ProHance®

gadoteridol

Stability
you can see

Summary
of product characteristics

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LIFE FROM INSIDE

Summary of product characteristics

For prescribing information please refer to the approved SPC in your country.

ProHance®

gadoteridol

ProHance, 0.5 M solution for injection

Composition. 1 ml of solution for injection contains: gadoteridol 279.3 mg/ml (0.5 M).

Excipients. Calteridol Calcium; Tromethamine USP; Hydrochloric Acid Ph Eur; Sodium Hydroxide Ph Eur; Water for Injections Ph Eur.

Therapeutic indications. Using Magnetic Resonance Imaging (MRI), ProHance provides contrast enhancement of the brain, spine and surrounding tissues resulting in improved visualization (compared with unenhanced MRI) of lesions with abnormal vascularity or those thought to cause a disruption of the normal blood-brain barrier. ProHance can also be used for whole body MRI including the head, neck, liver, breast, muscoloskeletal system and soft tissue pathologies. ProHance should be used only when diagnostic information is essential and not available with unenhanced magnetic resonance imaging (MRI).
Posology. The recommended dose of ProHance for imaging most brain and spinal pathologies and for whole body MRI is 0.1 mmol/kg. The lowest dose that provides sufficient enhancement for diagnostic purposes should be used. The dose should be calculated based on the patient's body weight, and should not exceed the recommended dose per kilogram of body weight detailed in this section.

Contra-indications. Hypersensitivity to the active substance, or to any of the excipients or to other gadolinium-based contrast.

Special warnings and special precaution for use. Patients with a history of allergy, drug reactions, or other hypersensitivity-like disorders should be closely observed during the procedure and the contrast medium administration, as well as for the time the physician deems useful given the patient condition. As with other gadolinium chelates, there have been reports of anaphylactic/anaphylactoid/hypersensitivity reactions with gadoteridol. These reactions manifested with various degrees of severity, including anaphylactic shock or death. They involved one or more body systems, mostly respiratory, cardiovascular and/or mucocutaneous systems. Anaphylactic shock has been very rarely been reported with the use of gadoteridol. Appropriate drugs and instruments for emergency measures must be readily available. In patients suffering from epilepsy or brain lesions the likelihood of convulsions during the examination may be increased. Precautions are necessary when examining these patients (e.g. monitoring of the patient) and the equipment and medicinal products needed for the rapid treatment of possible convulsions should be available. Transitory changes in serum iron (within normal range in the majority of cases) have been observed in some patients after administration of ProHance and these changes were shown not to be clinically significant. Since Gadoteridol is renally cleared from the body, caution should be exercised in patients with severely impaired renal function.

Undesirable Effects. The accepted safety considerations and procedures that are required for Magnetic Resonance Imaging are applicable when ProHance is used for contrast enhancement. The following adverse reactions have been reported with ProHance. Adverse reactions from clinical trials have been included with an indication of the frequency. Adverse reactions from spontaneous reporting are included with the frequency "not known". There were no adverse reactions with an incidence greater than 2%. Common (≥ 1/100, < 1/10): *Gastrointestinal disorders*; Nausea Uncommon (≥ 1/1,000, < 1/100): *Nervous system disorders*; headache, paraesthesia, dizziness, taste disturbance. *Eye disorders*; increased lacrimation. *Vascular disorders*; flushing, hypotension. *Gastrointestinal disorders*; dry mouth, vomiting. *Skin and subcutaneous tissue disorders*; pruritus, rash, urticaria. *General disorders and administration site conditions*; injection site pain, asthenia. *Investigations*; heart rate increased. Rare (1/10,000, < 1/1,000): *Immune system disorders*; Anaphylactic/anaphylactoid reactions. *Psychiatric disorders*; anxiety. *Nervous system disorders*; mental impairment, abnormal coordination, convulsion. *Ear and labyrinth disorders*; tinnitus. *Cardiac disorders*; nodal arrhythmia. *Respiratory, thoracic and mediastinal disorders*; laryngospasm, dyspnoea, rhinitis, cough, apnea, wheezing. *Gastrointestinal disorders*; abdominal pain, tongue oedema, oral pruritus, gingivitis, loose stools. *Skin and subcutaneous tissue disorders*; oedema face. *Musculoskeletal and connective tissue disorders*; musculoskeletal stiffness. *General disorders and administration site conditions*; chest pain, pyrexia. Not known (cannot be estimated from the available clinical trial data): *Nervous system disorders*; loss of consciousness, coma, vasovagal reactions. *Cardiac disorders*; cardiac arrest. *Renal and urinary system*; acute renal failure; *Respiratory, thoracic and mediastinal disorders*; respiratory arrest, pulmonary oedema.

Additional Safety Information. Isolated cases of nephrogenic systemic fibrosis (NSF) have been reported with ProHance, most of which were in patients co-administered other gadolinium containing contrast agents (see below).
Impaired renal function). **Prior to administration of ProHance, it is recommended that all patients are screened for renal dysfunction by obtaining laboratory tests.** There have been reports of nephrogenic systemic fibrosis (NSF) associated with use of some gadolinium-containing contrast agents in patients with acute or chronic severe renal impairment (GFR < 30 ml/min/1.73 m^2). Patients undergoing liver transplantation are at particular risk since the incidence of acute renal failure is high in this group. As there is a possibility that NSF may occur with ProHance, it should therefore only be used in patients with severe renal impairment and in patients in the perioperative liver transplantation period after careful risk/benefit assessment and if the diagnostic information is essential and not available with non-contrast enhanced MRI. Haemodialysis shortly after ProHance administration may be useful at removing ProHance from the body. There is no evidence to support the initiation of haemodialysis for prevention or treatment of NSF in patients not already undergoing haemodialysis.
Infants from 6 months to 1 year of age. Due to immature renal function in infants up to 1 year of age, ProHance should only be used in patients 6 to 12 months of age after careful consideration at a dose not exceeding 0.1 mmol/kg body weight. More than one dose should not be used during a scan. Because of the lack of information on repeated administration, ProHance injections should not be repeated unless the interval between injections is at least 7 days. Use of ProHance is not recommended in children less than 6 months of age. Use for whole body MRI is not recommended in children less than 18 years of age.
Elderly (aged 65 years and above). As the renal clearance of gadoteridol may be impaired in the elderly, it is particularly important to screen patients aged 65 years and older for renal dysfunction.

Please note. The peel-off tracking label on the vials should be stuck onto the patient records to enable accurate recording of the gadolinium contrast agent used (EU). The dose used should also be recorded. Consult the locally approved package insert. The Marketing Authorisation Holder, the Marketing Authorisation number and the date of approval may be different in different countries. For current prescribing information refer to the package insert and/or contact your local BRACCO organisation.

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