

GADOVIST® Abridged Prescribing Information

To be sold by retail on prescription by Radiologist and Oncologist for diagnostic use only. For the use of a Registered Medical Practitioner Hospitals or Laboratory only

Composition: Each ml contains Gadobutrol 604.72 mg. **Indications:** In adults, adolescence and children aged 2 years and older for: 1. Contrast enhancement in cranial and spinal magnetic resonance imaging (MRI). 2. Contrast enhancement MRI of other body regions: liver, kidneys. 3. Contrast enhancement in Magnetic Resonance Angiography (CE-MRA). 4. For MRI of the breast to assess the presence and extent of malignant breast disease. **Posology and Method of Administration:** This medicinal product is for intravenous administration only. *For Adults:* Dosage depends on indication. A single intravenous injection of 0.1 mmol gadobutrol per kg body weight (equivalent to 0.1 ml Gadovist per kg body weight) is generally sufficient. A total amount of 0.3 mmol gadobutrol per kg body weight (equivalent to 0.3 ml Gadovist per kg body weight) may be administered at maximum. *a) For Contrast enhancement in cranial and spinal magnetic resonance imaging (MRI); Contrast enhancement MRI of other body regions: liver, kidneys & For MRI of the breast to assess the presence and extent of malignant breast disease:* administration of 0.1 ml Gadovist per kg body weight is sufficient to answer the clinical question. *b) Contrast enhancement in Magnetic Resonance Angiography (CE-MRA):* i) imaging of one field of view: 7.5 ml for body weight less than 75 kg, 10 ml for body weight of 75 kg or more; ii) imaging of more than one field of view: 15 ml for body weight less than 75 kg, 20 ml for body weight of 75 kg or more. **Special Patient population:** *For children aged 2 years and older:* recommended dose is 0.1 mmol Gadobutrol per kg body weight for all indications. For Geriatric patients, patients with hepatic and renal impairment: No dosage adjustment is recommended. **Contraindications:** No absolute contraindications. **Special warnings and precautions for use:** Special precautions and careful benefit-risk assessment is required in patients with: Hypersensitivity, previous reaction to contrast media, history of bronchial asthma, history of allergic disorders, impaired renal function and seizure disorder Gadolinium retention: Reports of gadolinium retention in several organs with highest concentrations in the bone, followed by other organs (brain, skin, kidney, liver, and spleen). Retention is lowest and similar among the macrocyclic GBCAs. **Use in special population: Pregnancy-** Gadovist should not be used during pregnancy unless clearly necessary. **Lactation:** At clinical doses, no effects on the infant are anticipated and Gadovist can be used during breastfeeding. **Undesirable effects:** Reported undesirable adverse events were: Immune system disorders: Uncommon- *Hypersensitivity/ anaphylactoid reactions (eg. anaphylactoid shock, circulatory collapse, respiratory arrest, pulmonary edema, bronchospasm, cyanosis, oropharyngeal swelling, laryngeal edema, hypotension, urticarial, angioedema, conjunctivitis§, eyelid edema, flushing, hyperhidrosis§, cough§, sneezing§, burning sensation, pallor); Nervous system disorders: Common- Headache; Uncommon- dizziness, dysgeusia, parasthesias; Rare- Loss of consciousness, Convulsion, Parosmia.; Cardiac disorders: Rare- tachycardia, palpitations; Not known- cardiac arrest; Respiratory disorders: Uncommon- Dyspnea; Gastrointestinal disorders: Common-nausea; Uncommon- vomiting; Rare-dry mouth; Skin and subcutaneous tissue disorders: Uncommon- erythema, pruritus, rash, Not known- Nephrogenic Systemic Fibrosis (NSF) ; general disorders and administration site conditions: Uncommon-injection site reactions, feeling hot/ cold; Rare- malaise, feeling cold. **Overdose:** In case of inadvertent overdosage, cardiovascular monitoring (including ECG) and control of renal function are recommended as a measure of precaution. **Instructions for use / handling:** Store at a temperature not exceeding 30°C, protected from light and moisture. Keep out of reach and sight of children. **y.** This medicinal product should be visually inspected before use and should not be used in case of severe*

discoloration, the occurrence of particulate matter or a defective container. Vials: Gadovist should only be drawn into the syringe immediately before use. The rubber stopper should never be pierced more than once. Any contrast medium solution not used in one examination must be discarded. Prefilled syringes: The prefilled syringe must be taken from the pack and prepared for the injection immediately before the administration. The tip cap should be removed from the refilled syringe immediately before use. Any contrast medium solution not used in one examination must be discarded. Please refer full prescribing information before use. **Source: Version no. GD_2022_01 dated 28 Jun 2022. Based on CCDS version 20 dated 08 March 2019 & US PI dated April 2022, Revised 1 Oct 2018. Date of API: 25 Sep 2024.**