ProHance® Injection

Consumer Medicine Information

WHAT IS IN THIS LEAFLET?

This leaflet answers some common questions about ProHance®.

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 ProHance® 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. You might need to read it again.

WHAT PROHANCE® IS USED FOR AND HOW IT WORKS

Prohance® is a substance known as a paramagnetic contrast medium. It is used in magnetic resonance imaging (MRI) to enhance or improve the scans or images (pictures) of certain parts of the body (in particular, the brain, spine and surrounding tissue), obtained by MRI alone. ProHance® can also be used for whole body MRI, including the head, neck, liver, breast, musculoskeletal system (all of the muscles, bones, joints and related structures that are involved in the movement of the parts and organs of the body) and diseases of the soft tissues.

ProHance® is given by injection into a vein. ProHance® is not recommended for use in children under the age of 2 years as there is not enough experience with the use of ProHance® in this group.

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

BEFORE YOU HAVE AN INJECTION OF PROHANCE®

You must NOT have an injection of ProHance®:

If you are allergic to the active ingredient of ProHance®, gadoteridol, or the other ingredients in ProHance® injection, or to similar active ingredients of other paramagnetic contrast media, e.g. gadopentetic acid and gadodiamide (brand name: Omniscan®).

Children under 6 months of age must not be given ProHance®.

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.

Use in pregnancy

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

THEREFORE, BEFORE HAVING AN INJECTION OF ProHance®, TELL YOUR RADIOLOGIST IF:

1. you are allergic to:

- the active ingredient of ProHance®, gadoteridol, or the other ingredients in ProHance® injection, or to similar active ingredients of other paramagnetic resonance contrast media, e.g. gadopentetic acid and gadodiamide (Omniscan®)
- any other medicines or any foods, dyes or preservatives,

2. you suffer from any other medical conditions including kidney disease,
3. your child (who is undergoing an MRI examination) is under 2 years of age,
4. you are pregnant,
5. you are breastfeeding,
6. you have kidney disease,
7. you are diabetic and suffer from kidney disease,
8. you carry a pacemaker,
9. you have been implanted any metallic objects, such as replacement joints, aneurism clips, plates, screws,
10. if you have had a diagnostic examination (X-ray or MRI) with the injection of a contrast medium within the last 24 hours.

Taking other medicines

No interactions between ProHance® and other medicines are known.

HOW PROHANCE® IS USED

ProHance® is injected into a vein in the course of the MRI procedure. The dose depends on your bodyweight and will be decided by the radiologist. It is likely to be between 0.2 to 0.6mL per kg of body weight for adults and to be 0.2mL per kg of body weight for children aged 2 years and older. The radiologist will take special care when injecting elderly patients with ProHance®.

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

The MRI procedure is usually completed within an hour of the ProHance® injection.

What if you receive too much (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.

DURING THE MRI EXAMINATION

Follow the radiologist's instructions during the MRI examination.

AFTER THE INJECTION OF PROHANCE ®:

While ProHance® 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 examination.

SIDE EFFECTS

The most common side effects of ProHance® are an unusual taste in the mouth (possibly a metallic taste) and nausea. These side effects occur in about 1.4% of patients.

Rarely (in less than 1% of patients), it may cause swelling of the face, stiff neck, pain, pain at the spot where the injection was given, a reaction at the spot where the injection was given, pain in the chest, headache, fever, itching, watery eyes, stomach cramps, tingling sensation in the throat, closure of the vocal chords, flushed feeling, fainting, allergic reaction, low blood pressure, fast heart beat, changes in the rhythm of the heart, swollen and/or itching tongue, sore gums, dry mouth, loose bowels, vomiting, frequency and urgency to pass the urines, kidney insufficiency in patients with diabetes and kidney disease, anxiety, dizziness, tingling sensations, mental decline, loss of co-ordination in the arm, staring, fits, breathlessness/shortness of breath, runny nose, cough, rash, itchy rash, hives, reddening and inflammation of the skin, tingling sensation in the extremities, fingers and toes, ringing in the ears, temporary non-harmful changes in the amount of iron in the blood.

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

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

PRODUCT DESCRIPTION

What it looks like

ProHance® is a sterile solution (clear, colourless to slightly yellow in colour). It is available in the

following strengths and sizes of vials and syringes:

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

Syringes: 10mL and 15mL; cartons of 1 and 5.

Ingredients

ProHance® contains gadoteridol (the active ingredient) in a strength of 279.3mg per mL. It also contains the following inactive ingredients: calteridol calcium, trometamol, hydrochloric acid, sodium hydroxide and water for injections.

STORAGE

ProHance® should be stored below 25°C and protected from light and secondary X-rays. Do not freeze.

FURTHER INFORMATION

ProHance® is registered in Australia with the registration numbers:

Vials

AUST R 263733 ProHance® gadoteridol 2.793g/10mL

AUST R 72671 ProHance® gadoteridol 4.1895g/15mL

AUST R 72672 ProHance® gadoteridol 5.586g/20mL

Syringes

AUST R 72674 ProHance® gadoteridol 2.793g/10mL

AUST R 72675 ProHance® gadoteridol 4.1895g/15mL

SPONSOR

Bracco Pty Ltd
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DISTRIBUTOR

Regional Health Care Products
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