Driving and using machines
Venography (intrathecal examination). Visipaque may cause side effects 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

• 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 1 hour. If you are feeling unwell, stay where you are
• Do not drive, operate machinery or sign legal documents until you are feeling well

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 any back pain or weakness, you may be asked
• To rest with your head and chest raised for one hour, or six hours if you stay in the area
• To get up slowly and avoid sudden movements

Arthrography
This medicine can also be given you before or during a scan of your head or neck, usually to X-ray your spine. There is usually less than 5 ml injected.

4. Possible side effects
Visipaque can cause side effects, although no one gets them.

4.1 Therapeutic indications

• In patients with phaeochromocytoma undergoing interventional procedures, alpha blockers should be given as prophylaxis to avoid a hypertensive crisis.

4.2 Ppocedure and method of administration

• Iodixanol is a non-ionic, dimeric, hexaiodinated, water-soluble X-ray contrast medium. Pure aqueous solutions of iodixanol ... with normal body fluids by addition of electrolytes. The osmolality and viscosity values of VISIPAQUE are as follows:

4.3 Dosage and administration

• If you have acute pelvic inflammatory disease you should not have x-ray examination of the pelvic organs. In this case, other contrast media may be used in place of Visipaque.

4.4 Post-administration care

• Check the condition of your eyes at least once a year. If you are treated with iodixanol, this check should be done more frequently. If you have any questions, ask your doctor or pharmacist.

4.5 Interactions with other medicinal products and other forms of treatment

• If you suffer from severe thyroid gland problems

• If you have epilepsy

• If you have kidney problems

Other examinations
Visipaque may also be used to X-ray the brain or spinal cord before or during surgery. It can also be used to X-ray the eye. The aim is to show the size, position and shape of certain parts of the brain or spinal cord.

5. How to store Visipaque

• We hope that this leaflet will be useful for you. If you have any further questions, ask your doctor or pharmacist.

6. Further information

• This medicine can also be given you before or during a scan of your head or neck, usually to X-ray your spine. There is usually less than 5 ml injected.

7. What to do if you think you have had too much Visipaque

• Ask your doctor or pharmacist if you are not sure what to do with your remaining medicine. You may need to take extra precautions while using this medicine.

8.icone: http://www.visipaque.com

9. Orphan designation

• In patients with phaeochromocytoma undergoing interventional procedures, alpha blockers should be given as prophylaxis to avoid a hypertensive crisis.

10. Additional information

• This medicine can also be given you before or during a scan of your head or neck, usually to X-ray your spine. There is usually less than 5 ml injected.

11. Given all of this be careful before you are given Visipaque:

12. Conclusion

13. Notes for patients

• This medicine can also be given you before or during a scan of your head or neck, usually to X-ray your spine. There is usually less than 5 ml injected.

14. Summary of product characteristics (SMPC)

• This medicine can also be given you before or during a scan of your head or neck, usually to X-ray your spine. There is usually less than 5 ml injected.

15. How to search for further information

• This medicine can also be given you before or during a scan of your head or neck, usually to X-ray your spine. There is usually less than 5 ml injected.

16. How to report suspected adverse reactions

• This medicine can also be given you before or during a scan of your head or neck, usually to X-ray your spine. There is usually less than 5 ml injected.
5. How to store Visipaque

Keep out of the reach and sight of children.

Do not use Visipaque after the expiry date which is stated on the label on the container.

Store the 20 ml, 50 ml, 100 ml and 200 ml vial in the refrigerator at temperatures not exceeding 2 to 8°C. Store the other containers at room temperature.

Always have in medicines remaining at the pharmacy. To protect the environment, do not throw medicines remaining in the daar, toilet or bin.

6. Further information

6.1 Pharmaceutical properties

Pharmaceutical group:

Biochemical group:

Pharmacological group:

Other relevant data:

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products. A separate syringe should be used.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Keep in the container in the same carton. Protect from secondary exposure to light.

6.5 Nature and content of container

Vials: 20 ml, 50 ml and 100 ml vials are rigid glass vials with a cap of type 1.

Bottle: of 150 ml, 300 ml and 500 ml are glass containers (chamber type 1/2) with a polypropylene cap.

6.6 Overdose

Overdose in humans has been managed by supportive treatment of the symptoms. There is no specific antidote. Treatment of overdose is symptomatic.

6.7 Effects on ability to drive and use machines

Visipaque may affect the ability to drive, concentration, memory, motor control and coordination.

6.8 Undesirable effects

The following undesirable effects may be associated with Visipaque which occur with a frequency of less than 3/10,000.

7. Side effects

7.1 Description of expected and possible side effects

The following side effects may occur during radiographic procedures which include the use of Visipaque.

7.2 Very common

7.3 Uncommon

7.4 Rare

7.5 Very rare

7.6 Not known

7.7 Allergic reactions

Allergic reactions are rare. On intravenous administration of iodixanol in healthy volunteers, no significant deviation from preinjection values has been found. The few changes observed in the laboratory parameters were minor and considered to be of no clinical importance.

7.8 Very common

7.9 Uncommon

7.10 Rare

7.11 Very rare

7.12 Not known

7.13 Other side effects

7.14 Special studies

7.15 Genotoxicity

7.16 Non-genotoxicity

7.17 Reproductive toxicity

7.18 Teratogenicity

7.19 Carcinogenicity

7.20 Mutagenicity

7.21 Immunogenicity

7.22 Local side effects

7.23 Pharmacokinetics

7.24 Pharmacokinetics, route effects

7.25 Pharmacokinetics, time effects

7.26 Pharmacokinetics, interindividual differences

7.27 Pharmacokinetics, interindividual differences, route effects

7.28 Pharmacokinetics, interindividual differences, time effects

7.29 Pharmacokinetics, interindividual differences, route and time effects

7.30 Pharmacokinetics, intraindividual differences

7.31 Pharmacokinetics, intraindividual differences, route effects

7.32 Pharmacokinetics, intraindividual differences, time effects

7.33 Pharmacokinetics, intraindividual differences, route and time effects

7.34 Pharmacokinetics, interintraindividual differences

7.35 Pharmacokinetics, interintraindividual differences, route effects

7.36 Pharmacokinetics, interintraindividual differences, time effects

7.37 Pharmacokinetics, interintraindividual differences, route and time effects

7.38 Pharmacokinetics, interindividual intraindividual differences

7.39 Pharmacokinetics, interindividual intraindividual differences, route effects

7.40 Pharmacokinetics, interindividual intraindividual differences, time effects

7.41 Pharmacokinetics, interindividual intraindividual differences, route and time effects

7.42 Pharmacokinetics, intraindividual intraindividual differences

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7.45 Pharmacokinetics, intraindividual intraindividual differences, route and time effects

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7.53 Pharmacokinetics, interindividual interintraindividual differences, route and time effects

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7.100 Pharmacokinetics, intraindividual interindividually differences, route and time effects

8. Marketing Authorisation Holder

9. Date of first authorisation/renewal of the authorisation

10. Date of revision of the text

11. Reference