

## PATIENT INFORMATION LEAFLET

### VECUBLOC 10 mg powder and solvent for solution for i.v. injection

#### For intravenous administration.

#### Sterile

- **Active substance:** Vecuronium bromide 10 mg.
- **Excipients:** Citric acid anhydrate, dibasic sodium phosphate anhydrate, mannitol, sodium hydroxide solution and phosphoric acid solution (for pH adjustment), 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 than your recommended dose.*

#### **The following subjects are covered herein:**

1. *What is VECUBLOC and what is it used for?*
2. *Before you are given VECUBLOC*
3. *How you will be given VECUBLOC?*
4. *Possible side effects*
5. *How to store VECUBLOC*

#### **1. What is VECUBLOC and what is it used for?**

VECUBLOC belongs to a group of medicines called muscle relaxants.

VECUBLOC 10 mg contains 1 g of vecuronium bromide per ml.

Muscle relaxants are used during an operation as part of a 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, your nerves send messages called impulses to your muscles. VECUBLOC 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. During the operation your anaesthetist will keep a check on the effect

of the muscle relaxant, and if necessary will give you some more.

At the end of surgery, the effects of the drug are allowed to wear off and you will start breathing on your own. Sometimes the anaesthetist will give you another drug to help speed this up.

## **2. Before you are given VECUBLOC**

### **DO NOT USE VECUBLOC under the following circumstances**

If you are allergic (hypersensitive) to vecuronium, the bromide ion or any of the other ingredients of VECUBLOC.

### **USE VECUBLOC with CAUTION if**

- If you have any of the following conditions, tell your anaesthetist before take in this medicine:
  - if you are allergic to muscle relaxants
  - if you have had kidney, heart, liver or gall bladder disease
  - if you have fluid retention (oedema).
  - if you have had diseases affecting nerves and muscles
  
- Some conditions may influence the effects of
  
- VECUBLOC. For example:
  - Low potassium levels in the blood
  - High magnesium levels in the blood
  - Low levels of calcium in the blood
  - Low levels of protein in the blood
  - Loss of too much water from the body (for example vomiting, diarrhea or sweating)
  - Over-breathing leading to too little carbon dioxide in the blood
  - Too much carbon dioxide in the blood
  - General ill-health
  - Being very overweight (obesity)
  - Burns
  - Very low body temperature (hypothermia)

If you have any of these conditions, your anaesthetist will take this into account when deciding the correct dose of VECUBLOC for you.

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

### **Using VECUBLOC with food and beverages**

No interaction with food and drinks because of the route of administration.

### **Pregnancy**

*Please consult your physician or pharmacist before taking the drug.*

Your anaesthetist may still give you VECUBLOC, but you need to discuss it first. VECUBLOC may be given to you if you are having a Caesarean section.

### **Lactation**

*Please consult your physician or pharmacist before taking the drug.*

### **Ability to drive and use machines**

Do not drive or use machines until advised it is safe to do so. Because VECUBLOC is given as part of a general anaesthetic, you may feel tired, weak or dizzy for some time afterwards. Your anaesthetist will be able to advise you on how long the effects are likely to last.

### **Vital information regarding some of the excipients contained in VECUBLOC**

This medicinal product contains mannitol, but no warning is required due to its route of administration.

This medicinal product contains less than 1 mmol (23 mg) of sodium per vial; no effects associated with sodium are expected.

### **Use in combination with other drugs**

Tell your anaesthetist if you are taking, have recently taken or might take any other medicines. This includes medicines or herbal products that you have bought without a prescription. VECUBLOC may affect other medicines or be affected by them.

Medicines which increase the effect of VECUBLOC:

- Certain antibiotics
- Certain medicines for heart disease or high blood pressure (water tablets, calcium channel blockers, beta-blockers and quinidine)
- Certain anti-inflammatory medicines (corticosteroids)
- Medicines for manic depressive illness (bipolar disorder)
- Magnesium salts
- The medicine called cimetidine, used to treat stomach ulcers, heartburn or acid reflux;

Medicines which decrease the effect of VECUBLOC:

- Certain medicines for epilepsy
- Calcium chloride and potassium chloride

In addition, you may be given other medicines before or during surgery which can alter the effects of VECUBLOC. These include certain anaesthetics, other muscle relaxants, medicines such as phenytoin and medicines which reverse the effects of VECUBLOC. VECUBLOC may make certain anaesthetics work more quickly.

Your anaesthetist will take this into account when deciding the correct dose of VECUBLOC for you.

*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 VECUBLOC**

#### **Instructions regarding correct use and dosage/administration frequency:**

VECUBLOC can be used in adults and children of all ages. Your anaesthetist will decide the dose you need based on the following factors. The type of anaesthetic, other drugs you are taking, the expected length of the operation, your age and health status.

The normal dose is 80 – 100 micrograms per kg body weight and the effect will last 24 – 60 minutes. During the procedure it will be checked whether VECUBLOC is still working. You may be given additional doses if they are needed.

#### **Route and method of administration:**

VECUBLOC will be given to you by your anaesthetist. It is injected into a vein as solution. It may be given either as single injection or as a continuous infusion.

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

#### **If you have taken more VECUBLOC than you should have:**

As your anaesthetist will be monitoring your condition carefully while VECUBLOC is administered and it is unlikely that you will be given too much VECUBLOC. However if this happens, your anaesthetist will keep you breathing artificially (on a ventilator) until you can breathe on your own. You will be kept asleep while this takes place.

*If you have used VECUBLOC more than you should have or more than prescribed, consult a physician or a pharmacist*

#### **If you forget to take VECUBLOC:**

This is not the case for VECUBLOC.

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

### **4. Possible side effects**

Like all medicines, VECUBLOC may cause side effects in patients sensitive to its ingredients. If these side effects occur while you are under anaesthetic, they will be seen and treated by your anaesthetist.

Uncommon side effects (may affect up to 1 in 100 people):

- Increase in heart rate
- Lowering of blood pressure
- Increased or decreased effect
- VECUBLOC's muscle relaxant effect is prolonged

Very rare side effects (may affect up to 1 in 10.000 people):

- Hypersensitivity reactions (difficulty in breathing, collapse of the circulation and shock)
- Wheezing of the chest
- Muscle weakness
- Swelling, a rash or redness of the skin
- Pain at the injection site

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

#### Reporting side effects:

If any side-effects occur, regardless of whether they have been listed in the Patient Information Leaflet, please contact your physician, pharmacist or nurse. In addition, please kindly report the side effects to Turkish Pharmacovigilance Center (TÜFAM) by clicking on “Drug Side Effect Reporting” icon on the website [www.titck.gov.tr](http://www.titck.gov.tr) or by calling the phone line 0 800 314 00 08. By reporting side-effects, you will contribute to the collection of additional information regarding the safety of the medicine you are using.

#### **5. How to store VECUBLOC**

*Keep VECUBLOC out of the sight and reach of children, and in its original packaging.*

VECUBLOC is stored in the hospital.

Store at room temperature below 25°C, in its packaging.

After reconstitution, it is stable at 2-8°C for 24 hours. After reconstitution, it maintains its physical and chemical stability for 24 hours at room temperature and in daylight. From a microbiological point of view, the product should be used immediately after opening. In addition, physical and chemical compatibility with 5% dextrose solution, 5% dextrose/0.9% NaCl solution, lactated ringer solution has been demonstrated at room temperature for 12 hours.

Shake/swirl until product is completely dissolved during reconstitution.

#### **Use in compliance with the expiry date.**

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

Do not throw away drugs that have expired or are not used! Deliver to the collection system determined by the local regulations.

Do not use VECUBLOC if you notice defects on the product and/or its packaging.

Do not use VECUBLOC when the solution after reconstitution contains particles or is not clear.

***Marketing Authorization Holder:***

POLİFARMA İLAÇ SAN. VE TİC. A.Ş.  
Vakıflar OSB Mahallesi, Sanayi Caddesi, No: 22/1  
Ergene/Tekirdağ/TURKEY  
Tel: +90 282 675 14 04  
Fax: +90 282 675 14 05  
E-mail: [info@polifarma.com.tr](mailto:info@polifarma.com.tr)

***Manufacturing Site (vial):***

AROMA İLAÇ SANAYİ LTD. ŞTİ.  
Vakıflar OSB Mahallesi, Sanayi Caddesi, No:22/1 Kat:2  
Ergene/Tekirdağ/TURKEY  
Tel: +90 282 675 10 06  
Fax: +90 282 675 14 05

***Manufacturing Site (solvent ampoule):***

İDOL İlaç Dolum Sanayi ve Ticaret A.Ş.  
Davutpaşa Cad. CebeAli Bey Sok. No:20 34010  
Topkapı/Zeytinburnu/İstanbul/TURKEY  
Tel: +90 212 449 00 00  
Fax: +90 212 449 00 20

***Manufacturing Site (solvent ampoule):***

AROMA İLAÇ SANAYİ LTD. ŞTİ.  
Vakıflar OSB Mahallesi, Sanayi Caddesi, No: 22/1  
Kat: 2, Ergene/Terkidağ/TURKEY  
Tel: +90 282 675 10 06  
Fax: +90 282 675 14 05

*This leaflet was approved on 09.04.2019.*

**THE FOLLOWING INFORMATION IS FOR HEALTHCARE PROFESSIONALS:**

VECUBLOC is for intravenous route only and should be used after being reconstituted. VECUBLOC may be diluted in 5% dextrose/water, 5% dextrose/0.9% NaCl, lactated Ringer solutions. Unused parts of infusion solutions should be disposed of immediately.