

יוני 2021

רופא/ה נכבד/ה,
רוקח/ת נכבד/ה,
ברצוננו להודיעך על עדכון בעלון לרופא של התכשיר:

CYCLOLUX 0.5 MMOL/ML

חומר פעיל: GADOTERIC ACID 27.932 G / 100 ML

צורת מינון: Solution for injection

צורת מתן: I.V.

נוסח ההתוויה המאושרת לתכשיר:

Enhancement of contrast in magnetic resonance imaging. Aencephalic and spinal pathologies: brain tumours tumours of the spine and the surrounding tissue intervertebral disk prolapse infectious diseases. Abdominal pathologies: primary and secondary liver tumours. Osteo-articular pathology: bone and soft tissue tumours synovial diseases. Magnetic resonance imaging for angiography.

העדכונים בעלון לרופא:

- בהודעה זו מצוינים סעיפים בהן נעשה עדכון המהווה החמרה- מודגש **בצהוב**.
- בעלון קיימים עדכונים נוספים אשר מהווים שינוי נוסח בלבד.
- למידע מלא אודות התרופה יש לעיין בעלון לרופא המצורף

4.2 Posology and method of administration

Posology

The lowest dose that provides sufficient enhancement for diagnostic purposes should be used.

The recommended dose is 0.1 mmol/kg, i.e. 0.2 mL/kg, in adults, children and infants. In angiography, depending on the results of the examination being performed, a second injection may be administered during the same session if necessary.

In some exceptional cases, as in the confirmation of isolated metastasis or the detection of leptomeningeal tumours, a second injection of 0.2 mmol/kg can be administered.

[...]

4.4 Special warnings and precautions for use

[...]

Paediatric population

Neonates and infants

Due to immature renal function in neonates up to 4 weeks of age and infants up to 1 year of age, gadoteric acid should only be used in these patients after careful consideration.

In neonates and infants the required dose should be administered by hand.

Depending on the amount of gadoteric acid to be given to the child, it is preferable to use gadoteric acid vials with a single use syringe of a volume adapted to this amount in order to have a better precision of the injected volume.

[...]

Gadolinium retention

Gadolinium is retained for months or years in several organs. The highest concentrations (nanomoles per gram of tissue) have been identified in the bone, followed by other organs (e.g. brain, skin, kidney, liver, and spleen). The duration of retention also varies by tissue and is longest in bone. Linear GBCAs cause more retention than macrocyclic GBCAs.

The current evidence suggests that gadolinium may accumulate in the brain after multiple administrations of GBCAs. Increased signal intensity on non-contrast T1-weighted images of the brain has been observed after multiple administrations of GBCAs in patients with normal renal function. Gadolinium has been detected in brain tissue after multiple exposures to GBCAs, particularly in the dentate nucleus and Globus pallidus. The evidence suggests that the risk of gadolinium accumulation is higher after repeat administration of linear than after repeat administration of macrocyclic agents. The clinical significance of gadolinium accumulation in the brain is presently unknown; however, gadolinium accumulation may potentially interfere with the interpretation of MRI scans in the brain. In order to minimize potential risks associated with gadolinium accumulation in the brain, it is recommended to use the lowest effective dose and perform a careful benefit risk assessment before administering repeated doses.

While clinical consequences of gadolinium retention have not been established in patients with normal renal function, certain patients might be at higher risk. These include patients requiring multiple lifetime doses, pregnant and paediatric patients, and patients with inflammatory conditions. Consider the retention characteristics of the agent when choosing a GBCA for these patients. Minimize repetitive GBCA imaging studies, particularly closely spaced studies when possible.

4.8 Undesirable effects

[...]

System Organ Class	Frequency: adverse reaction
Immune system disorders	Uncommon: hypersensitivity Very rare: anaphylactic reaction, anaphylactoid reaction
Psychiatric disorders	Rare: anxiety Very rare: agitation
Nervous system disorders	Uncommon: headache, dysgeusia, dizziness, drowsiness , paraesthesia (including burning sensation) Rare: presyncope Very rare: coma, convulsion, syncope, tremor, parosmia

Eye disorders	Rare: eyelid oedema Very rare: conjunctivitis, ocular hyperaemia, blurred vision, excess tears
Cardiac disorders	Rare: palpitations Very rare: tachycardia, cardiac arrest, arrhythmia, bradycardia
Vascular disorders	Uncommon: hypotension, hypertension, Very rare: pallor, vasodilatation
Respiratory, thoracic and mediastinal disorders	Rare: sneezing Very rare: cough, dyspnoea, nasal congestion, respiratory arrest, bronchospasm, laryngospasm, pharyngeal oedema, dry throat, pulmonary oedema
Gastrointestinal disorders	Uncommon: nausea, abdominal pain Very rare: vomiting, diarrhoea, salivary hypersecretion
Skin and subcutaneous tissue disorders	Uncommon: rash Rare: urticaria, pruritus, hyperhidrosis Very rare: erythema, angioedema, eczema Not known: nephrogenic systemic fibrosis
Musculoskeletal and connective tissue disorders	Very rare: muscle cramps, muscular weakness, back pain
General disorders and administration site conditions	Uncommon: feeling hot, feeling cold, asthenia, injection site reactions (extravasation, pain, discomfort, oedema, inflammation, coldness) Rare: chest pain, chills Very rare: malaise, chest discomfort, pyrexia, face oedema, injection site necrosis (in case of extravasation), phlebitis superficial
Investigations	Very rare: decreased oxygen saturation

[...]

העלון לרופא נשלח למשרד הבריאות לצורך העלאתו למאגר התרופות שבאתר משרד הבריאות. כמו כן, ניתן לקבל עלון זה מודפס על ידי פניה ישירה לבעל הרישום: אי.י.אל. מדי-מרקט בע"מ, רח' הקטיף 3, ת.ד. 12177, פארק תעשיות עמק חפר, מיקוד 3877701, טלפון: 09-8844451, פקס: 09-8844919

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