

HEXABRIX 320 (320 mg I/mL), solution for injection
Meglumine ioxaglate and sodium ioxaglate

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What **HEXABRIX 320**, solution for injection is and what it is used for
2. What you need to know before you use **HEXABRIX 320**, solution for injection
3. How to use **HEXABRIX 320**, solution for injection
4. Possible side effects
5. How to store **HEXABRIX 320**, solution for injection
6. Contents of the pack and other information

1. WHAT HEXABRIX 320 IS AND WHAT IT IS USED FOR

HEXABRIX 320 is a contrast agent. It belongs to the group of contrast agents used for radiological examinations.

HEXABRIX 320 is used to enhance the contrast of the images obtained during these examinations, in order to improve the visualisation and delineation of certain parts of the body, such as:

- Certain hollow organs (opacification of body cavities),
- The uterus and fallopian tubes (ducts connecting the uterus to the ovaries) in female patients (hysterosalpingography),
- Blood vessels (angiography),
- Joints (arthrography),
- Urinary system (urography).

This medicine is for diagnostic use only.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE HEXABRIX 320

Your doctor must never give you HEXABRIX 320 in the following cases:

- If you are allergic to the active substance (ioxaglic acid) or any of the other ingredients of HEXABRIX 320. The list of these ingredients can be found in section 6. Contents of the pack and other information.
- If you have already had an allergic reaction following the injection of a medicinal product containing the same active ingredient (ioxaglic acid) (also refer to section 4. Possible side effects).
- If you suffer from excessively high levels of thyroid hormones (thyrotoxicosis).
- If you are pregnant, if you think you are pregnant or if you have inflammation or pain in the pelvic region, and you are to undergo an examination of the uterus and fallopian tubes (hysterosalpingography).
- If you are to undergo an examination of the spinal cord (myelography).

Take special care with HEXABRIX 320:

As with any iodinated contrast medium, no matter what the method of administration and the dose, there is a possibility of side effects; which can be minor but can also be life-threatening. These reactions can occur within an hour or, more rarely, up to 7 days after administration. They are often unexpected but the risk of these is higher if you have already had a reaction following previous administration of an iodinated contrast medium (see section 4 "Possible side effects").

Before the examination, you must inform your doctor if one of the following situations applies to you:

- If you have already had a reaction to an iodinated contrast medium during an examination.
- If you suffer from poor kidney function (renal impairment).
- If you suffer from both poor kidney function and poor liver function (renal and hepatic impairment).
- If your heart does not work properly (heart failure) or if you have any other heart or vascular disease
- If the level of sugar in your blood is high (diabetes).
- If you are asthmatic and you have had an asthma attack in the 8 days leading up to the examination.
- If you suffer from epilepsy.
- If you have had a stroke, if you recently experienced bleeding inside your skull (intracranial haemorrhage).
- If the quantity of liquid inside your brain is increased (cerebral oedema).
- If your body produces an excess of hormones, leading to very high arterial pressure (pheochromocytoma).
- If you have a disease of the muscles (myasthenia).
- If you have thyroid disease or a history of thyroid disease.
- if you are to have a thyroid examination or treatment with radioactive iodine in the near future.
- If you have a bone marrow disease (myeloma, monoclonal gammopathy, multiple myeloma or Waldenström's disease).
- If you are anxious, nervous, or in pain (side effects can be increased in such cases).
- If you regularly drink large quantities of alcohol or if you use drugs.
- If you suffer from any other disease.

This product contains 352 mg of sodium per 100 ml. You should take this into account if you are on a low sodium diet.

Other medicines and HEXABRIX 320

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines like:

- a medicinal product used to treat high levels of sugar in the blood (metformin),
- a medicinal product used to treat a heart disease or high blood pressure (diuretics, beta blockers and angiotensin converting enzyme inhibitors, angiotensin receptor blockers).
- a medicinal product used, among others, to treat certain cancers (interleukin-2).

Please tell your doctor or pharmacist if you are taking or have recently taken other medicines, including ones obtained without prescription.

Pregnancy, breast feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You must never be given HEXABRIX 320 if you are pregnant or think you can be pregnant and you are to undergo an examination of the uterus and the fallopian tubes (ducts connecting the uterus and the ovaries).

HEXABRIX 320 contains sodium

This medicine contains sodium (also refer to section “Take special care with HEXABRIX 320”).

3. HOW TO USE HEXABRIX 320

Dosage

The dose injected will be determined by your doctor.

This dose will depend:

- on the type of examination performed,
- on the technique used by your doctor to perform this examination,
- on your age,
- on your weight,
- on your cardiac output (volume of blood pumped out by your heart),
- and on your general health status.

Method of administration

Your doctor will administer this contrast medium to you by means of an injection, before performing the examination. This product must never be injected into the spinal cord (myelography).

If you have been given too much HEXABRIX 320

It is highly unlikely that you will receive an excessive dose of HEXABRIX 320, as it will be administered to you in a medical setting by a qualified staff. In the event of an overdose, HEXABRIX 320 can be eliminated from the body by haemodialysis (procedure to clean the blood).

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Contact your doctor or other nursing staff immediately if you notice any of the following side effects during or after the Hexabrix injection.

You may experience allergic reactions to this medicine with one or several of the following described signs which may appear at the same time or one after the other. These side effects most often affect skin, lungs and/or heart and blood circulation. Each side effect should be regarded as a potential warning sign of a starting shock reaction. Shock reactions may very rarely lead to death.

- Skin reactions :
 - You may experience one or several of the following signs: red blotches, flush, itching (localized or extensive hives), sudden swelling of the face and neck and, in exceptional cases, severe and very serious skin disturbances, such as blisters on the entire body.
 - These skin reactions may be localised, widespread or generalised, they are very rare and occur usually very rapidly (often within 1 hour) but sometimes may be delayed up to several days after the injection.
- Effects on breathing:
 - You may experience one or several of the following signs: cough, nose inflammation, tightness in the throat, swelling of the throat, moderate or severe difficulty in breathing with cough, stopping breathing..
 - These effects on breathing are very rare.

- Effects on heart and vessels:
 - You may experience one or several of the following signs: low blood pressure, dizziness, fainting, fast heart rate, heart attack..
 - These effects on heart and vessels are very rare.

Other side effects may also occur, including:

Very rare side effects:

- disorder of the thyroid function,
- feeling of agitation, confusion or having hallucinations,
- headache, memory loss, having speech disorders, mild or partial paralysis (paresis), abnormal sensations on or beneath the skin (paresthesia), convulsions, feeling abnormally sleepy, loss of consciousness or coma,
- eye or ear disorders may occur such as light sensitivity (photophobia), reduced vision, temporary blindness, reduced hearing, vertigo,
- you may experience sensation of chest pain, pressure, or squeezing which may be signs of an angina pectoris or a heart attack,
- Sneezing problems related to the digestive tract may occur: nausea, vomiting, stomach pain, saliva secretion disorders, diarrhoea,
- other skin problems such as eczema may occur,
- disorder of the kidney function including symptoms such as anuria (nonpassage of urine).
- You may experience effects at the injection site of Hexabrix such as:
 - transient (not serious) pain and swelling,
 - formation of blood clots in the veins of the lower extremities (thrombophlebitis).
 - skin infection or even local destruction of skin tissue, this may happen if Hexabrix leaks into the tissues outside the blood vessels into which the medicine was injected.

Unknown frequency side effects:

- Others effects on the heart, such as abnormal heartbeats may occur (ventricular fibrillation and torsades de pointes).
- Fever, shivering, discomfort and reddening may occur.
- Fainting.

Effects in connection with special examinations:

- In connection with an examination of the joints (arthrography): moderate or passing joint pain and/or swelling can occur.
- Pelvic pain can occur with examination of the uterus and Fallopian tubes (hysterothy).

Reporting of side effects:

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system :

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 HEXABRIX 320

Keep out of the sight and reach of children.

Do not use HEXABRIX 320 after the expiry date which is stated on the carton.

The expiry date refers to the last day of that month.

Do not store above 25°C.

This medicine is sensitive to light; keep it in its outer carton.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What HEXABRIX 320 contains

The active substance is ioxaglic acid, present as:

- Meglumine ioxaglate (39.30 g per 100 mL)
- Sodium ioxaglate (19.65 g per 100 mL).

The other ingredients are: meglumine, sodium calcium edetate, water for injections, sodium hydroxide (for adjustment of the pH).

What HEXABRIX 320 looks like and contents of the pack

The HEXABRIX 320 pack contains vials with 20mL, 50mL and 100mL of solution for injection.

Carton of 10 or 25 bottles.

Marketing Authorisation Holder and Manufacturer

GUERBET

BP 57400

95943 Roissy CdG Cedex

France

This leaflet was last revised in March 2015.