acid, water for injection.

Please read this entire leaflet carefully before you start having 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. Do not give to other people.*
- *During use of this medicine, when you go to a doctor or a hospital, tell your doctor that you are using it.*
- *Follow the instructions, written in this leaflet, exactly. Do not use **higher or lower** doses other than the recommended dose to you.*

This leaflet includes following topics:

1. What MYOCRON is and what it is used for?

MYOCRON is packed in carton boxes containing 1 and 10 glass vials of 5 ml.

MYOCRON is a member of a group of drugs called muscle relaxants. Muscle relaxants are used during an operation as part of a general anesthetic. When you have an operation your muscles must be completely relaxed. This makes it easier for the surgeon to perform the operation.

Normally, nerves send messages called impulses to muscles. MYOCRON acts by blocking these impulses so that your muscles relax. Because your breathing muscles also relax, you

will need help to breathe (artificial ventilation) during and after your operation until you can breathe on your own again.
The effect of the muscle relaxant is constantly checked, and if necessary a little more muscle relaxant is given. At the end of surgery, the effects of the drug are allowed to wear off and you will start breathing on your own. Sometimes you are given another drug to help speed this up.
MYOCRON can also be used in Intensive Care Unit to keep your muscles relaxed.

2. Before you use MYOCRON

DO NOT USE MYOCRON in the following cases

Do not use MYOCRON, if you have hypersensitivity (allergy) to rocuronium, bromide ion or any of other excipients of MYOCRON.

Take SPECIAL CARE with MYOCRON in the following cases:

Your medical history may be affected to use in you. If you have any of the following or have been, tell to your doctor:

- Allergy of muscle relaxants
- Decrease in kidney function or kidney disease
- Heart disease
- Edema (exp: fluid retention in ankle)
- Liver or biliary disease and kidney or decreasing of liver function
- Disease which affected to nerves or muscles
- Sudden fever with rapid heart rate, rapid breathing, muscle pain and / or weakness

Specified medical situation is effective on mechanism of action of MYOCRON. For example,

- The low potassium levels in the blood
- The high magnesium level in the blood
- The low calcium level on the blood
- The low protein level in the blood
- Excessive water loss in the body, e.g. due to illness, diarrhea or sweating
- Too much carbon dioxide in the blood
- Too much carbon dioxide (alkalosis) due to excessive breathing,
- Impairment of general state of health

- Excess weight (obesity)
- Burns
- Hypothermia (decrease in body temperature)

If you have one of these situations, your doctor will be considered to it when decided to dose of MYOCRON.

If these alerts are true for you even if at any time in the past, please consult your doctor.

Pregnancy

Consult your doctor or pharmacist before using this medication.

If you are pregnant, suspect that you are pregnant, or if you are breastfeeding, ask your specialist's advice before giving you MYOCRON. MYOCRON can be applied to you during cesarean section.

If you notice that you are pregnant before anesthesia, consult your doctor immediately.

Breast-feeding

If you are breastfeeding, ask your specialist's advice before giving MYOCRON.

If you notice that you are pregnant before anesthesia, consult your doctor immediately.

Driving and using machines

After giving you MYOCRON, your doctor will tell you when you can safely use car or any machine that may be dangerous.

Important information about some excipients that is present in MYOCRON

MYOCRON contains sodium less than 1 mmol (23mg), any effects is not expected due to sodium for this dose.

Using other medicines

Drugs below can cause change in effect of MYOCRON:

Medicines which increase the effect of MYOCRON:

- Certain medicines which is used for sleep during surgery (anesthetics)
- Certain anti-inflammatory drugs (corticosteroids)
- Certain medicines which are used in treatment of bacterial infection (antibiotics)
- Certain medicines which are used in treatment of bipolar disorder (manic depressive)

- Certain medicines which are used in treatment of heart disease or hypertension (quinidine, antagonist to calcium, beta blockers, diuretics)
- Certain medicines which are used in treatment of malaria
- Magnesium salts
- Medicines which are used in the treatment of epilepsy during surgery (phenytoin)

Medicines which decrease the effect of MYOCRON:

- Using epilepsy medicine for a long time
- Calcium chloride and potassium chloride
- Certain protease inhibitors used in the treatment of HIV or hepatitis; gabexate, ulinastatin
- The effect of local anesthetics (lidocaine) may increase.

In addition, you may be given medicines that will differentiate the effect of MYOCRON before and during the operation. These are drugs that reverse the effects of certain anesthetics, other muscle relaxants, phenytoin or MYOCRON. MYOCRON may cause certain anesthetics to act more quickly. When your anesthetist chooses the right dose of MYOCRON for you, this will be taken into account.

If you are using or have recently used any prescribed or unprescribed medicine, please give information to your doctor or pharmacist.

3. How to use MYOCRON?

Instructions for appropriate usage and dose / frequency of application:

Your doctor will determine the dose of MYOCRON according to the following information.

- Anesthetic type
- Operation time
- Other medications you use
- Your health condition

At the normal dose of 0.6 mg / kg body weight, the effect will take 30-40 minutes.

Administration route and method:

MYOCRON will be applied to you by your doctor. MYOCRON can be administered as a continuous infusion (serum) to the vein in one single pass.

Different age groups:

Usage in children:

MYOCRON can be used for children including adolescents up to the age from 30 days and adults but at first, your doctor should consider your past medical history.

Usage in old people:

MYOCRON can be used in advanced age. However, your doctor must first evaluate the medical history of the patient.

Special use cases:

Kidney failure

It should be used with caution as it may show a prolonged effect.

Liver failure

It should be used with caution as it may show a prolonged effect.

If you have more MYOCRON than you should:

There is not any possibility to give more MYOCRON because of monitoring your condition by medical personnel during surgery. Nevertheless overdose occurred, artificial respiration is continued until you can aspirate yourself. While this is happening, you will continue to be asleep.

If you forget to take MYOCRON

It is not applicable.

Effects that may occur when treatment with MYOCRON is terminated:

Not applicable.

4. Possible side effects

Like all medicines, side effects may occur in patients, who are sensitive to the substances present in MYOCRON.

Very common : in at least 1 of 10 patients
Common : less than one in 10 patients, but more than one in 100 patients
Uncommon : less than one in 100 patients, but more than one or more in 1,000 patients
Rare : less than one in 1,000 patients, but more than one in 10,000 patients or more
Very rare : less than one in 10,000 patients
Unknown : It cannot be predicted by moving from the available data

Uncommon:

- Over-effective or not sufficiently effective of MYOCRON
- Effect for longer than desired effect of MYOCRON
- Increased heart rate
- Reduction of blood pressure (hypotension)
- Pain and reaction in the injection site

Very rare:

- Allergic (hypersensitivity) reactions (chest tightness, circulatory impairment, shock)
- Muscle cramps in the airways (bronchospasm) resulting in chest compression
- Wheezing in the chest
- Swelling, rash or redness on skin
- Rapid heartbeat, sudden fever, muscle retention, pain and / or weakness
- Edema in the face
- Fever, increase in heart rate and stiffness in muscles during anesthesia (malign hyperthermia)

If you notice any side effects not listed in this package leaflet, consult your doctor or your pharmacist.

Reporting Side Effects

If you get any side effects, which are mentioned or not mentioned in Package Insert, talk to your doctor, pharmacist or nurse. Moreover, report side effects that you have experienced to Turkey Pharmacovigilance Center (TÜFAM) by clicking icon "Reporting Side Effects" on the website www.titck.gov.tr or by calling 0 800 314 00 08, which is the line of Reporting Side Effects". By reporting side effects, you can help to provide more information on the safety of this medicine.

5. How to store MYOCRON?

MYOCRON is stored at hospital. Keep in 2°C-8°C (in refrigerator). Product may be stored outside of refrigerator at room temperature up to 25°C for maximum 6 months. Product that is taken from refrigerator should not be put in refrigerator again. Preservation period cannot exceed the shelf life.

Use in accordance with expiration date.

Do not use MYOCRON after the expiration date specified on package/use before the expiration date.

Do not use MYOCRON if you notice that solution is not clear or has particles.

Marketing Authorization Holder:

VEM İlaç San. ve Tic. A.Ş.
Söğütözü Mahallesi 2177. Cadde No:10 B/49
Çankaya/ANKARA/TURKEY

Manufacturer:

VEM İlaç San. ve Tic. A.Ş.
Çerkezköy Organize Sanayi Bölgesi
Karaağaç Mah. Fatih Blv. No:38
Kapaklı/TEKİRDAĞ/TURKEY

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THE FOLLOWING INFORMATION IS INTENDED FOR HEALTHCARE PROFESSIONALS

Compatibleness studies were performed with infusion solutions that are specified below. Rocuronium bromide was compatible at 0.5mg/ml and 2.0mg/ml nominal concentrations with 0.9% NaCl, 5% dextrose, 5% dextrose in saline (salt water), sterile water for injection, Ringer Lactate and Haemaccel.

Administration should be started immediately after mixing and it should be completed within 24 hours. Unused product should be disposed.