MultiHance® Injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about MultiHance®.

It does not contain all the available information.

It does not take the place of talking with your radiologist, your doctor or your pharmacist.

All products of this type have risks and benefits. Your radiologist and your doctor have weighed the risk of you being given MultiHance® 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 with the medicine.
You might need to read it again.

What MultiHance® is used for

MultiHance® is a substance known as a paramagnetic contrast medium. It is used in magnetic resonance imaging (MRI) for adults; in particular:

- For the enhancement of Magnetic Resonance Imaging (MRI) in order to improve the scans or images (pictures) of certain parts of the body (in particular, the brain, spine and surrounding tissue) and liver.
- In adult patients with suspected or known vascular disease for contrast-enhanced Magnetic Resonance Angiography (MRA) of the abdominal or peripheral arteries where it improves the diagnostic accuracy for detecting vascular diseases

This medicine belongs to a group of medicines called contrast agents.

MultiHance® is given by injection into a vein. MRI and MRA are relatively new medical technologies which use magnetic fields and radio waves to produce images of parts of the body, which a doctor can then use to make a diagnosis. MRI and MRA examinations are carried out by specialist doctors called radiologists, using sophisticated medical equipment. MRI and MRA do not use X-rays and therefore the minor risks associated with X-rays are avoided.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.
Your doctor may have prescribed it for another reason.

Before you are given an injection of MultiHance®

When you must not take it:

Do not take MultiHance® if you have an allergy to:

- any medicine containing the active ingredient dimeglumine gadobenate
- Any of the ingredients listed at the end of this leaflet.
- Any other similar medicines

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue, neck or other parts of the body
- inflammation of the eyes, nose or throat
- rash, itching or hives on the skin
- injection site reaction
- feeling hot
- fainting
- throat spasm

Do not give this medicine to a child under the age of 18 years.
Safety and effectiveness in children younger than 18 years have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.
If it has expired or is damaged, return it to your pharmacist for disposal.

If you have any questions not answered in this leaflet please ask the medical staff supervising your scan.

Before you start to take it:

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- you are allergic to: the active ingredient of MultiHance®, dimeglumine gadobenate, or the other ingredients in MultiHance® injection, or to similar active ingredients of other paramagnetic resonance contrast media, for example gadopentetic acid and gadodiamide, any other medicines or any foods, dyes or preservatives,
- you suffer from any other medical conditions including kidney disease,
- you are diabetic and suffer from kidney disease,
- your child (who is undergoing an MRI examination) is under 18 years of age,
- you carry a pacemaker,
- you have been implanted any metallic objects, such as replacement joints, aneurism clips, plates, screws,
- if you have had a diagnostic examination (X-ray or MRI) with the injection of a contrast medium within the last 24 hours.
- if you suffer from a heart problem or raised blood pressure

Which precautions or warnings should be observed?

Caution must be taken if you have severe kidney disease. There have been reported cases of nephrogenic systemic fibrosis (NSF) (a disease that causes thickening and hardening of the skin and may involve other organs) after the injection of some gadolinium-containing contrast agents in patients with severe kidney disease.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Please refer to 'Use in pregnancy' and 'Use in breastfeeding' below for further information'.
Your doctor can discuss with you the risks and benefits involved.

Use in pregnancy

It is not known if MultiHance® harms the developing baby. Hence, it should only be used in pregnancy if the benefit to the mother outweighs the risk to the developing baby. Therefore, do not have an injection of MultiHance® unless you have discussed the risks and benefits involved with your radiologist and doctor and decided to do so.

Use in breastfeeding

It is not known if MultiHance® passes into human milk. Because many substances do pass into human milk, discuss with your radiologist if it is necessary to temporarily discontinue breastfeeding.

If you have not told your doctor about any of the above, tell him/her before you start taking MultiHance®.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.
No interactions between MultiHance® and other medicines are known.

How to take MultiHance®

Follow all directions given to you by your doctor, radiologist or pharmacist carefully.
They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor for help.

How much to take

The dosage you will be given will depend on your bodyweight and will be decided by the radiologist. The radiologist will take special care when injecting elderly patients with MultiHance®.

The usual dosage for MRI or MRA is as follows:

- MRI of the liver: 0.1mL per kilogram of body weight
- MRI of brain and spine: 0.2mL per kilogram of body weight
- MRA of arteries: 0.2mL per kilogram of body weight

How to take it

MultiHance® will be injected into a vein in the course of the MRI or MRA procedure by the radiologist.

Following the injection of MultiHance®, the radiologist will inject 5mL of normal saline to flush the MultiHance® through.

The MRI or MRA procedure is usually completed within an hour of the MultiHance® injection.

What if you receive too much (an overdose)?

The radiologist giving you MultiHance® will be experienced in its use, so it is unlikely that you will be given an overdose. No cases of overdose have occurred as yet. In the unlikely event that you should receive an overdose, your radiologist will know how to treat you.

Immediately telephone the Poison Information Centre on 13 11 26 in Australia or 0800 764 766 in New Zealand for any advice if you think you or anyone else may have taken too much MultiHance®. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using MultiHance®

Things you must do

Follow the radiologist's instructions during the MRI or MRA examination.

Things to be careful of:

While MultiHance® will not affect your ability to drive or operate machinery, you may wish to have a family member or friend drive you home after the MRI or MRA examination. Your radiologist will make appropriate records during your treatment and will note any unexpected effects you may experience.

SIDE EFFECTS

TELL THE RADIOLOGIST IMMEDIATELY IF YOU ARE NOT FEELING WELL AFTER RECEIVING AN INJECTION OF MULTIHANCE®, DURING THE MRI or MRA EXAMINATION AND AFTERWARDS.

All medicines can have side effects. Sometimes that are serious, most of the time they are not. You may need medical attention if you get some of the side effects

Ask your doctor or radiologist to answer any questions you may have.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask you doctor or radiologist to answer any questions you may have.

Tell you doctor or radiologist if you notice any of the following and they worry you:

Most common side effects:
(Occurring in more than 1 out of 100 persons and fewer than 1 out of 10 persons)

- headache,
- high blood pressure,
- nausea,
- feeling hot ,
- fever
- sweating
- local reactions where the injection site was given such as: swelling, redness, pain, itching, numbness or an unusual sensation at the injection site.

Uncommon side effects:
(Occurring in more than 1 out of 1,000 persons and fewer than 1 out of 100 persons)

- Changes in blood pressure and in heart rate or rhythm, abnormal electrocardiogram (a test that monitors changes in your heart beat)
- Pain in the chest
- Dry mouth, changes in taste, vomiting, diarrhoea
- Dizziness, acute sensitivity to touch/pain/or other stimulus numbness, tingling
- Sweating, feeling weak, chills, raised body temperature
- Feeling hot
- Itching, skin rash, redness
- Fainting
- Heart burn,
- Abdominal pain
- Eye pain
- Thirst
- Pain in the back or in muscles
- Strange smell, increase in salivation
- Leakage out of veins that can cause a burning sensation and blistering around the injection site
- Inflammation of nose or throat
- Swollen face and neck
- Decrease in calcium levels in blood
- Blocked heart valve
- Presence of protein, glucose and blood in the urine
- Abnormal lab test results

Rare side effects:
(Occurring in more than 1 out of 10,000 persons and fewer than 1 out of 1,000 persons)

- an allergic reaction, which infrequently can lead to shock, may include, besides itching, skin rash, fainting, swollen face and neck,
- Inflammation on the nose, throat or eyes (conjunctivitis)
- Shortness of breath
- Throat spasm
- Wheezing
- Tremor
- Ringing in ears
- Incontinence of urine and stool, urgency to urinate, difficulty in defecation
- Inflammation of the pancreas (pancreatitis)
- Fluid in lungs (pulmonary oedema)
- Increase in fluid pressure in the brain (intracranial hypertension)
- Loss of strength in arm, leg and sometimes face on one side of the body (hemiparesis)
- Muscle spasms
- Feeling tired
- Decrease in sensation in your mouth
- Decrease in white blood cells
- Increase in sugar levels
- Decrease in sugar levels
- Increase in potassium
- Increase in blood fat
- Change in smell
- Altered Electrocardiogram results and abnormal lab test results

Tell your doctor if you notice anything else that is making you feel unwell.
Other side effects not listed above may occur in some patients.

Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

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

There have been some cases of life-threatening allergic reaction with similar products and therefore the possibility of allergic reaction occurring with MultiHance® cannot be ruled out.

Your radiologist has appropriate medicines and equipment on hand to treat you, in the unlikely event that you should experience an allergic reaction to MultiHance®.

STORAGE OF MultiHance®

MultiHance® should be stored below 25°C.

Do not freeze.

PRODUCT DESCRIPTION

What it looks like

MultiHance® is a sterile solution (clear, colourless to slightly yellow in colour) for intravenous (IV) injection only. It is available in the following strengths and sizes of vials:

- Vials: 5mL, 10mL, 15mL and 20mL; cartons of 10.

Ingredients

MultiHance® contains dimeglumine gadobenate (the active ingredient) in a strength of 0.529g per mL (0.5M).

It also contains the following inactive ingredient: water for injections.

FURTHER INFORMATION

MultiHance® is registered in Australia with the following registration numbers:

Vials
AUST R 94307 - MultiHance® dimeglumine gadobenate 2.645g/5mL solution for injection
AUST R 94308 - MultiHance® dimeglumine gadobenate 5.29g/10mL solution for injection
AUST R 94309 - MultiHance® dimeglumine gadobenate 7.935g/15mL solution for injection
AUST R 94310 - MultiHance® dimeglumine gadobenate 10.58g/20mL solution for injection

SPONSOR:

Bracco Pty Ltd
C/o Ernst & Young
Level 15
321 Kent Street
Sydney NSW 2000

DISTRIBUTOR

Regional Health Care Products
Mediconsumables Pty Ltd
(ACN 001 394 323)
3-11 Primrose Avenue
Rosebery NSW 2018
Australia

Regional Health Limited
PO Box 101-140
North Shore Mall Centre
Auckland
New Zealand

This Consumer Medicine Information was approved on
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