

## PATIENT INFORMATION LEAFLET

### OMNIPOL 300 mgI/ml Solution for I.A. I.V. Intrathecal Injection

**Intra-arterial, intravenous, intrathecal administration and body cavities.**

Sterile, apyrogen.

**Active Substance:** Each ml contains 647 mg of Iohexol equivalent to 300 mg of I.

**Excipients:** Trometamol, Sodium calcium edetate, Hydrochloric acid/Sodium hydroxide (for pH adjustment) and water for injection.

This medicinal product contains 0.012 mg of sodium per ml.

**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 the written instructions exactly. Do not use **higher or lower** dose than the recommended dose.*

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

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

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

European Pharmacopoeia Type I grade, colorless durable borosilicate glass bottles. Bottle volumes are 1x50 ml and 1x100 ml. Not all pack sizes may be marketed.

This medicine contains the active substance Iohexol and is for diagnostic use only. It is used only to help diagnose an illness and not for therapeutic purpose.

OMNIPOL 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’. 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 OMNIPOL**

**Do not use OMNIPOL if you have the following circumstances:**

If,

- you have a history of allergy to drugs called “contrast medium like OMNIPOL.
- you suffer from severe thyroid problems
- you are hypersensitive to Iohexol or any of the other ingredients of OMNIPOL.

**USE OMNIPOL with CAUTION if:**

- you have any thyroid problems.
- you have ever had any allergies.
- you have asthma.
- you have diabetes.
- you have any brain disease or tumor
- you have severe cardiac disease involving heart or blood vessels including irregular heartbeats (arrhythmias)
- you have kidney problems or both liver and kidney problems.
- you have an illness called ‘myasthenia gravis’ (a condition causing severe muscle weakness).
- you have a ‘phaeochromocytoma’ (constant or attacks of high blood pressure due to a rare tumor of your adrenal gland).
- you have any problems with your blood or bone marrow.
- you have ever been dependent on alcohol or drugs.
- you have epilepsy.
- you are having a thyroid function test in the next weeks.
- 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 OMNIPOL.

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

#### Children and adolescents

Make sure to drink plenty of fluid before and after receiving OMNIPOL. This applies especially to infants and small children. Drugs that can damage the kidneys should not be taken at the same time as OMNIPOL. Thyroid function should be checked in neonates during the first week of life, if the mother has received OMNIPOL during pregnancy.

OMNIPOL 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).

Please consult your doctor even if these warnings apply to you at any time in the past.

#### **Using OMNIPOL with food and beverages**

There is no known effect.

#### **Pregnancy**

*Before using this medicine consult your doctor or pharmacist.*

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. It is necessary to avoid radiation as much as possible during pregnancy. If you are pregnant, your doctor should make a decision by evaluating the risk and benefit of this examination and apply if it is absolutely necessary.

*If you realize that you are pregnant during your treatment, immediately consult your physician or pharmacist.*

#### **Breastfeeding**

*Before using this medicine consult your doctor or pharmacist.*

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

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

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

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

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

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

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

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

Please tell your doctor if you are diabetic and are taking any medicine containing metformin, 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 or interferons. This is because some medicines can affect the way OMNIPOL works.

*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 OMNIPOL?**

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

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

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

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

### **After you have been given OMNIPOL:**

- 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 and
- 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 OMNIPOL.

If you are not sure about any of the above ask your doctor.

**Method of administration:**

OMNĪPOL 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**

OMNĪPOL 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:**

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

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

The advice above applies only if you have had OMNĪPOL 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 the drug is given will vary.

**Oral use:**

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

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

**If you have taken more OMNĪPOL than you should have:**

OMNĪPOL will be given in a health facility and by health personnel.

Your doctor may decide to treat water or electrolyte imbalances and give other treatments in case of overdose.

This medicine has no special antidote.

**If you forget to take OMNĪPOL:**

OMNĪPOL is given under the supervision of a doctor.

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

### **Possible effects once OMNIPOL treatment is concluded**

Talk to your doctor if you experience any problem after you have been given OMNIPOL.

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

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

Allergic reactions:

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

- wheezing, 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 OMNIPOL 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 OMNIPOL 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 OMNIPOL was given to you. Ask your doctor if you are not sure how you were given OMNIPOL.

#### **General (applies to all patients given OMNIPOL)**

Common (affects 1 to 10 users in 100):

- Feeling hot

Uncommon (affects 1 to 10 users in 1000):

- 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 (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 1000):

- Pain and discomfort

Rare (affects 1 to 10 users in 10,000):

- Dizziness
- Diarrhea
- Irregular heartbeats, including fast heart rate
- Kidney problems
- Cough, fever, general discomfort

Very rare (affects less than 1 user in 10,000)

- seizures, clouding consciousness, disturbance of senses (like touch), trembling
- Flushing
- Difficulty breathing (including severe breathing difficulties caused by fluid in the lungs)
- Short-term brain disorders (encephalopathy) including short-term memory loss, coma, dizziness and Retrograde amnesia
- Sleepy state
- Heart attack

Not known (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 arrest of the heart
- 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
- joint pain, muscle spasms, back pain
- Severe skin reactions
- Psoriasis flare-up
- Speech disorders including unable to speak and difficulties with pronouncing words
- Coma

- Retrograde amnesia
- Asthma attack

**After an injection into your spine:**

Very Common (affects more than 1 user in 10):

- Headache (may be severe and prolonged)

Common (affects 1 to 10 users in 100):

- Nausea, vomiting

Uncommon (affects 1 to 10 users in 1000):

- Inflammation of the membranes that surround the brain and spinal cord (vomiting, high fever, headache, mental disorders may develop)

Rare (affects 1 to 10 users in 10,000):

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

Not known (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, dizziness and Retrograde amnesia
- Speech disorders including unable to speak, difficulties with pronouncing words

**After use in body cavities**

(Such as uterus, ovarian tubes, bladder, pancreas and 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) (abdominal pain, nausea, vomiting may develop)
- Abnormal amount of a substance produced by the pancreatic gland detected by lab investigation

Not known (Cannot be estimated from the available data):

- Pain

**After an injection into your joints:**

Very Common (affects more than 1 user in 10):

- Pain at the injection site

Not known (Cannot be estimated from the available data):

- Inflammation of the joint

**After oral use**

Very Common (affects more than 1 user in 10):

- Diarrhea

Common (affects 1 to 10 users in 100):

- Nausea, vomiting

Uncommon (affects 1 to 10 users in 1000):

- Pain around your stomach area

Additional side effects in children and adolescents:

A short-term abnormality of the thyroid function has been reported in premature infants, neonates and in other children after receiving OMNIPOL. This condition is temporary and later reverts to normal. Normally, no symptoms are seen. Premature infants are particularly sensitive to the effect of iodine.

A short-term abnormality of the thyroid function has been reported in an infant whose mother was repeatedly exposed to OMNIPOL.

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

**5. How to store OMNIPOL?**

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

Like all parenteral products, OMNIPOL should be inspected visually. Precipitation and discoloration in the vial and the integrity of the packaging should be checked prior to use.

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

Do not use after the expiry date stated on the label. The expiry date refers to the last day of that month.

Store at room temperature below 25°C. Keep in the outer carton. Protect from secondary X-rays.

This product is for single use only. Once opened, it should be used immediately.

*Do not throw away expired or remained products! Please follow the local regulations.*

***Marketing Authorization Holder:***

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