

## PATIENT INFORMATION LEAFLET

### **BIEMEXOL 300 mg I /ml Solution for Injections**

**It is administered into body cavities as IA, IV and intrathecal Sterile-Apyrogen**

**Active Substance:** Each vial contains 300 mg Iodine equivalent to 647 mg iohexol

**Excipients:** Trometamol, calcium disodium EDTA, hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment) and water.

**Before using this medicine, please read this patient information leaflet carefully, because it contains important information for you.**

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, consult your doctor or your pharmacist.*
- *This medicine has been prescribed for you personally; you should not pass it on to others.*
- *During use of this medicine please tell to your doctor that you use this medicine when you go to the doctor or hospital.*
- *Follow the information in the leaflet exactly. Do not use lower or higher dosages rather than recommended dosages regarding the medicine.*

### **In this patient information leaflet:**

- 1. What is BIEMEXOL and what it is used for?**
- 2. What you need to know before you use BIEMEXOL?**
- 3. How to use BIEMEXOL**
- 4. What are the possible side effects of BIEMEXOL?**
- 5. How to store BIEMEXOL**

- 1. What is BIEMEXOL and what it is used for?**

BIEMEXOL 300 is presented in 50 ml and 100 ml, colorless, type 1 glass vial with bromobutly closure and blue tear off cap.

BIEMEXOL contains the active substance iohexol. This medicine is for diagnostic use only. It is used only to help identify an illness and not in connection with treatment.

BIEMEXOL is a 'contrast medium'. It is given before an X-ray to make the picture that your doctor takes clearer.

- Once injected, it can help your doctor tell apart normal or abnormal appearance and shape of some organs in your body.
- It can be used for X-rays of your urinary system, spine or blood vessels, including blood vessels of your heart.
- You may be given this medicine before or during a scan of your head or body using 'computed tomography' (also called a CAT scan). This type of scan uses X-rays.
- It can also be used to look at your salivary glands, stomach and intestine, or for looking in body cavities, such as in your joints or womb and ovarian tubes.

Your doctor will explain which part of your body will be scanned.

## 2. What you need to know before you use BIEMEXOL?

### Do not use BIEMEXOL:

- If you have ever had an allergic reaction after a medicine similar to BIEMEXOL, called a 'contrast medium'.
- If you suffer from severe thyroid problems
- If you are allergic (hypersensitive) to iohexol or any of the other ingredients of BIEMEXOL

### Take special care with BIEMEXOL

- If you have any thyroid problems.
- If you have ever had any allergies.
- If you have asthma.
- If you have diabetes
- If you have any brain disease or tumours
- If you have or have had severe cardiac disease (involving heart or blood vessels) including irregular heartbeats (arrhythmias)
- If you have kidney problems or both liver and kidney problems.
- If you have an illness called 'myasthenia gravis' (a condition causing severe muscle weakness).
- If you have a 'phaeochromocytoma' (constant or attacks of high blood pressure due to a rare tumour of your adrenal gland).
- If you have any problems with your blood or bone marrow.
- If you have ever been dependent on alcohol or drugs.
- If you have epilepsy.
- If you are having a thyroid function test in the next weeks.
- If you have pulmonary hypertension (high blood pressure in the arteries to your lungs)
- If you have paraproteinaemias (the presence of excessive amount of an abnormal protein in your blood)
- If you are having blood or urine samples taken on the same day.

If you are not sure if any of the above apply to you, talk to your doctor before having BIEMEXOL.

Make sure to drink plenty of fluid before and after receiving BIEMEXOL. This is especially important for patients with multiple myeloma (white blood cells disease), diabetes, kidney problems, patients in bad general condition, children and elderly patients.

### Children and adolescents:

Make sure to drink plenty of fluid before and after receiving BIEMEXOL. This is especially important for infants and small children. Drugs that can damage the kidneys should not be taken at the same time as BIEMEXOL. Thyroid function should be checked in neonates during the first week of life, if the mother has received BIEMEXOL during pregnancy BIEMEXOL may be removed from an infant's body more slowly than an adult.

Young infants (less than 1 year of age) and especially newly born are susceptible to changes in certain laboratory tests (in balance in salts and minerals) and circulatory changes in blood circulation (blood flow to the heart).

This precautions are valid for you now or in the past, please consult to your doctor.

### **Usage of BIEMEXOL with food and drinks**

There is no known effects.

### **Pregnancy**

*Before usage of this medicine, please consult to your doctor or pharmacist.*

You must tell your doctor if you are pregnant or think you may be pregnant. Your doctor will only use this product if it is considered that the benefit outweighs the risk for both the mother and the baby.

During pregnancy, you must avoid radiation. If you are pregnant, your doctor will decide whether this investigation will perform or not by evaluations of risks and benefits and it must administer if clearly required.

*If you have been noticed that you are pregnant during treatment, immediately consult to your doctor or pharmacist.*

### **Lactation**

*Before usage of this medicine, consult to your doctor or pharmacist.*

Breast-feeding may be continued normally after an examination with BIEMEXOL.

### **Driving and using machines**

Do not drive or use tools or machines after your last injection of BIEMEXOL for:

- 24 hours, if it has been given into your spine, or
- one hour in all other cases.

This is because you may feel dizzy or have other signs of a reaction afterwards

### **Important information about excipients in contents BIEMEXOL:**

BIEMEXOL contains less than 1 mmol sodium in each dosage (23 mg). So it can be accepted as that “this product does not contain sodium”.

### **Other medicines and BIEMEXOL**

Please tell your doctor if you are diabetic and are taking any medicine containing metformin. Tell your doctor if you are taking have recently taken any or might take any other medicines, including medicines obtained without a prescription or if you are using beta-blockers, (medicines used to treat high blood pressure) or have recently been treated with interleukin-2. This is because some medicines can affect the way BIEMEXOL works.

*If you have been taking prescribed or non-prescribed medicines now or in the past, please give information to your doctor or pharmacist about these product.*

### 3. How to use BIEMEXOL?

BIEMEXOL will always be given to you by a specially trained and qualified person.

- BIEMEXOL will always be used in a hospital or clinic.
- They will tell you anything you need to know for its safe use.

#### **Instructions for use and for frequency of dosage/administration**

Your doctor will decide the dose that is best for you. Usually it is one single injection or you may be asked to swallow it.

#### **After you have been given BIEMEXOL**

You will be asked:

- to drink plenty of fluids afterwards (to help flush the medicine from your body),
- to stay in or around the area where you had your scan or X-ray for around 30 minutes,
- to stay in the clinic or hospital for one hour. However, delayed reactions may occur.

If you have any side effects during this time, tell your doctor straight away (see section 4 'possible side effects').

The advice above applies to **all patients** who have had BIEMEXOL. If you are not sure about any of the above ask your doctor.

#### **Administration route and method:**

BIEMEXOL may be given in lots of different ways, a description of the ways it is usually given can be found below:

##### Injection into an artery or vein:

BIEMEXOL will most commonly be injected into an arm vein or leg vein. Sometimes it will be given through a thin plastic tube (catheter), inserted into an artery usually in your arm or groin.

##### Injection into your spine:

BIEMEXOL will be injected into the space around the spinal cord to see your spinal canal. If you have been given BIEMEXOL into your spine afterwards you will be asked to follow the advice below:

- to rest with your head and body upright for one hour, or six hours if you stay in bed,
- to walk carefully and try not to bend down for six hours,
- not to be completely alone for the first 24 hours after having BIEMEXOL, if you are an outpatient and have ever had fits.

The advice above applies *only* if you have had BIEMEXOL *injected in to your spine*. If you are not sure about any of the above ask your doctor.

### Use in your body cavities or joints:

Body cavities may be the joints, uterus and ovarian tubes. How and where BIEMEXOL is given will vary.

### Use by mouth:

For examination of the gullet, stomach or small bowel, BIEMEXOL is normally given by mouth. BIEMEXOL may be diluted with water for these examinations.

*If you think that the effect of BIEMEXOL is too high or too low, please consult your doctor or your pharmacist.*

### **If you receive more BIEMEXOL than you should:**

Biemexol is administered by health professional in hospital.

In overdosage, your doctor can correct un-balancing of water or electrolyte and apply other therapies.

There is no antidote for this product.

### **If you forget to use BIEMEXOL**

Biemexol is administered under doctor control.

*Do not take a double dose to make up for a missed dose.*

### **Effects may be seen when treatment with BIEMEXOL is stopped:**

If you have notice any problem after administration of BIEMEXOL, please tell to your doctor.

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

Like all medicines, BIEMEXOL can cause side effects, although not everybody gets them.

### Allergic reactions

If you have an allergic reaction when you are in hospital or a clinic having BIEMEXOL, tell the doctor straight away. The signs may include:

- wheeziness, difficulty in breathing or tightness or pain in your chest
- skin rash, lumps, itchy spots, blisters on skin and in mouth or other allergic symptoms
- swelling of your face
- dizziness or feeling faint (caused by low blood pressure)

The above side effects may happen several hours or days after BIEMEXOL is given. If any of these side effects happen after you leave the hospital or clinic, go straight to the emergency department of your nearest hospital.

A short term decrease in formation of urine due to decreased kidney function is common after BIEMEXOL is given. This may lead to damage to the kidney.

Other side effects that you may have are listed below; these depend on how or why BIEMEXOL was given to you. Ask your doctor if you are not sure how you were given BIEMEXOL.

General:

(applies to all uses of BIEMEXOL)

Common: affects 1 to 10 users in 100

- feeling hot

Uncommon: affects 1 to 10 users in 1,000

- feeling sick (nausea)

Rare: affects 1 to 10 users in 10,000

- allergic (hypersensitivity) reactions
- slow heart rate
- headache, vomiting, fever

Very rare: affects less than 1 user in 10,000

- momentary change in sense of taste
- high or low blood pressure, shivering (chills)
- diarrhea, pain around your stomach area

Not known: frequency cannot be estimated from the available data

- allergic reaction, including severe allergic reaction leading to shock and collapse, see 'Allergic reactions' above for other signs
- iodism (excessive amounts of iodine in the body) resulting in swelling and tenderness (pain) of your salivary glands

After an injection into an artery or vein:

Uncommon: affects 1 to 10 users in 1,000

- pain and discomfort

Rare: affects 1 to 10 users in 10,000

- dizziness
- diarrhoea
- irregular heartbeats, including fast heart rate
- kidney problems
- cough, fever, general discomfort

Very rare: affects less than 1 user in 10,000

- seizures (fits), clouding consciousness, disturbance of senses (like touch), trembling
- flushing
- difficulty breathing (including serious difficulty in breathing because of liquid in lungs)
- short-term brain disease(encephalopathy) including short-term memory loss, coma, dizziness and not remembering the memories
- stupor ("sleepy state")
- myocardial infarction

Not known: frequency cannot be estimated from the available data

- feeling confused, feeling disorientated,
- overactive thyroid gland (thyrotoxicosis), short-term underactive thyroid gland (transient hypothyroidism)
- difficulty moving around for awhile
- short-term loss of memory
- short-term blindness (hours to a few days), short-term hearing loss
- chest pain, heart problems, including heart failure/tightness in chest or troubled

breathing worsening of an inflammation of the pancreas (an organ behind the stomach)

- pain and swelling of your vein, blood clots (thrombosis),
- joint pain, injection site reaction, back pain
- severe skin reactions
- psoriasis flare-up
- speech disorders including aphasia (unable to speak), dysarthria (difficulties with pronouncing words)
- coma
- retrograde amnesia (loss of memories),
- asthma attack

After an injection into your spine:

Very common: affects more than 1 user in 10

- headache (may be severe and lasting)

Common: affects 1 to 10 users in 100

- feeling sick (nausea), vomiting

Uncommon: affects 1 to 10 users in 1,000

- inflammation of the membranes that surround the brain and spinal cord (it can be seen as vomiting, high fever, headache, mental disorders)

Rare: affects 1 to 10 users in 10,000

- seizures (fits), dizziness, pain in arms or legs, neck pain, back pain

Not known: frequency cannot be estimated from the available data

- abnormal electric activity of the brain in an examination called electroencephalography
- intolerance of bright light, neck stiffness
- difficulty moving around for a while, feeling confused
- disturbance of senses (like touch), short-term blindness (hours to a few days), short-term hearing loss
- tingling sensations, muscle contractions (spasms), injection site reaction
- short term brain disorders (encephalopathy) including short term memory loss, coma, stupor (“sleepy state”) and retrograde amnesia (loss of memory).
- speech disorders including aphasia (unable to speak), dysarthria (difficulties with pronouncing words)

After use in body cavities:

(such as uterus and ovarian tubes, bladder, pancreas or hernia)

Very common: affects more than 1 user in 10

- pain around your stomach area

Common: affects 1 to 10 users in 100

- inflammation of the pancreatic gland (pancreatitis) (it can be seen with pain in the stomach, nausea, vomiting )
- abnormal amount of a substance produced by the pancreatic gland detected by lab investigation

Not known: frequency cannot be estimated from the available data

- pain

### After injection into your joints:

Very common: affects more than 1 user in 10

- pain where it was injected

Not known: frequency cannot be estimated from the available data

- inflammation of the joint

### After being given it by mouth:

Very common: affects more than 1 user in 10

- diarrhoea

Common: affects 1 to 10 users in 100

- feeling sick (nausea), vomiting

Uncommon: affects 1 to 10 users in 1,000

- pain around your stomach area

### Additional side effects in children and adolescents:

A short-term abnormality of the thyroid function which later reverts to normal (transient hypothyroidism) has been reported in premature infants, neonates and in other children after receiving BIEMEXOL. Normally, no symptoms are seen. Premature infants are particularly sensitive to the effect of iodine.

A short-term abnormality of the thyroid function which later reverts to normal (transient hypothyroidism) has been reported in a premature breast fed infant. The nursing mother was repeatedly exposed to BIEMEXOL.

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet.

## **5. How to store BIEMEXOL**

*Keep out of the sight and reach of children and store in the original pack.*

Like all parenteral products, BIEMEXOL should be inspected visually for particulate matter, discolouration and the integrity of the container prior to use.

Do not use BIEMEXOL after the expiry date (Exp:) which is stated on the label. The expiry date refers to the last day of that month.

Store below 25°C. Keep the container in the outer carton. Protect from light. Protect from secondary X-Rays.

This medicinal product is for single use only. Once opened, use immediately. Discard any remaining content.

Do not throw away any medicines via wastewater or household waste. To protect the environment, ask your pharmacist how to throw away medicines you no longer use.



**MA Holder:**

Biem İlaç San. ve Tic. A.Ş.  
Anıttepe Mah. Turgut Reis Cad. No: 21  
Tandoğan / Çankaya – Ankara  
Tel: +90 312 230 29 29  
Fax: +90 312 230 68 00

**Production Site:**

İDOL İLAÇ DOLUM SAN. ve TİC. A.Ş.  
Davutpaşa Cad. CebeAli Bey Sok.No:20  
Zeytinburnu / İSTANBUL

*This leaflet was approved on 17.12.2015*