

VISIPAQUE™ Injection

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about VISIPAQUE. 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 VISIPAQUE 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 VISIPAQUE is used for

VISIPAQUE is one of a group of medicines known as “contrast media” for diagnostic use.

VISIPAQUE is used to improve the clarity of X-ray images of the internal organs of the body by increasing the degree of contrast of different structures within the body.

VISIPAQUE is used to study the heart, veins and arteries in the body's circulatory system and the urinary tract.

VISIPAQUE is intended for use in hospitals and radiology clinics only and will be given to you as an injection. Your doctor may have prescribed VISIPAQUE for another reason. Ask your doctor if you have

any questions about why VISIPAQUE has been prescribed for you.

How does VISIPAQUE work?

As VISIPAQUE flows through your blood vessels and organs, the Iodine in VISIPAQUE makes them appear darker during radiographic examinations. This makes them stand out on the X-ray film. This aids the doctor in identifying any problems with a particular organ.

Before you are given VISIPAQUE

When you must not be given it.

VISIPAQUE should not be given to you if:

1. You have ever had an allergic reaction to VISIPAQUE or, 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. 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.

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. If you receive Visipaque whilst pregnant, your newborn should be tested to ensure they are producing the correct amount of thyroid hormone.
2. You have, or have had, the following medical conditions:
 - Asthma
 - Allergies, for example hay fever or hives, or allergies to iodine-containing contrast media, any medicines or other substances, such as foods, preservatives or dyes.
 - Thyroid gland problems.
 - Sickle cell disease
 - Diabetes
 - Kidney and/or liver disease
 - Epilepsy
 - Problems with your body producing certain enzymes (homocystinuria)
 - Heart disease and/or circulatory system problems
 - Multiple myeloma (cancer of blood cells) and other blood problems (paraproteinaemia)
 - Pheochromocytoma (a tumour which raises blood pressure).
3. You plan to have surgery

If you have not told your doctor about any of the above, tell them before you are given VISIPAQUE.

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 VISIPAQUE. 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 VISIPAQUE.
- Medicines used to treat high blood pressure or irregular heart beats (Adrenergic beta-blockers)
- Medicines used to treat cancer
- Contrast agents for the study of the gall bladder and bile ducts
- General anaesthetics

These medicines may interact or affect the way VISIPAQUE works. Your doctor or pharmacist has more information to be careful with or avoid when using VISIPAQUE.

How VISIPAQUE is used

You will be given VISIPAQUE before or during your X-ray examination. VISIPAQUE will be injected into a vein 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

As VISIPAQUE will be administered by a qualified person familiar with the procedure, overdosage is unlikely. In the event of overdosage, qualified personnel will be equipped to handle such an occurrence.

While you are using VISIPAQUE

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

If you have any blood or urine tests on the day of your examination with VISIPAQUE, **tell your doctor you are using VISIPAQUE.**

VISIPAQUE may affect the results of some laboratory tests.

If you are about to start on any new medicine within the next day or two, tell your doctor and pharmacist that you have been given VISIPAQUE.

If you plan to have surgery that needs general anaesthetic, tell your doctor or dentist that you have been given VISIPAQUE.

Tell all doctors, dentists and pharmacists who are treating you that you have been given VISIPAQUE.

Things to be careful of

Delayed reactions of iodine-containing dyes may occur.

If you feel light-headed, dizzy or faint as a result of the procedure, get up slowly when getting out of bed or standing up. Be careful if you are elderly, unwell or taking other medicines. Some people may experience side effects such as dizziness and unsteadiness as a result of the procedure, which may increase the risk of a fall.

Side effects

During and after your examination

Tell your doctor or healthcare worker as soon as possible if you do not feel well while you are

being given, or after you have been given VISIPAQUE.

Usually, VISIPAQUE does not cause any serious side effects. It can, however, sometimes cause unwanted effects in some people. All medicines can have side effects. You may need medical treatment if you get some of the side effects during or after the procedure. Although there is a risk that you might get an unwanted effect, your doctor will have chosen this contrast medium by considering these risks and the benefits of the examination.

The type of side effect experienced may depend on the area of the body under examination.

The most frequent side effects are headache, nausea, changes in your sensation of taste, dizziness, rash, chest pain, itching and visual disturbances.

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

- swelling of the face, lips, mouth or throat which may cause wheeziness, difficulty in breathing or tightness, pain in the chest or changes in the way your heart beats
- fainting
- hives, lumps, swelling, itching throat or spots or other allergic symptoms,

you should tell the doctor straight away or go to Accident and Emergency at your nearest hospital as delayed reactions may occur occasionally.

These are very serious side effects. If you have them, you may have had a serious allergic reaction to VISIPAQUE. You may need urgent medical attention or hospitalisation.

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

- pain at the site of injection
- headache, dizziness, fainting, seizure, altered taste or smell sensation or other types of sensory disturbance

- weakness
- fluid retention
- neck stiffness
- numbness, paralysis, amnesia, hallucination or speech disturbance
- twitching
- hearing disturbance
- muscle cramps or back pain
- blurred vision or visual impairment
- confusion, anxiety or trembling
- warmth or rash
- flushing, feeling hot, feeling cold, chills
- shortness of breath, cough, sneezing, throat irritation or tightness
- chest pain, heart attack, change in blood pressure or heart rate
- nausea, vomiting, abdominal pain, diarrhoea, swelling or enlargement of salivary glands
- Hypothyroidism (a condition in which your thyroid gland does not produce enough thyroid hormone).

These effects are usually mild to moderate and of short duration, resolving without any treatment. **If they become severe or last more than a few days, tell your doctor.**

If you experience any other unwanted effects, please tell your doctor.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Other side effects not listed above may also occur in some patients.

Tell your doctor if you notice anything else that is making you feel unwell.

Product description

What it looks like

VISIPAQUE is a colourless to pale yellow injectable solution.

Ingredients

Active Ingredient:

Iodixanol

Other Ingredients

trometamol, sodium calcium edetate, sodium chloride, calcium chloride dihydrate, water for injection and hydrochloric acid

Storage

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

Supplier

VISIPAQUE is supplied in Australia by GE Healthcare Australia Pty Limited
241 O'Riordan St
Macot NSW 2020
Tel: 1300 88 77 64
Fax: 1300 434 232

It is available in the following strengths:*

270 mg 1/mL: In pack sizes of

20mL glass vial - AUST R 154369
50mL glass and PPE bottle - AUST R 49603
100mL glass and PPE bottle - AUST R 49604
150mL glass and PPE bottle - AUST R 49605
200mL glass and PPE bottle - AUST R 49606
10mL PPE ampoule - AUST R 75923
20mL PPE ampoule - AUST R 75924
40mL PPE ampoule - AUST R 75929
50mL PPE ampoule - AUST R 75925
100mL injection bag - AUST R 49607
150mL injection bag - AUST R 49608
200mL injection bag - AUST R 49609

320 mg 1/mL: In pack sizes of

20mL glass vial - AUST R 154370
50mL glass and PPE bottle - AUST R 49594

100mL glass and PPE bottle - AUST R 49597
150mL glass and PPE bottle - AUST R 49598
200mL glass and PPE bottle - AUST R 49599
10mL PPE ampoule - AUST R 75927
20mL PPE ampoule - AUST R 75928
40mL PPE ampoule - AUST R 75930
50mL PPE ampoule - AUST R 75926
100mL injection bag - AUST R 49600
150mL injection bag - AUST R 49601
200mL injection bag - AUST R 49602

- Some presentations may not be marketed in Australia

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