MultiHance®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

1. Why am I using MultiHance®?

MultiHance® contains the active ingredient dimeglumine gadobenate. MultiHance® is used in magnetic resonance imaging (MRI) to enhance or improve the scans or images of certain parts of the body, as well as for contrast-enhanced Magnetic Resonance Angiography (MRA) to detect vascular diseases in adults.

For more information, see Section 1. Why am I using MultiHance®? in the full CMI.

2. What should I know before I use MultiHance®?

Do not use if you have ever had an allergic reaction to MultiHance® or any of the ingredients listed at the end of the CMI.

Talk to your doctor or radiologist if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use MultiHance®? in the full CMI.

3. What if I am taking other medicines?

Tell your radiologist if you are taking any medicines, including any medicines, vitamins or supplements.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use MultiHance®?

- MultiHance® is given as an injection into a vein in the course of the MRI or MRA procedure. Your radiologist will determine the correct dose for you.

More instructions can be found in Section 4. How do I use MultiHance®? in the full CMI.

5. What should I know while using MultiHance®?

Things you should do	• Tell the radiologist immediately if you are not feeling well after receiving an injection of MultiHance®, during the MRI or MRA examination and afterwards.
Driving or using machines	• 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.

For more information, see Section 5. What should I know while using MultiHance®? in the full CMI.

6. Are there any side effects?

Less serious side effects may include: swollen face and neck, injection site reactions, itching, skin rash, redness, feeling hot, sweating, weakness, chills, fever, raised body temperature, tingling, numbness, increased sensitivity, ringing in ears, back pain, muscle pain, muscle spasms, fatigue, urinary or stool incontinence, wheezing, eye pain, conjunctivitis, nausea, abdominal pain, diarrhoea, vomiting, dry mouth, taste changes, strange smell, increased salivation, reduced mouth sensation, nose or throat inflammation, throat spasm, thirst, heartburn, dizziness, fainting, headache.

Serious side effects may include: vein leakage at injection site, urgency to urinate, difficulty defecating, pancreatitis, protein in urine, glucose in urine, blood in urine, blocked heart valve, chest pain, blood pressure changes, heart rhythm changes, abnormal ECG, abnormal lab results, low white blood cells, abnormal blood sugar, high blood fat, high potassium, high blood pressure, low blood calcium, increased brain pressure, hemiparesis, tremor, shock, shortness of breath, pulmonary oedema.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

WARNING: NEPHROGENIC SYSTEMIC FIBROSIS

Gadolinium-based contrast agents increase the risk of nephrogenic systemic fibrosis (NSF) in patients with acute or chronic severe renal insufficiency (glomerular filtration rate < 30 mL/min/1.73m2), or acute renal insufficiency of any severity due to the hepato-renal syndrome or in the perioperative liver transplantation period.

MultiHance®

Active ingredient(s): *Dimeglumine gadobenate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using MultiHance®. **You should also speak to your radiologist, doctor or pharmacist if you would like further information or if you have any concerns or questions about using MultiHance®.**

Where to find information in this leaflet:

1. Why am I using MultiHance®?
2. What should I know before I use MultiHance®?
3. What if I am taking other medicines?
4. How do I use MultiHance®?
5. What should I know while using MultiHance®?
6. Are there any side effects?
7. Product details

1. Why am I using MultiHance®?

MultiHance® contains the active ingredient dimeglumine gadobenate. MultiHance® is a paramagnetic contrast medium for magnetic resonance imaging (MRI).

MultiHance® is used in adults for enhancement of magnetic resonance images or scans of certain parts of the body (in particular, the brain, spine and surrounding tissue) and liver. MultiHance® can also be used in adult patients with suspected or known vascular disease for contrast-enhanced Magnetic Resonance Angiography (MRA) of the abdominal or peripheral arteries.

2. What should I know before I use MultiHance®?

Warnings

Do not use MultiHance® if:

- you are allergic to dimeglumine gadobenate, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- Children under the age of 18 years must not be given MultiHance®.

Check with your doctor or radiologist if you:

- have any other medical conditions like severe kidney disease, diabetes and renal impairment. 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.
- Have a heart problem or raised blood pressure.
- carry a pacemaker.
- have been implanted any metallic objects, such as replacement joints, aneurism clips, plates and screws.
- have had a diagnostic examination (X-ray or MRI) with the injection of a contrast medium within the last 24 hours.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor or radiologist if you are pregnant or intend to become pregnant.

Talk to your doctor or radiologist if you are breastfeeding or intend to breastfeed.

MultiHance® should not be used during pregnancy unless you have discussed the risks and benefits involved with your radiologist and doctor and decided to do so.

Discuss with your radiologist if it is necessary to temporarily discontinue breastfeeding before the administration of MultiHance®.

Paediatric use

- MultiHance® should not be given to children under 18 years of age.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your radiologist, doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect MultiHance®.

4. How do I use MultiHance®?

How much is given

- The dose depends on your bodyweight and will be decided by the radiologist.
- Following the injection of MultiHance®, the radiologist will inject 5mL of normal saline to flush the MultiHance® through.

When MultiHance® is given

- MultiHance® is injected into a vein in the course of the MRI or MRA procedure.
- The MRI or MRA procedure is usually completed within an hour of the MultiHance® injection.

If you are given too much MultiHance®

In the unlikely event that you should receive an overdose, your radiologist will know how to treat you.

If you think that you have been given too much MultiHance® and need urgent medical attention,

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using MultiHance®?

Things you should do

Tell the radiologist immediately if you are not feeling well after receiving an injection of MultiHance®, during the MRI and MRA examination and afterwards.

Call your doctor straight away if you:

- Experience an allergic reaction to MultiHance®.

Remind any doctor, dentist or pharmacist you visit that you have been given MultiHance®.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how MultiHance® affects you.

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.

Looking after your medicine

- MultiHance® should be stored below 25°C.
- Do not freeze.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
General: • Swollen face and neck • Local reactions at the site of injection, such as: swelling, redness, pain, itching, numbness or an unusual sensation and the injection site • Itching, skin rash, redness • Feeling hot • Sweating • Feeling weak • Chills • Raised body temperature • Tingling • Numbness • Acute sensitivity to touch/pain/or other stimulus • Ringing in the ears • Pain in the back or in muscles • Muscle spasms • Feeling tired • Incontinence of urine and stool, urgency to urinate or difficulty in defecation • Wheezing **Eyes:** • Eye pain • Inflammation of the eyes (conjunctivitis) **Gastrointestinal tract:** • Nausea • Abdominal pain • Diarrhoea • Vomiting **Nose, mouth and throat:** • Dry mouth • Changes in taste • Strange smell	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

• Increase in salivation • Decrease in sensation in your mouth • Inflammation of nose or throat • Throat spasm • Thirst **Heart and blood circulation:** • Heartburn **Nervous system:** • Dizziness • Fainting • Fever • Headache	

Serious side effects

Serious side effects	What to do
General: • Leakage out of veins that can cause a burning sensation and blistering around the injection site • Inflammation of the pancreas (pancreatitis) • Presence of protein, glucose and blood in the urine **Heart and blood circulation:** • Blocked heart valve • Pain in the chest • Changes in blood pressure • Changes in the rhythm of the heart or rhythm • Altered electrocardiogram results and abnormal lab test results • Decrease in white blood cells • Increase or decrease in sugar levels • Increase in blood fat • Increase in potassium • High blood pressure • Decrease in calcium levels in blood **Nervous system:** • 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) • Tremor • Shock **Respiration:** • Shortness of breath • Fluid in lungs (pulmonary oedema)	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is only available with a doctor's prescription.

What MultiHance® contains

Active ingredient (main ingredient)	Dimeglumine gadobenate
Other ingredients (inactive ingredients)	Water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What MultiHance® looks like

MultiHance® is a clear, colourless to slightly yellow solution contained in:

- Vials: 10 mL and 20 mL; cartons of 10 vials

MultiHance® is available in following sizes:

- 5.29 g/10 mL injection vial (AUST R 94308)
- 10.58 g/20 mL injection vial (AUST R 94310)

Who distributes MultiHance®

SPONSOR:

Bracco Pty Ltd

14 Allambie Avenue, East Lindfield,

NSW 2070

ealang57@gmail.com

DISTRIBUTOR:

Regional Health Care Products

Mediconsumables Pty Ltd

(ACN 001 394 323)

3-11 Primrose Avenue

Rosebery NSW 2018

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