PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Omnipaque 140 mg I/ml solution for injection
Omnipaque 180 mg I/ml solution for injection
Omnipaque 240 mg I/ml solution for injection
Omnipaque 300 mg I/ml solution for injection
Omnipaque 350 mg I/ml solution for injection

Iohexol

Read all of this leaflet carefully before you start using Omnipaque because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Omnipaque is and what it is used for
2. What you need to know before you use Omnipaque
3. How to use Omnipaque
4. Possible side effects
5. How to store Omnipaque
6. Contents of the pack and other information

1. What Omnipaque is and what it is used for

Omnipaque 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.

Omnipaque 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.
- It can also be used in cases of mammography examinations.

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

2. What you need to know before you use Omnipaque

Do not use Omnipaque:

- If you suffer from severe thyroid problems
- If you are allergic (hypersensitive) to iohexol or any of the other ingredients of Omnipaque (listed in Section 6).

Warnings and precautions

Check with your doctor before having Omnipaque:

- If you have ever had an allergic reaction after a medicine similar to Omnipaque, called a 'contrast medium'. (The signs of an allergic reaction may include one or more of the following; wheeziness, difficulty in breathing tightness or pain in your chest, skin rash, lumps, itchy spots, blisters on skin and in mouth, red/itchy eyes, cough, running nose, sneezing or other allergic symptoms, swelling of your face, dizziness or feeling faint caused by low blood pressure).
- 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; for example, tumours, swelling or inflammation of the brain, or any condition involving the blood vessels in the brain, including blood clot or bleeding.
- If you have or have had severe cardiac disease (involving heart or blood vessels) including high blood pressure, blood clots, stroke, and 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 "homocystinuria" (a condition with increased excretion of the amino acid cysteine in urine)
- If you have any problems with your blood or bone marrow.
- If you have an immune system disease.
- 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.

During or shortly after the imaging procedure you may experience a short-term brain disorder called encephalopathy. Tell your doctor straight away if you notice any of the signs and symptoms related to this condition described in Section 4.

Thyroid disorders may be observed following administration of Omnipaque in both children and adults. Infants may also be exposed through the mother during pregnancy. Your doctor may need to perform thyroid function tests before and/or after the administration of Omnipaque.

Contrast-enhanced mammography exposes you to higher levels of ionizing radiation than traditional mammography, however, it is still within the range defined by the international guidelines for mammography. Radiation dose depends on the thickness of the breast and the type of mammography machine used.

If you are not sure if any of the above apply to you, talk to your doctor before having Omnipaque. Make sure to drink plenty of fluid before and after receiving Omnipaque. This applies especially to 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 Omnipaque. This applies especially to infants and small children. Drugs that can damage the kidneys should not be taken at the same time as Omnipaque.

Omnipaque 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).

Taking other medicines

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 or might take any other medicines, including medicines obtained without a prescription or if you are using beta-blockers, vasoactive substances, ACE - enzyme inhibitors or angiotensin antagonists (medicines used to treat high blood pressure) or have recently been treated with interleukin-2 or interferons (medicines used to treat immune system diseases), antidepressants (medicines used to treat mental disorders like depression). This is because some medicines can affect the way Omnipaque works.

Beta-blockers may increase your risk of experiencing breathing difficulties and may interfere with the treatment of severe allergic reactions, which is a risk of Omnipaque.

Laboratory tests

Tell the doctor or nurse that you have been given Omnipaque if you are asked to provide a sample of your blood or urine for any laboratory examinations on the same day as your scan. This is because Omnipaque may interfere with the results for some laboratory tests.

Fertility, pregnancy and breast-feeding

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. If Omnipaque has been given to the mother during pregnancy, it is recommended to monitor the infants thyroid function (see 'Warnings and precautions'). Breast-feeding may be continued normally after an examination with Omnipaque.

Driving and using machines

Do not drive or use tools or machines after your last injection of Omnipaque 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.

Omnipaque contains Sodium calcium edetate

Omnipaque contains sodium, however this medicinal product contains less than 1 mmol sodium (23 mg) per ml, i.e. essentially "sodium free".

3. How to use Omnipaque

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

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

You will be asked:

- to drink plenty of fluids afterwards (to help flush the medicine from your body), and
- 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 Omnipaque. If you are not sure about any of the above ask your doctor. Omnipaque 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

Omnipaque 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

Omnipaque will be injected into the space around the spinal cord to see your spinal canal. If you have been given Omnipaque 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, and
- to walk carefully and try not to bend down for six hours, and
- not to be completely alone for the first 24 hours after having Omnipaque, if you are an outpatient and have ever had fits.

The advice above applies only if you have had Omnipaque injected into 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 Omnipaque is given will vary.

Use by mouth

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

4. Possible side effects

Like all medicines, Omnipaque 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 Omnipaque, 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, red/itchy eyes, cough, running nose, sneezing 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 Omnipaque is given. If any of these side effects happen after you leave the hospital or clinic, go straight to the casualty department of your nearest hospital.

A short term decrease in formation of urine due to decreased kidney function is common after Omnipaque 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 Omnipaque was given to you. Ask your doctor if you are not sure how you were given Omnipaque.

General

(Applies to all uses of Omnipaque)

Common: affects 1 to 10 users in 100
- feeling hot

Uncommon: affects 1 to 10 users in 1,000
- feeling sick (nausea)
- increased/abnormal sweating, cold feeling, dizziness/fainting
- headache

Rare: affects 1 to 10 users in 10,000
- allergic (hypersensitivity) reactions (may be fatal)
- slow heart rate
- pain around your stomach area, 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
- allergic reaction, including severe allergic reaction leading to shock and collapse, see 'Allergic reactions' above for other signs

Not known: frequency cannot be estimated from the available data
- swelling and tenderness (pain) of your salivary glands

After an injection into an artery or vein

Common: affects 1 to 10 users in 100
- short-term changes in breathing rate, respiratory problems

Uncommon: affects 1 to 10 users in 1,000
- pain and discomfort
- acute kidney injury

Rare: affects 1 to 10 users in 10,000
- diarrhea
- irregular heartbeats, including slow or fast heart rate
- cough, stopped breathing, fever, general discomfort
- dizziness, feeling weak, muscle weakness
- intolerance to bright light
- feeling abnormally tired
- skin rash and itching, reddening of the skin
- reduced eyesight (including double vision, blurred vision)

Very rare: affects less than 1 user in 10,000
- seizures (fits), clouding consciousness, stroke, disturbance of senses (like touch), trembling, stupor ('sleepy state')
- flushing
- difficulty breathing
- myocardial infarction
- chest pain

Not known: frequency cannot be estimated from the available data
- severe skin reactions including severe rash, blistering, and peeling of skin
- feeling confused, feeling disorientated, feeling agitated, restless or anxious

- overactive thyroid gland (an excess of thyroid hormones in the blood causing a variety of symptoms, as e.g., rapid heartbeat, sweating, anxiety), short-term underactive thyroid gland (an abnormality of the thyroid function which later reverts to normal)
- difficulty moving around for a while
- short-term blindness (hours to a few days), short-term hearing loss
- heart problems, including heart failure, spasms of the heart arteries and cyanosis (blue to purple colour of skin because of decreased oxygen)
- tightness in chest or troubled breathing including swelling of the lungs, spasms in the airways
- worsening of an inflammation of the pancreas (an organ behind the stomach) causing stomach pain that is worsened with eating
- pain and swelling of your vein, blood clots (thrombosis)
- joint pain, injection site reaction, back pain
- psoriasis flare-up
- speech disorders including aphasia (unable to speak), dysarthria (difficulties with pronouncing words)
- asthma attack
- iodism (excessive amounts of iodine in the body) resulting in swelling and tenderness (pain) of your salivary glands
- memory loss (amnesia)
- short term brain disorder (contrast encephalopathy) which can cause headache, difficulties with vision, loss of vision, seizures, confusion, disorientation, drowsiness, loss of consciousness, coma, loss of coordination, loss of movement in one side of the body, problems with speech, memory loss and swelling of the brain
- thrombocytopenia (a condition where the platelet count is low causing the blood not to clot as well as it does normally)
- blood creatinine increased

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

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
- feeling agitated
- feeling anxious
- feeling disorientated
- 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
- seizure (lasting more than five minutes)
- tingling sensations, muscle contractions (spasms), injection site reaction
- short term brain disorder (contrast encephalopathy) which can cause headache, difficulties with vision, loss of vision, seizures, confusion, disorientation, drowsiness, loss of consciousness, coma, loss of coordination, loss of movement in one side of the body, problems with speech, memory loss and swelling of the brain
- speech disorders including aphasia (unable to speak), dysarthria (difficulties with pronouncing words)

After use in body cavities

(such as uterus and ovarian tubes, gall bladder and 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)
- 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
- diarrhea

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

If any of the side effects gets serious, or if you notice any side effects not listed, please tell your doctor.

<u>Additional side effects in children and adolescents</u>
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 Omnipaque. 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 Omnipaque.

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly to:
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Omnipaque

- Like all parenteral products, Omnipaque should be inspected visually for particulate matter, discolouration and the integrity of the container prior to use.
- Keep this medicine out of the sight and reach of children.
- Do not use Omnipaque after the expiry date (Exp:) which is stated on the label. The expiry date refers to the last day of that month.
- Store below 30°C. Keep the container in the outer carton. Protect from secondary X-rays.
- The product in glass vials/bottles may be stored at 37°C for up to 3 months prior to use.
- The product in polypropylene bottles; 50, 75, 100, 150, 175, 200 and 500 ml fill volumes may be stored at 37°C for up to 1 month prior to use.
- 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.

6. Contents of pack and other information

What Omnipaque contains

The active substance is iohexol.

Omnipaque 140 mg I/ml contains 302 mg iohexol per ml (equivalent to 140 mg iodine per ml).
Omnipaque 180 mg I/ml contains 388 mg iohexol per ml (equivalent to 180 mg iodine per ml).
Omnipaque 240 mg I/ml contains 518 mg iohexol per ml (equivalent to 240 mg iodine per ml).
Omnipaque 300 mg I/ml contains 647 mg iohexol per ml (equivalent to 300 mg iodine per ml).
Omnipaque 350 mg I/ml contains 755 mg iohexol per ml (equivalent to 350 mg iodine per ml).

The other ingredients are small amounts of trometamol, sodium calcium edetate, hydrochloric acid (for pH adjustment), and water.

What Omnipaque looks like and contents of the pack

Omnipaque is a solution for injection. The product is clear, colourless to pale yellow, aqueous solution.

Contents of pack

Omnipaque is supplied as:

140 mg I/ml	10 glass bottles of 50 ml 6 glass bottles of 200 ml
180 mg I/ml	10 vials of 10 ml 10 vials of 15 ml 10 glass bottles of 50 ml
240 mg I/ml	10 vials of 10 ml 10 vials of 15 ml 6 vials of 20 ml 25 vials of 20 ml 1 polypropylene bottle of 50 ml 10 polypropylene bottles of 50 ml 10 glass bottles of 50 ml 1 polypropylene bottle of 100 ml 10 polypropylene bottles of 100 ml 10 glass bottles of 100 ml 1 polypropylene bottle of 200 ml 10 polypropylene bottles of 200 ml 6 glass bottles of 200 ml

	1 polypropylene bottle of 500 ml
	6 polypropylene bottles of 500 ml
	1 glass bottle of 500 ml
	6 glass bottles of 500 ml
300 mg I/ml	10 vials of 10 ml
	6 vials of 20 ml
	25 vials of 20 ml
	10 polypropylene bottles of 50 ml
	10 glass bottles of 50 ml
	1 polypropylene bottle of 75 ml
	10 polypropylene bottles of 75 ml
	10 glass bottles of 75 ml
	1 polypropylene bottle of 100 ml
	10 polypropylene bottles of 100 ml
	10 glass bottles of 100 ml
	1 polypropylene bottle of 150 ml
	6 glass bottles of 150 ml
	10 polypropylene bottles of 150 ml
	1 polypropylene bottle of 175 ml
	10 polypropylene bottle of 175 ml
	1 polypropylene bottle of 200 ml
	6 glass bottles of 200 ml
	10 polypropylene bottles of 200 ml
	1 polypropylene bottle of 500 ml
	1 glass bottle of 500 ml
	6 polypropylene bottles of 500 ml
	6 glass bottles of 500 ml
350 mg I/ml	6 vials of 20 ml
	25 vials of 20 ml
	10 glass bottles of 40 ml
	1 polypropylene bottle of 50 ml
	10 polypropylene bottles of 50 ml
	10 glass bottles of 50 ml
	1 polypropylene bottle of 75 ml
	10 polypropylene bottles of 75 ml
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	1 polypropylene bottle of 150 ml
	10 polypropylene bottles of 150 ml
	6 glass bottles of 150 ml
	1 polypropylene bottle of 175 ml
	10 polypropylene bottles of 175 ml
	1 polypropylene bottle of 200 ml
	10 polypropylene bottles of 200 ml
	6 glass bottles of 200 ml
	1 polypropylene bottle of 500 ml
	6 polypropylene bottles of 500 ml
	1 glass bottle of 500 ml
	6 glass bottles of 500 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder:
GE Healthcare AS, P.O.Box 4220 Nydalen,
NO-0401 Oslo, Norway

Manufactured by
GE Healthcare AS, Nycoveien 1, NO-0485 Oslo, Norway

or

GE Healthcare Ireland Limited
IDA Business Park
Carrigtohill
Co. Cork, Ireland

Local representative
GE Healthcare Limited
Little Chalfont
Buckinghamshire HP7 9NA
England

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