PACKAGE LEAFLET: INFORMATION FOR THE USER

Visipaque 270 mg I/ml solution for injection Glass container
Visipaque 320 mg I/ml solution for injection Glass container
Visipaque 270 mg I/ml solution for injection Polypropylene container
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iodixanol

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Ask your doctor if you need more information or advice.
- 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 Visipaque is and what it is used for

Visipaque is a "contrast agent" for diagnostic use in adults and children. It is used only to help identify an illness and not in connection with treatment.

- Once injected, it can help your doctor tell apart normal or abnormal appearance and shape of some organs in your body.
- You can have Visipaque before examination of your urinary system, joints, ovarian tubes, spinal cord, blood vessels, including blood vessels of your heart and the gullet, stomach and the intestine.
- This medicine can also be given to you before or during a scan of your head or body using "computed tomography" (CT-scan).

Your doctor might give you Visipaque for something else. Ask your doctor.

2. What you need to know before you use Visipaque

Do not use Visipaque:

- If you suffer from severe thyroid gland problems.
- If you are allergic (hypersensitive) to iodixanol or any of the other ingredients of Visipaque (listed in section 6).
- If you have acute pelvic inflammatory disease you should not have X-ray examination of your uterus and ovarian tubes.

If you are uncertain of any of the above, ask your doctor.

Warnings and precautions

Talk to your doctor before using Visipaque:

- If you have ever had an allergic reaction after a medicine similar to Visipaque, called a "contrast medium".
- If you have any thyroid gland problems.
- If you have ever had any allergies or asthma, as it may bring on an attack.
- If you have diabetes.
- If you have kidney problems, or both liver and kidney problems.
- If you have epilepsy, blood clot in the brain, stroke or a tumour in the brain.
- If you have a heart or lung disease.
- If you have an illness called 'myasthenia gravis' (a condition causing severe muscle weakness).
- If you have "phaeochromocytoma" (high blood pressure due to a tumour near the kidney).
- 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 your bone marrow.
- If you have ever been dependent on alcohol or drugs.
- If you are having a thyroid function test in the next few weeks.
- 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 symptoms related to this condition described in Section 4.

Thyroid disorders may be observed following administration of Visipaque 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 Visipaque.

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

Other medicines and Visipaque

Tell your doctor if you are taking, have recently taken or might take any other medicines.

This includes medicines obtained without a prescription or medicines bought abroad.

Tell your doctor if you

- Take metformin for diabetes.
- Take or recently (within two weeks before your investigation) have taken medicine to inhibit the immune defence, e.g. in connection with transplantation (interleukin-2).
- Take medicines to lower the blood pressure (beta blockers).

Other medicines may affect how Visipaque works, and Visipaque may affect how other medicines work. This usually has no consequences. Ask your doctor if you want further information.

Pregnancy, breast-feeding and fertility

Pregnancy

You must tell your doctor if you are pregnant or think you may be pregnant. You should never have an X-ray examination of your uterus and ovarian tubes if pregnant. You will normally not have an X-ray examination and be given Visipaque, if you are pregnant. The doctor will evaluate in each case. If Visipaque has been given to the mother during pregnancy, it is recommended to monitor the infant's thyroid function.

Breast-feeding

The amount of Visipaque in breast milk is probably small and it is not believed to have any harmful effect on the infant. Breastfeeding may be continued normally when Visipaque has been given to the mother.

Fertility
The effect of Visipaque on human reproduction has not been established. Animal studies do not indicate direct or indirect effects with respect to reproduction.

Driving and using machines

Do not drive or use tools or machines for 24 hours after an injection in your skull (intrathecal examination). Visipaque may cause side effects such as dizziness which more or less can affect safety to work with machines and the ability to move safely in the traffic.

Ask your doctor for advice.

Important information about the sodium content in Visipaque

Visipaque contains sodium. The amount present will depend on what kind of examination you will have. You must tell your doctor if you are on a diet that should not contain sodium or are on a sodium controlled (salt restricted) diet.

3. How to use Visipaque

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

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

The usual dose is:

You will usually have Visipaque injected into a blood vessel before or during the X-ray examination or you may be asked to drink it or if you are a child can get it rectally. The amounts injected may vary depending on the type of examination, the technique used and your age and weight. Make sure you drink plenty of fluids before the examination.

After you have been given Visipaque

- Make sure to drink plenty of fluid afterwards (to help flush the medicine from your body).
- Stay in or around the area where you had your scan or X-ray for around 30 minutes.

If you have any side effects during this time, tell your doctor immediately (see section 4).

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

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

Urography (examination of the bladder and urinary tract)

Visipaque will most commonly be injected into a blood vessel in your arm (an arm vein). The amount injected is usually 40-80 ml. The volume is adjusted for children.

Computer tomography (CT-scan, a computerised X-ray examination)

Visipaque will most commonly be injected into an arm vein. The amount injected is usually 50-150 ml.

Venography (examinations of the veins)

Visipaque will most commonly be injected into a limb vein after insertion of a thin plastic tube. The amount injected is usually 50-150 ml per leg.

Arteriographies (examination of the arteries)

Visipaque will be injected after insertion of a thin plastic tube into the artery branch of interest. The amount injected will vary depending on the kind of examination, usually 5-60 ml per injection.

Myelography (examination of the spinal canal)

Visipaque will be injected into the space around the spinal cord. Usually less than 12 ml will be injected.

If you have been given Visipaque into the space around the spinal cord or brain, you will be asked

- To rest with your head and chest raised 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 alone for the first 24 hours after having Visipaque if you are an outpatient and have ever had fits.

Other examinations

For examination of the gullet, stomach or small bowel, a volume of 10-200 ml is normally given by mouth. Visipaque may be mixed with water for these examinations. For examination of body cavities (e.g. joints, womb and fallopian tubes) a volume of 5-20 ml will normally be given.

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

If you use more Visipaque than you should

As you will be given Visipaque by a trained person, overdose is not likely to occur. If very large doses are given to patients with damaged kidneys, these patients may need to undergo dialysis (cleansing of the blood) to remove excess iodixanol. The patients will also need infusion of water and minerals.

4. Possible side effects

Like all medicines this medicine 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 Visipaque, tell the doctor straight away. The signs may include:

- wheeziness, difficulty 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 fainting (caused by low blood pressure)

The above side effects may happen several hours or days after Visipaque 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.

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

After an injection into an artery or vein

Uncommon (affects less than 1 in 100 people)

- allergic reaction also known as hypersensitivity reaction, see “Allergic reactions” above for the signs
- itching, breaking out of the skin, rash, lumps, itchy spots, blisters on skin
- headache
- flushing
- nausea, vomiting
- short term injury or damage to the kidney
- feeling hot
- feeling cold
- chest pain

Rare (affects less than 1 in 1,000 people)

- feeling dizzy
- sensory disturbances (including taste and smell disturbance, tingling, numbness or burning sensation of the skin)
- irregular heartbeats
- low blood pressure
- heart attack
- cough, sneezing
- shivers, fever
- skin redness
- pain and local reactions (where it was injected)
- feeling uncomfortable

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

- feeling agitated
- anxiety
- stroke
- fainting
- transient shivering
- high blood pressure
- difficulty breathing
- swelling of throat
- throat irritation
- transient blindness
- transient reduced eyesight (including double vision, unclear vision)
- swelling of eyelids
- feeling cold
- pain or discomfort around the stomach area (abdominal pain)
- diarrhoea
- arrest of the heart
- awareness of heart beat (palpitations)
- short term memory loss
- unease
- extreme tiredness
- back pain
- swelling of the face or other localised swelling
- excessive sweating
- muscle spasm
- decreased blood supply (ischaemia)

Unknown (the number of people affected is not known)

- allergic reaction, allergic shock leading to shock and collapse, including life-threatening or fatal allergic reactions, also skin rash, lumps, itchy spots, blisters on skin see “Allergic reactions” above for the other signs
- allergic skin reaction that may include round or oval patches of redness and swelling of the skin, blistering, and itching (fixed drug eruption). Darkening of the skin in affected areas, which might persist after healing, may also occur. Fixed drug eruption usually reoccurs at the same site(s) if the medication is used again.
- feeling confused
- coma
- fainting
- difficulty moving
- cramps
- blood clots (thrombosis)
- spasm of one of the arteries including arteries to the heart
- shock

- decrease in pumping activity of the heart
- pain and swelling of your vein
- severe breathing difficulties (due to fluid in your lungs), stopped breathing, tightening of airways of lungs, throat tightness
- pancreatic problems (acute or worsening inflammation of the pancreas)
- enlarged salivary gland
- thyroid disorders
- swelling
- pain in your joints
- heart and lung arrest
- short term brain disorders (encephalopathy) which can cause confusion, memory loss, hallucinations, difficulties with vision, loss of vision, seizures, loss of coordination, loss of movement in one side of the body, problems with speech, and loss of consciousness
- seizures (fits)
- increased level of creatinine in your blood
- iodine poisoning (iodism)

After an injection into the space around your spinal cord

Uncommon (affects less than 1 in 100 people)

- headache (may be severe and lasting for hours)
- vomiting

Unknown (the number of people affected is not known)

- feeling dizzy
- nausea
- shivering
- pain (where it was injected)
- allergic reaction, see "Allergic reactions" above for the signs
- short term brain disorders (encephalopathy) which can cause confusion, memory loss, hallucinations, difficulties with vision, loss of vision, seizures, loss of coordination, loss of movement in one side of the body, problems with speech, and loss of consciousness
- muscle spasm

After use in body cavities (such as uterus and ovarian tubes)

Very common (affects more than 1 in 10 people)

- pain around the stomach area
- bleeding from the vagina

Common (affects less than 1 in 10 people)

- headache
- feeling sick (nausea)
- high temperature

Unknown (the number of people affected is not known)

- vomiting
- shivering
- local reactions (where it was injected)
- allergic reaction, see "Allergic reactions" above for the signs

After injection into your joints

Common (affects less than 1 in 10 people)

- pain where it was injected

Unknown (the number of people affected is not known)

- shivering
- allergic reactions, see “Allergic reactions” above for the signs

After being given it by mouth

Common (affects less than 1 in 10 people)

- diarrhoea
- feeling sick (nausea)
- pain around the stomach area

Uncommon (affects less than 1 in 100 people)

- vomiting

Unknown (the number of people affected is not known)

- shivering
- allergic reaction, see “Allergic reactions” above for the signs

Reporting of side effects

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 Visipaque

- Keep out of the sight and reach of children.
- Do not use Visipaque after the expiry date which is stated on the label on the vial or bottle.
- Do not store above 30°C. Store in the outer carton in order to protect this medicine from light and from secondary X-rays.

Always hand in medicines remains at the pharmacy. To protect the environment, do not throw medicines remains in the drain, toilet or bin.

6. Contents of the pack and other information

What Visipaque contains

The active substance is iodixanol.

Visipaque 270 mg I/ml contains 550 mg iodixanol per ml (equivalent to 270 mg iodide per ml).

Visipaque 320 mg I/ml contains 652 mg iodixanol per ml (equivalent to 320 mg iodine per ml).

Other ingredients are trometamol, sodium chloride, calcium chloride dihydrate, sodium calcium edetate, hydrochloric acid (for pH adjustment), and water for injections.

Visipaque 270 mg I/ml contains 0.76 mg (0.03 mmol) sodium per ml.

Visipaque 320 mg I/ml contains 0.45 mg (0.02 mmol) sodium per ml.

What Visipaque looks like and contents of the pack

Appearance

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

Contents of pack

Visipaque is supplied as:

270 mg I/ml

10 glass vials of 20 ml
10 glass bottles of 50 ml
1 glass bottle of 100 ml
10 glass bottles of 100 ml
1 glass bottle of 200 ml
6 glass bottles of 200 ml
1 glass bottle of 500 ml
6 glass bottles of 500 ml

1 polypropylene bottle of 50 ml
10 polypropylene bottles of 50 ml
1 polypropylene bottle of 75 ml
10 polypropylene bottles of 75 ml
1 polypropylene bottle of 100 ml
10 polypropylene bottles of 100 ml
1 polypropylene bottle of 150 ml
10 polypropylene 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
1 polypropylene bottle of 500 ml
6 polypropylene bottles of 500 ml

320 mg I/ml

10 glass vials of 20 ml
10 glass bottles of 50 ml
1 glass bottle of 100 ml
10 glass bottles of 100 ml
1 glass bottle of 200 ml
6 glass bottles of 200 ml
1 glass bottle of 500 ml
6 glass bottles of 500 ml

1 polypropylene bottle of 50 ml
10 polypropylene bottles of 50 ml
1 polypropylene bottle of 75 ml
10 polypropylene bottles of 75 ml
1 polypropylene bottle of 100 ml
10 polypropylene bottles of 100 ml
1 polypropylene bottle of 150 ml
10 polypropylene 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
1 polypropylene bottle of 500 ml
6 polypropylene bottles of 500 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

GE Healthcare AS
Nycoveien 1
0485 Oslo
Norway

Manufacturer:

GE Healthcare AS
Nycoveien 1
0485 Oslo
Norway

or

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

Local representative

GE Healthcare Limited
Pollards Wood
Nightingales Lane
Chalfont St Giles
Buckinghamshire HP8 4SP
United Kingdom

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