04/2023

XENETIX 250, XENETIX 300, XENETIX 350

Active ingredient and its quantity: החומר הפעיל וכמותו:

XENETIX 250: Iobitriol (Iodine corresponding to) 250 mg/ml
XENETIX 300: Iobitriol (Iodine corresponding to) 300 mg/ml
XENETIX 350: Iobitriol (Iodine corresponding to) 350 mg/ml

Approved indications: התוויות מאושרות:

XENETIX 250:
For adults and children undergoing: phlebography, chest CT scan, intra - arterial digital subtraction angiography.

XENETIX 300, XENETIX 350:
For adults and children undergoing: intravenous urography, brain or whole body CT scan, intravenous digital subtraction angiography, arteriography, angiocardiography

רופא/ה, רוקח/ת נכבד/ה,

אנו מתכבדים להודיע על עדכון העלון לרופא של התכשיר שבנדון.
בהודעה זו מצוינים השינויים המהווים החמרה. בעלון כלולים שינויים נוספים.
טקסט שהתווסף מסומן בקו תחתי, טקסט שהוסר מסומן בקו חוצה. החמרות מסומנות בצהוב.

העדכונים העיקריים בעלון לרופא:

4.3. Contraindications

[…]

- Manifest thyrotoxicosis.

4.4. Special warnings and ~~special~~ precautions for use

4.4.1. General information applicable to all iodinated contrast agents

4.4.1.1 Warnings

Prior to administration of iodinated contrast agent, it is important to ensure that the patient is not due to undergo a scintigraphic or biological examination of the thyroid or receive radioactive iodine for therapeutic purposes.

Other warnings

Extravasation is a non-exceptional complication (0.04% to 0.9%) of intravenous injections of contrast agents. This occurs more frequently with the high osmolar products, most of the injuries are minor, however severe injuries such as skin ulceration, tissue necrosis, and compartment syndrome may occur with any iodinated contrast medium….

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4.4.1.2. Precautions for use

Severe cutaneous adverse reactions

Severe cutaneous adverse reactions (SCARs), such as drug rash with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS), Lyell's syndrome (toxic epidermal necrolysis or TEN) and acute generalised exanthematous postulosis (AGEP), potentially life-threatening, have been reported in patients to whom Xenetix had been administered (see section 4.8, Undesirable effects). When initiating the treatment, patients should be informed of the signs and symptoms and should be monitored closely to detect serious adverse skin reactions. Xenetix should be discontinued immediately if a severe hypersensitivity reaction is suspected. In the event of a severe cutaneous adverse reaction in a patient taking Xenetix, Xenetix should never be re-administered to this patient (see Section 4.3).

4.4.1.2.4. Asthma

It is recommended that asthma be brought under control before the injection of an iodinated contrast agent.

Due to an increased risk of bronchospasm, special caution should be taken in patients who suffered an asthmatic attack within 8 days prior to the examination.

4.4.1.2.5. Dysthyroidism

[…] there is a risk of either hyperthyroidism flaring up or hypothyroidism being induced. There is also a risk of hypothyroidism in newborns who have received, or whose mother has received, an iodinated contrast agent. […]

4.4.1.2.6. Cardiovascular diseases (see Section 4.8 Undesirable effects)

In patients with cardiovascular disease […] the risk of cardiovascular reactions is increased after administration of an iodinated contrast agent.

4.4.1.2.7. Central nervous system disorders

- […] neurological symptoms in patients with transient ischaemic attack, acute cerebral infarction, recent intracranial haemorrhage, cerebral oedema, or idiopathic or secondary (tumour, scar) epilepsy.
- if the case of intra-arterial use in alcoholics (acute or chronic alcoholism) and in people addicted to other substances.

4.4.1.2.8. Phaeochromocytoma

Patients with phaeochromocytoma […]

4.4.1.2.9. Myasthenia gravis

Administration of a contrast agent may worsen the symptoms of myasthenia gravis.

4.5. Interaction with other medicinal products and other forms of interaction

4.5.1. Medicinal products

+ Radiopharmaceuticals (see Section 4.4 Warnings)

Iodinated contrast agents disrupt radioactive iodine uptake by thyroid tissue for several weeks, which may lead to impaired uptake in thyroid scintigraphy and decreased efficacy of iodine 131 treatment.

+ Interleukin 2

There is a risk of increased reaction to contrast agents following recent treatment with interleukin 2 [..]

4.8. Undesirable effects

System Organ Class	**Frequency: adverse reaction**
Immune system disorders	Rare: hypersensitivity Very rare: anaphylactic shock, anaphylactoid reaction, anaphylactic reaction
Endocrine disorders	Very rare: thyroid disorders Not known: transient neonatal hypothyroidism
Nervous system disorders	Rare: presyncope (vasovagal reaction), tremor*, paresthesia* Very rare: coma*, convulsions*, confusion*, visual disorders*, amnesia*, photophobia*, transient blindness*, drowsiness *, agitation*, headache Not known: dizziness**
Ear and labyrinth disorders	Rare: dizziness Very rare: hearing impaired
Cardiac disorders	Rare: tachycardia, bradycardia Very rare: cardiac arrest, myocardial infarction (more frequent after intracoronary injection), arrhythmia, ventricular fibrillation, angina pectoris, Torsades de Pointes, coronary arteriospasm
Vascular disorders	Rare: arterial hypotension (low blood pressure), high blood pressure Very rare: circulatory collapse Not known: cyanosis**
Respiratory, thoracic and mediastinal disorders	Rare: dyspnoea, cough, tightness in the throat, sneezing Very rare: respiratory arrest, pulmonary oedema, bronchospasm, laryngospasm, laryngeal oedema
Gastrointestinal disorders	Uncommon: nausea Rare: vomiting Very rare: abdominal pain
Skin and subcutaneous tissue disorders	Rare: angioedema, urticaria (localised or extensive), erythema, pruritus Very rare: Acute Generalized Exanthematous Pustulosis, Stevens-Johnson syndrome, Lyell's syndrome, eczema, maculopapulous exanthema (all as delayed hypersensitivity reactions) (see Section 4.4)

	Undetermined frequency: systemic drug hypersensitivity syndrome with eosinophilia (DRESS) and systemic symptoms (see Section 4.4).
Renal and urinary disorders	Very rare: acute renal insufficiency, anuria
General disorders and administration site conditions	Uncommon: feeling of warmth Rare: facial oedema, malaise, chills, injection site pain Very rare: injection site necrosis following extravasation, injection site inflammation following extravasation, injection site oedema
Investigations	Very rare: blood creatinine increased

העלון לרופא נשלח לאגף הרוקחות במשרד הבריאות לצורך העלאתו למאגר התרופות שבאתר המרשתת. ניתן לקבל עלון מודפס על ידי פניה ישירה לבעל הרישום:
פרומדיקו בע"מ, השילוח 6, ת.ד. 3340, פתח תקווה 4917001, טלפון: 03-9373737

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