

PATIENT INFORMATION LEAFLET

MUSCOBLOC 50 mg/5 ml Solution for I.V. Injection

For intravenous administration.

Sterile

- **Active Substance:** Each vial contains 50 mg of rocuronium bromide.
- **Excipients:** Sodium acetate, sodium chloride, acetic acid (as pH adjuster), 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 doctor or hospital.*
- *Follow these instructions exactly as written. Do not use **higher or lower** dose other than your recommended dose.*

The following subjects are covered herein:

- 1. What is MUSCOBLOC and what is it used for?***
- 2. What you need to know before you use MUSCOBLOC?***
- 3. How you will be given MUSCOBLOC?***
- 4. Possible side effects***
- 5. How to store MUSCOBLOC***

The titles are included.

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

MUSCOBLOC is packed in a box containing 5 or 10 glass vials of 5 ml.

MUSCOBLOC belongs to a group of medicines called muscle relaxants. Muscle relaxants are used during an operation as part of the general anaesthetic. When you have an operation, your muscles must be completely relaxed; this makes it easier for the surgeon to perform the operation.

Normally the nerves send messages to the muscles by impulses. MUSCOBLOC acts by blocking these impulses so the muscles are relaxed. Because the muscles needed for breathing also become relaxed you will need help with your breathing (artificial respiration) during and after your operation until you can breathe on your own.

During the operation, the effect of the muscle relaxant is constantly checked and if necessary some

more drug is given. At the end of the operation the effects of MUSCOBLOC are allowed to wear off and you can start breathing on your own. Sometimes another drug is given to help speed this up.

MUSCOBLOC can also be used in Intensive Care to keep your muscles relaxed.

2. What you need to know before you use MUSCOBLOC?

DO NOT USE MUSCOBLOC under the following circumstances:

Do not use MUSCOBLOC if you are hypersensitive (allergic) to rocuronium bromide ion or other excipients of MUSCOBLOC.

USE MUSCOBLOC with CAUTION if:

Your medical history may affect the use of MUSCOBLOC you. Tell your doctor if you have or have had any of the following medical conditions:

- an allergy to muscle relaxants
- Impaired renal function or kidney disease
- A heart disease
- Oedema (e.g. Fluid retention in your ankles)
- Liver or gallbladder disease or decreased liver function
- Diseases affecting nerves or muscles
- Sudden fever with rapid heartbeat, rapid breathing and stiffness, pain and/or weakness in your muscles

Certain medical conditions may affect how MUSCOBLOC works. For example:

- Low potassium levels in the blood
- High magnesium levels in the blood
- Low calcium levels in the blood
- Low levels of protein in the blood
- Loss of too much water from the body, for example by being sick, diarrhea or, sweating
- Too much carbon dioxide in the blood
- Over-breathing leading to too little carbon dioxide in the blood (alkalosis)
- General ill-health
- Being very overweight (obesity)

- Burns
- Hypothermia (very low body temperature)

If you have any of these conditions, your physician will take it into account when deciding the correct dose of MUSCOBLOC for you.

If these warnings apply or applied to you, please consult your physician.

Pregnancy

Please consult your physician or pharmacist before taking the drug.

If you are pregnant, think you may be pregnant or breast-feeding, ask your physician for advice before taking MUSCOBLOC. MUSCOBLOC may be given to you during a Caesarean section.

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.

If you are breastfeeding, ask your physician for advice before taking MUSCOBLOC.

Ability to drive and use machines

Your doctor will tell you when it is safe to drive and operate potentially dangerous machinery after you have been given MUSCOBLOC.

Vital information regarding some of the excipients contained in MUSCOBLOC

This medicinal product contains less than 1 mmol (23 mg) sodium per ml, i.e. it is essentially "sodium free".

Use in combination with other drugs

Following medications may alter the effects of MUSCOBLOC:

Medicines which increase the effect of MUSCOBLOC:

- Certain medicines to make you sleep during surgery (anaesthetics)
- Certain anti-inflammatory medicines (corticosteroids)
- Certain medicines used to treat bacterial infections (antibiotics)
- Certain medicines used to treat bipolar disorder (manic depressive illness)
- Certain medicines for heart disease or high blood pressure (quinidine, calcium channel

blockers, beta-blockers, diuretics)

- Certain medicines used to treat malaria
- Magnesium salts
- Medicines used to treat epilepsy during surgery (phenytoin)

Medicines which decrease the effect of MUSCOBLOC:

- Prolonged use of epilepsy drugs
- 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 other medicines before or during surgery which can alter the effects of MUSCOBLOC. These include certain anaesthetics, other muscle relaxants, medicines which reverse the effects of MUSCOBLOC may make certain anesthetics work more quickly. Your anaesthetist will take this into account when deciding the correct dose of MUSCOBLOC.

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 MUSCOBLOC

Instructions regarding correct use and dosage/administration frequency:

Your doctor will determine the dose of MUSCOBLOC based on the following information:

- The type of anaesthetic
- The length of the operation
- Other medicines you are taking
- Your state of health

With the normal dose of 0.6 mg per kg body weight, the effect will last 30–40 minutes.

Route and method of administration:

MUSCOBLOC will be given to you by your doctor. MUSCOBLOC is given intravenously either as single injections or as a continuous infusion (a drip).

Injections should be made by a doctor or nurse.

Various age groups:

Use in children:

MUSCOBLOC can be used in children from one month to adolescent and in elderly. But your doctor should first assess the patient's medical history.

Use in elderly

MUSCOBLOC can be used in elderly. But your doctor should first assess the patient's medical history.

Special usage cases

Renal failure

Caution is advised due to prolonged effect.

Hepatic failure

Caution is advised due to prolonged effect.

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

If you have taken more MUSCOBLOC than you should have:

As a healthcare professional will be monitoring your condition carefully it is unlikely that you will be given too much MUSCOBLOC. However, if overdose happens, artificial breathing will continue until you can breathe on your own. You will be kept asleep while this takes place.

If you have used MUSCOBLOC more than you should have or more than prescribed, consult a physician or a pharmacist.

If you forget to take MUSCOBLOC

Not applicable.

Do not double-dose to make up for forgotten doses

Possible effects once MUSCOBLOC treatment is concluded

Not applicable

4. Possible side effects

Like all medicines, MUSCOBLOC may cause side effects in patients sensitive to its ingredients.

Very common: may be seen in at least 1 of 10 patients;

Common: may be seen in less than one of 10 patients but more than one of 100 patients;

Uncommon: may be seen in less than one of 100 patients but in one or more than one of 1.000 patients;

Rare: may be seen in less than one of 1.000 patients but in one or more than one of 10.000 patients;

Very rare: may be seen in at least one of 10.000 patients;

Not known: Cannot be estimated from the available data.

Uncommon:

- MUSCOBLOC is too effective, or not effective enough
- MUSCOBLOC is active for longer than expected
- Increase in heart rate
- Decreased blood pressure (hypotension),
- Pain and reaction at the site of injection

Very rare:

- Allergic (hypersensitivity) reactions (chest tightness, circulatory disorder, shock)
- Tightness in the chest due to muscle cramps of the airways (bronchospasm)
- Wheezing of the chest
- Swelling, rash or redness of the skin
- Sudden fever with rapid heartbeat, stiffness, pain and/or weakness in muscles
- Face oedema
- Fever, increased heartbeat and stiffness in muscles during anesthesia (malignant hyperthermia)

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

5. How to store MUSCOBLOC

Store MUSCOBLOC in its original packaging and keep out of the reach and sight of children.

MUSCOBLOC is stored in the hospital. Store at 2-8°C (in the refrigerator). The product can be stored outside the refrigerator at a temperature of up to 30°C for a maximum of 12 weeks. It should be used immediately after dilution. The product removed from the refrigerator should not be put back in the refrigerator. The storage period must not exceed the shelf-life.

Use in compliance with the expiry date.

Do not use MUSCOBLOC if you notice that the solution is not clear and not free from particles.

Do not use MUSCOBLOC after the expiry date which is stated on the label or use before the expiry date.

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This patient information leaflet was approved on 03.08.2018.

THE FOLLOWING INFORMATION IS INTENDED FOR MEDICAL OR HEALTHCARE PROFESSIONALS ONLY

Compatibility studies with the following infusion fluids have been performed. In nominal concentrations of 0.5 mg/ml and 2.0 mg/ml MUSCOBLOC has been shown to be compatible with the following infusion fluids: 0.9% NaCl, 5% dextrose, 5% dextrose in saline (saltwater), sterile water for injections, Lactated Ringers and Haemaccel.

Administration should be begun immediately after mixing, and should be completed within 24 hours.

Any unused solution should be discarded.