

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about OMNIPAQUE. It does not contain all the available information. It does not take the place of talking to your radiologist (the specialist doctor who does X-rays), doctor or pharmacist.

All preparations of this type have risks and benefits. Your radiologist and/or your doctor have weighed the risks of you receiving OMNIPAQUE against the benefits they expect it will have for you.

If you have any concerns about being given this preparation, ask your radiologist, doctor or pharmacist.

Keep this leaflet. You may need to read it again.

What OMNIPAQUE is used for

OMNIPAQUE is one of a group of medicines known as "contrast media" for diagnostic use. OMNIPAQUE is used in X-ray examinations in many different parts of the body for adults and children. It can make it easier to find and see abnormalities, and improves the diagnostic information needed by the doctor.

Before you are given OMNIPAQUE

When you must not be given it

OMNIPAQUE should not be given to you if:

1. You have ever had or are allergic to OMNIPAQUE, to any of the ingredients listed at the end of this leaflet (see Product description) or to any other contrast medium. Symptoms of an allergic reaction may include wheeziness, difficulty in breathing or tightness or pain in the chest, skin rash, swelling or itching.
2. You have thyroid gland problems.
3. You have had recent heart disease or problems with your heart.
4. The expiry date on the pack has passed. If you use it after the expiry date, it may have no effect at all, or worse, an entirely unexpected effect.
5. You have an infection or open wound near the site to be examined.
6. You are pregnant or intend to become pregnant.

Before you are given it

You must tell your doctor if:

1. You are pregnant, intend to become pregnant or breast-feeding or plan to breast-feed.
2. You have, or have had, the following medical conditions:
 - Asthma
 - Allergies, for example hay fever or hives, or allergies to iodine-containing dyes, any medicines or any other substances, such as foods, preservatives or dyes.
 - Heart disease or problems with your heart.
 - An overactive thyroid gland or goitre (neck swelling of the thyroid gland).
 - Diabetes
 - Kidney and/or liver disease

- Any disorder or injuries affecting your brain or nervous system, for example, stroke, bleeding inside the skull or brain tumours or tumours (or cancer) spreading to the brain, epilepsy, transient ischaemic attacks (mild strokes), or migraines
- Alcoholism and/or addiction to, or dependence on drugs or medicines (there is an increased risk of seizure (fit))
- Multiple myeloma (cancer of blood cells)
- Pheochromocytoma (a tumour which raises blood pressure)
- Waldenström's paraproteinemia [a disorder of the immunoglobulins (cells involved in the body's natural ability to fight disease)]
- Myasthenia gravis (disease of the muscles causing drooping eyelids, double vision, difficulty in speaking and swallowing and sometimes muscle weakness in the arms or legs)
- You are a diabetic

Taking other medicines

Tell the doctor if you are taking any other medicines,

including medicines you buy without a prescription from a pharmacy, supermarket or health food shop. Some medicines may interfere with OMNIPAQUE. These include:

- Biguanides (eg metformin) a medicine for diabetes. Your doctor may ask you not to take biguanides for 48 hours before receiving an injection of OMNIPAQUE.
- Interleukin-2.

These medicines may interact or affect the way OMNIPAQUE works. Check with your doctor or pharmacist if you are not sure whether you are taking biguanides or interleukin-2.

You should not eat or drink anything in the two hours before your examination with OMNIPAQUE. It is, however, important to drink plenty of water before the examination and after the examination.

How OMNIPAQUE is used

You will be given OMNIPAQUE before or during your X-ray examination. OMNIPAQUE will be injected by a qualified person. The amount injected can vary depending on the type of examination used, your age and your weight.

If you receive an overdose

An overdose may lead to serious effects on the kidneys. If you are given an overdose, your doctor will decide how to treat you.

While you are using OMNIPAQUE

After examination of the spinal canal (myelography), you will be asked to rest in bed in a sitting or semi-sitting position and to avoid bending down for the first few hours. It is not advisable to drive a vehicle or operate machinery for at least 24 hours following an intrathecal examination (myelography).

If you need to have a thyroid function test within the next 14 days after examination with OMNIPAQUE, **please tell your doctor before the test is done.**

If you have any blood or urine tests on the day of your examination with OMNIPAQUE, **tell your doctor you are using OMNIPAQUE.** OMNIPAQUE may affect the results of some laboratory tests.

Things to be careful of

Delayed reactions of iodine-containing dyes may occur.

Side effects

Usually, OMNIPAQUE does not cause any problems. It can, however, sometimes cause unwanted effects in some people. The most frequent effect is a mild sensation of warmth or pain during the injection. Although there is a risk that you might get an unwanted effect, your doctor will have chosen this treatment by considering these risks and the benefits for the examination.

If you get any of the following during or after the examination:

- Wheeziness, difficulty in breathing or tightness or pain in the chest;
- Skin rash, itching, swelling or other allergic symptoms;
- Dizziness or feeling faint;

you should tell your doctor straight away.

Other unwanted effects which are unusual, but which may occur during or after the examination include:

- Altered taste sensation in the mouth;
- Abdominal discomfort;
- Nausea, vomiting or diarrhoea;
- Headache, dizziness, restlessness;
- Chest pain, change in blood pressure or heart rate;
- Blurred vision, auditory disturbance, confusion or a change in your sensation of touch;
- Muscle weakness, numbness, spasms or seizures;
- Difficulty in voiding;
- Backache, pain in the arms and legs;
- Swelling and tenderness of the salivary glands for up to approximately 10 days after the examination.
- Flushing or feeling hot
- Shortness of breath or coughing

These effects are often mild and of short duration. If they become severe or last for more than a few days, tell your doctor. Sometimes, medical treatment is necessary.

If you get any of the following during or after myelography:

- Sensitivity to light
- Neck stiffness
- Muscle weakness or spasm

you should inform your doctor immediately.

Please tell your radiologist or doctor as soon as possible if you experience any other unwanted effects, or if you do not feel well after receiving an injection of OMNIPAQUE during the X-ray procedure or afterwards.

Product description

OMNIPAQUE is a sterile solution for injection which contains a substance called iohexol. The expiry date for OMNIPAQUE is printed on the label. The product should not be used after this date. OMNIPAQUE also contains the following inactive ingredients in small amounts:

trometamol, sodium calcium edetate, water for injection, hydrochloric acid and sodium hydroxide.

- **180 mg I/mL:**
 - 10mL glass vial, packs of 10* AUST R 12595
 - 15mL glass vial, packs of 10* AUST R 48215
 - 20mL glass vial, packs of 20* AUST R 48216
 - 10mL PPE ampoule, packs of 1* and 10* AUST R 76061
 - 15mL PPE ampoule, packs of 1* and 10* AUST R 76070
- **240 mg I/mL:**
 - 10mL glass vial, packs of 10* AUST R 12596
 - 10mL PPE ampoule, packs of 1* and 10* AUST R 76063
 - 15mL PPE ampoule, packs of 1* and 10* AUST R 76058
 - 20mL glass vial, packs of 25* AUST R 48217
 - 20mL PPE ampoule, packs of 1* and 10* AUST R 76072
 - 50mL glass and PPE* bottle, packs of 10 AUST R 39861
 - 50mL PPE ampoule, packs of 1* and 10* AUST R 76066
- **300 mg I/mL:**
 - 10mL glass vial, packs of 10* AUST R 15473
 - 10mL PPE ampoule, packs of 1* and 10* AUST R 76064
 - 20mL glass vial, packs of 10 AUST R 48220
 - 20mL PPE ampoule, packs of 1* and 10* AUST R 76071
 - 40mL PPE ampoule, packs of 1* and 10* AUST R 76059
 - 50mL glass and PPE* bottle, packs of 10 AUST R 39864
 - 50mL PPE ampoule, packs of 1* and 10* AUST R 76068
 - 75mL glass bottle, packs of 10 AUST R 48243
 - 100mL glass and PPE* bottle, packs of 10 AUST R 48244
- **350 mg I/mL:**
 - 20mL glass vial, packs of 10 AUST R 39868
 - 20mL PPE ampoule, packs of 1* and 10* AUST R 76069
 - 40mL PPE ampoule, packs of 1* and 10* AUST R 76060
 - 50mL glass and PPE* bottle, packs of 10 AUST R 15474
 - 50mL PPE ampoule, packs of 1* and 10* AUST R 76065
 - 75mL glass bottle, packs of 10 AUST R 48225
 - 100mL glass and PPE* bottle, packs of 10 AUST R 48233
 - 125mL glass bottle packs of 10* AUST R 48234
 - 150mL glass and PPE bottle, packs of 10* AUST R 48236
 - 175mL glass and PPE bottle, packs of 10* AUST R 48238
 - 200mL glass and PPE* bottle, packs of 6 AUST R 48241

Storing the medicine

OMNIPAQUE should be stored below 30°C, protected from the light. Do not freeze.

Other information

Please ask your doctor, radiologist or nurse if you would like to know more or have any questions about OMNIPAQUE.

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