

Medication Guide for Patients

This information is based on approvals granted by Japanese regulatory authority. Approval details may vary by individual countries. Medicines have undesirable effects (Adverse reactions) as well as efficacies.

Please make sure you fully understand the precautions to be taken when using this medicine and consult your doctor, pharmacists, or other healthcare professionals if you have any concerns.

Brand Name	ProHance (ProHance Intravenous Injection, ProHance Intravenous Syringe)
Active ingredient	Gadoteridol
Dosage Form	Injection

Effects of this medicine :

This medicine is a contrast agent for magnetic resonance imaging (MRI). It is a chelate compound of paramagnetic metal gadolinium ion which enhances contrasts of tissues and lesion by shortening relaxation time in MRI, and thus improves diagnostic capability.

It is usually used for contrast enhanced MRI examination of cerebral/myelon or the trunk/limbs.

How to take this medicine (Dosage and administration) :

In general, inject this medicine intravenously once or twice. It is used for MRI examination.

Things to check before testing with this medicine:

The following patients may need to be careful when using this medicine. Be sure to tell your doctor or pharmacist.

- If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines or foods.
- Extremely poor general condition.
- If you have bronchial asthma or renal impairment.
- If you, your parents, or your brothers/sisters have allergic predisposition.
- If you have had convulsion or epilepsy.
- If you have been administered gadolinium-based contrast agent before.
- If you are pregnant (including may become pregnant) or breastfeeding.
- If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

What to look out for after testing with this medicine:

- The most reported adverse reactions include hives, nausea, vomiting. **If any of these symptoms occur, consult with your doctor or pharmacist immediately.**
In rare cases, the following symptoms (early signs of adverse reactions) may occur, but this is not a list of all symptoms. **If you have any concerns other than the symptoms listed, be sure to contact your doctor or pharmacist.**

Early signs of adverse reactions	Suspected adverse reactions
facial pallor, cold sweat, stagger, difficulty breathing, swelling around eyes or lips	shock, anaphylaxis
general convulsion	convulsive seizure
Itchy, swollen, and stiff skin, stiff joints, and muscle weakness	nephrogenic systemic fibrosis

- You may experience symptoms, such as fever, rash, nausea, blood pressure decreased or difficulty breathing, one hour to several days after testing with this medicine. If you experience any of these symptoms, consult your doctor or pharmacist immediately.

For further information, talk to your doctor or pharmacist.

Information for healthcare professionals can be found on the website of the Pharmaceuticals and Medical Devices Agency.