

Data Sheet

HEXABRIX 320

Meglumine/sodium ioxaglate 320 mg iodine/ml

Presentation

HEXABRIX 320

Ampoules and bottles of a sterile solution of meglumine ioxaglate 39.30% w/v and sodium ioxaglate 19.65% w/v containing 320 mg iodine in combined form per ml. The solution is a light yellow colour. The aqueous solution also contains sodium calcium ededate BP 0.01% w/v.

Uses

Pharmacokinetics

HEXABRIX is rapidly eliminated by the kidneys with a half-life of about 90 minutes. 99% of the dose is eliminated in 24 hours. Biliary excretion may be of some importance in kidney impairment. The compound is not metabolised.

Indications

Low osmolar X-ray contrast medium for the opacification of the vascular system, urinary tract, joints and female genital tract, the indications for which are given below.

Dosage and Administration

For ease of injection it may be found helpful to warm HEXABRIX to near body temperature.

There are no specific dosage recommendations for the elderly.

Femoral and other peripheral arteriographies

15-20 ml injected into the femoral or iliac artery will produce excellent visualisation of the arterial tree of the leg. A similar or smaller dose is indicated for smaller arteries.

Cerebral angiography (carotid and vertebral)

Average adult dose 6 - 8 ml for each injection. Up to 10 injections each of 8 ml may be required.

Angio-cardiography

Multiple small test injections may be used for positioning catheter tip.

Adults and Children over 14 years

30-50 ml per injection.

Children (14 years and under) and infants

1-1.5 ml per kg bodyweight.

Multiple injections may be required. Total dosage should not normally exceed 4 ml per kg bodyweight. In exceptional circumstances, this total dose may be exceeded according to the clinical condition.

Abdominal aortography (direct puncture or catheterisation)

Adults

20-30 ml.

Up to 50 ml may be used particularly if films of the legs are also taken following the same injection.

Thoracic aortography (including arch aortography)

Adults and Children

0.5-1.0 ml per kg bodyweight up to 40 ml per injection.

This may be repeated if necessary. Total dosage should not normally exceed 4 ml per kg bodyweight.

Pulmonary angiography

Adults

20-40 ml.

Children

0.5-1.0 ml per kg bodyweight.

Special care should be exercised in patients with pulmonary arterial hypertension.

Coronary arteriography

Adults

3-8 ml per injection depending on size of artery.

Several injections are usually given for complete demonstration particularly in the left coronary artery.

Digital subtraction angiography

Dilute 50% with Water for Injection BP or Sodium Chloride and Dextrose Injection BP to produce a solution containing 160 mg iodine per ml. The appropriate volume of diluted medium (depending on part of the body to be visualised) should be injected into a suitable artery.

Intravenous aortography

Adults and Children

1.0 -1.5 ml per kg bodyweight.

In adults 100 ml is often used; frequently this amount is subdivided equally and given by simultaneous rapid bilateral injection.

Femoral venography

Adults

20-50 ml and/or inferior vena cavography.

Leg phlebography

Adults

20-50 ml injected into a vein in the foot.

Intravenous urography

Adults

20-80 ml.

60-100 ml may be used provided that the patient is not dehydrated

Children Under 12 kg

2 ml per kg bodyweight.

Children Over 12 kg

1.5 ml per kg bodyweight (with a minimum of 24 ml).

Children over 10 years of age

Lower range of adult dosage.

Patients with severe renal disease or diabetes should be well hydrated. Particular care is necessary in these patients as temporary deterioration in renal function has been reported.

Splenography portal venography

Adults

20-40 ml by splenic puncture.

Knee arthrography (double contrast)

Adults

By injection into the knee joint. 4.5 ml together with injections of air before and after the positive contrast medium.

Hysterosalpingography

About 10 ml are usually required, administered by slow injection into the uterine cervical canal via a syringe and suitable cannula, preferably under fluoroscopic control.

Contraindications

Do not use by subarachnoid or epidural routes. It is definitely contraindicated for myelography. HEXABRIX should not be used for hysterosalpingography during pregnancy or suspected pregnancy or in the presence of acute gynaecological or abdominal infection.

Pregnancy

There is no evidence that this product is safe during pregnancy, nor is there evidence in animal work that it is free from hazard. The product should not be used during pregnancy unless benefits outweigh the risks and the physician considers it essential. The ten day rule in women of childbearing age should be observed.

Warnings and Precautions

Since the causes of severe reaction to iodinated water-soluble contrast media are unknown and preliminary testing is unreliable as an indication that a patient will react unfavourably, the only other safeguards are physical examination and a careful evaluation of the patient's history to screen out subjects known to suffer from allergy, asthma, or severe cardiovascular disease. The provision of facilities for resuscitation and the training of staff members in their prompt use is mandatory.

A positive history of allergy, asthma or of untoward reactions during previous similar investigations does not necessarily contraindicate the use of the contrast agent, but it emphasises the need for extra caution, for a sensitivity-test dose before the definitive injection, possibly steroid cover, and for even greater than usual preparedness to deal promptly with any reaction that might occur.

Extra caution should be exercised in carrying out radiographic procedures with contrast media in patients with severe systemic disease, asthma, and in allergic subjects. In patients with advanced renal disease and inadequate renal functions as reflected by a raised blood urea, and in diabetics, the normally rapid excretion of the contrast medium may be markedly impaired. Even in patients with kidney disease substantial deterioration of renal function is minimised if the patient is well hydrated. Urine output must be carefully checked in these patients after the procedure.

Patients with hepatorenal insufficiency should not be examined unless the possibility of benefit clearly outweighs the additional risk. Re-examination should be delayed for five to seven days.

Special care should be exercised when HEXABRIX is injected into the right heart or pulmonary artery in patients with pulmonary arterial hypertension. Right heart angiography is probably best avoided in patients with pulmonary arterial hypertension.

Patients with myelomatosis, and to a lesser degree, diabetes, show poor tolerance of all intravenous radio-diagnostic compounds, the use of which should be avoided unless the possibility of benefit clearly outweighs the risk. These

patients must be particularly well hydrated should intravascular iodinated injections be necessary and urine output carefully monitored.

Sensitivity Testing

Hypersensitivity to HEXABRIX has been very rare but may be tested for by any of the standard techniques. It is doubtful, however, whether routine sensitivity testing is justified, providing careful enquiry has been made concerning a history of allergy or of untoward reactions on any previous occasion. A 'negative' sensitivity test-dose does not imply that the patient will tolerate a larger volume.

Resuscitation

It is essential to have at hand injections of adrenaline, a vasopressor, an anti-histamine and hydrocortisone, together with appropriate sterile syringes, needles etc. Means for administering oxygen under positive pressure and maintaining an adequate airway should always be available.

Adverse Effects

In cerebral arteriography, the only frequent side-effect is facial heat, usually of mild degree. In femoral and iliac arteriography a warm feeling is usually experienced and very rarely slight pain may be felt but leg movement and/or vocal protests are unusual.

Because of the possibility, remote though it may be, of a delayed reaction to the contrast agent, the patient should never be left unsupervised for the 30 minutes immediately after injection.

After the rapid injection of HEXABRIX for angiocardiology or aortography, patients may experience a wave of mild warmth, associated with flushing passing over the body. Slight coughing may occur after right heart or pulmonary artery injections. Other transient reactions reported rarely are nausea, vomiting, hypotension, headache, and a metallic taste.

A few ventricular extrasystoles are common after any rapid intraventricular injection and the injection flow should not exceed 12 ml/sec in the adult ventricle. Ventricular fibrillation may occur very infrequently after intra-cardiac or intra-coronary injection and a D.C. defibrillator and other equipment necessary for defibrillation must always be available during these studies.

As for all hystero-graphic examinations with hydrosoluble contrast media, nausea, syncope, blood pressure variations and some degree of pelvic pain may occur, although it may be difficult to distinguish that due to instrumentation and that due to the medium.

Following intracardiac, ascending aortic or coronary artery injection the QRST complex of the ECG may be altered briefly.

After prolonged cardiac catheterisation (with or without injection of a contrast medium), 5 to 10 percent of patients may develop some degree of shivering or shock.

In intravenous urography, nausea, vomiting, dizziness and urticaria have been reported occasionally but have been of little consequence.

Interactions

Special care should be exercised in patients being treated with a calcium ion antagonist (eg verapamil) and who are to undergo coronary angiography; in such circumstances, a few instances of serious arrhythmias have been reported.

All organic contrast media interfere with tests of thyroid function. If required, such diagnostic tests should be undertaken before procedures with HEXABRIX or a few weeks after the procedures.

Overdosage

In laboratory animals the main signs of toxicity are convulsions, pulmonary congestion and oedema, respiratory depression, prostration, darkening of the eyes and hypersalivation; it is most unlikely that such toxic signs would occur in man, as it would be necessary to inject far greater doses than the maximum recommended. In man, overdosage as such should not arise but, since the causes of severe reactions to iodinated water-soluble contrast media are unknown, the information detailed under precautions and resuscitation should be carefully studied.

Pharmaceutical Precautions

Protect from light.

Apart from Water for Injections and Dextrose Saline, HEXABRIX should not be mixed with any other substance.

All presentations are intended as 'one dose' containers; none contain a bacteriostat.

Medicine Classification

Prescription Medicine.

Package Quantities

HEXABRIX 320
20 ml ampoules: 10s, 25s

50 ml bottles: 10s, 25s

100 ml bottles: 10s

Further Information

Nil.

Name and Address

Distributed in New Zealand by:

Obex Medical Limited
Level 1, 303 Manukau Road,
P.O. Box 26511
Epsom
AUCKLAND 1344
Phone: 09 630 3456 or 0800 656 239
Fax: 09 630 9009
www.obex.co.nz

Manufactured by:

Guerbet | 

Guerbet
16-24 rue Jean Chaptal
93600 Aulnay-sous-Bois
FRANCE

Date of Preparation

8 July 2009