

## PATIENT INFORMATION LEAFLET

### **BTIRAY 300 Solution for Injection**

**Administered into veins, joints and spine.**

- **Active substance:** 1 ml contains 612,4 mg iopamidol equivalent to 300 mg iodine.
- **Excipients:** Trometamol (tromethamine), disodium calcium edetate, diluted hydrochloric acid, water for injection.

**Before use 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.*

### **What is in this leaflet:**

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

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

- BTIRAY is a special dye which is opaque to X-rays because it contains iodine (contrast substance).
- BTIRAY is provided in 50 and 100 ml vials. It is a clear and colourless to pale yellow solution. It contains no visible particle.
- BTIRAY helps your internal body structures to be seen on an X-ray picture. Your doctor has prescribed BTIRAY to help view the blood vessels, spine or brain using X-rays.

This medicine is for diagnostic use only.

#### **2. What you need to know before you use BTIRAY?**

##### **Do not use BTIRAY if**

- you are allergic (hypersensitivity) to BTIRAY or other contrast substance which contains iodine
- you are allergic to any other contents of BTIRAY

**Take special care with BTIRAY if you have**

- Allergy or asthma
- Blood clots, circulation problems, inflammations of veins
- Infection
- Diabetes
- Sickle cell disease (your body produces abnormally shaped red blood cells, which leads to anemia)
- Heart problems
- High blood pressure in the lungs
- Kidney or liver problems
- Over-active thyroid gland (this is particularly important in newborn babies)
- Myasthenia gravis (a disease causing weak muscles)
- Brain tumor or other brain diseases
- A history of epilepsy
- Alcoholism
- Pheochromocytoma (a tumor of the adrenal gland)
- Homocystinuria (an inherited condition affecting the muscles, nervous system and heart)
- Multiple sclerosis (MS) (a nervous system disease)
- Myelomatosis (a disease of the bone marrow)

Particular care should be taken in children under 1 year of age and in the elderly. These groups might be susceptible to adverse reactions.

Tell your doctor if you have had thyroid function tests performed in the past.

Please consult your doctor, even if these statements were applicable to you at any time in the past.

**Use of BTIRAY with food and drink**

It is not applicable due to its administration method.

**Pregnancy**

*Before use this medicine, consult your doctor or your pharmacist.*

If you are pregnant, you should only be given BTIRAY if your doctor believes it is clearly necessary.

**Breast-feeding**

*Before use this medicine, consult your doctor or your pharmacist.*

If you are breast-feeding, you should only be given BTIRAY if your doctor believes it is clearly necessary. You should stop breast feeding before administration you should not start breast feeding for at least 24 hours after the administration of BTIRAY.

**Ability of drive and use machines**

You should not drive or operate machinery for one hour after the injection because of possible side effects.

### **Important information on excipients which are in contents of BTIRAY**

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

### **Using with other medicines**

Especially tell your doctor if you are taking the following medicines, as they may react with BTIRAY:

- Painkillers
- Neuroleptics (treatments for mental illness)
- Antiemetics (treatments that prevent vomiting)
- Metformin (a treatment for diabetes)
- Antihistamines (treatments for allergies)
- Sedatives
- Anti-epileptics (treatment for epileptic fits)
- Vasopressors such as papaverine (used to treat impotence)

Even if you use these drugs, you may still be given BTIRAY. Your doctor will decide what is suitable for you.

*If you are taking or have recently taken any other medicines, including medicines obtained without a prescription, please tell your doctor or your pharmacist.*

### **3. How to use BTIRAY**

- **Instructions for use and for frequency of dosage/administration:** The actual dose depends on which part of the body is being X-rayed and is usually in the range 5-250 ml. Your doctor may decide to vary this dose or to repeat the dose if required
- **Administration route and method:** BTIRAY will be given to you by a doctor or a healthcare personnel, in hospital or clinic. It will be injected into an artery or a vein or into the spine or into a joint.
- **Different age groups**
  - Use in children:** The dose for children also depends on the age and the body size.
  - Use in elderly:** There is no special condition for use in elderly.
- **Special conditions**
  - Renal/Liver impairment:** There is no special condition for use in the patients with renal/liver impairment.

### **If you receive more BTIRAY than you should,**

You should be sure that the hospital or clinic where BTIRAY is administered to you is well equipped to treat any effects of overdose.

### **4. What are possible side effects?**

Like all medicines, side effects can be observed in the patients who have sensitivity to the contents of BTIRAY.

**If you notice below conditions following administration of BTIRAY, inform the healthcare personnel who has done your examination, immediately.**

- Sudden wheeziness
- Difficulty in breathing
- Swelling of eyelids, face or lips
- Rash or itching (especially affecting your whole body)

All of these signs are very serious side effects.

If you notice any of the above serious side effects, you might have allergic reaction to BTIRAY which can be serious and might require medical treatment or hospitalization.

These very serious side effects are seen very rarely.

**If you notice one of below side effects, tell your doctor.**

- Feeling sick (nausea),
- Vomiting,
- Redness of skin, rash or swelling of skin
- Itching,
- Hot and pain in injection site,
- Back pain,
- Neck pain
- Dry mouth,
- Flushing,
- Headache,
- Nasal obstruction
- Swelling of the throat
- Swelling
- Fever,
- Over-active thyroid,
- Sweating,
- Weakness,
- Dizziness,
- Pallor,
- Difficulty in breathing,
- Low blood pressure,
- Kidney problems,
- Reduced thrombocyte count (this can be detected by a test carried out by a doctor),

- Asthma,
- Shortness of breath due to pulmonary oedema,
- Decreased or increased heart rate or cardiac arrest,
- Mental confusion,
- Loss of consciousness,
- Agitation
- Coma,
- Loss of movement
- Temporary loss of vision
- Seizure

*If you notice any side effects not listed in this leaflet, please tell your doctor or your pharmacist.*

### **5. Storage of BTİRAY**

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

- Protect from strong light. Store at room temperature, below 25 °C.
- BTİRAY should be administered to you immediately once drawn up into the syringe
- Medicine should not be disposed of in waste-water or with household garbage. These measures will help to protect the environment.

**Please use BTİRAY in accordance with expiry date.**

*Do not use BTİRAY after expiry date written on the box.*

### **Registration holder:**

BIEM İlaç San. ve Tic. A.Ş.,  
Turgut Reis Cad., No: 21, 06570,  
Tandoğan- Ankara / TURKEY  
Tel: +90 312 230 29 29  
Faks: +90 312 230 68 00

### **Manufacturing site:**

İdol İlaç Dolum San. ve Tic. A.Ş.  
Davutpaşa Cad. Cebealibey Sk.  
No: 20 Topkapı – İstanbul / TURKEY

*This leaflet was approved on .../.../.....*