

02/2021

מטפלת/ת נכבד/ה,

חברת אלדן ציוד אלקטרוני בע"מ מבקשת להודיע על עדכון עלון התכשיר:

## CERETEC powder for solution for injection

### סרטק להמסה להכנת הזרקה

החומר הפעיל וכמותו:

**Exametazime 0.5 mg/vial**

התכשיר מאושר לטיפול בהתוויות כדלקמן:

**Regional cerebral blood flow scintigraphy- leucocytes labelling.**

**עודכן מידע בטיחותי בעלון לצרכן שמתכונתו כמכונת עלון לרופא כדלקמן:**

**עדכון פרק 4.4 שכותרתו Special warnings and precautions for use (הוספה):**

#### Potential for hypersensitivity or anaphylactic reactions

The possibility of hypersensitivity including anaphylactic/anaphylactoid reactions should always be considered. If hypersensitivity or anaphylactic reactions occur, the administration of the medicinal product must be discontinued immediately and intravenous treatment initiated, if necessary. To enable immediate action in emergencies, the necessary medicinal products and equipment such as endotracheal tube and ventilator must be immediately available.

#### Re-injected Ceretec labelled leucocytes only:

When preparing technetium-99m-labelled leucocytes it is essential that cells are washed free of sedimentation agents before they are re-injected into the patient as materials used in cell separation may cause hypersensitivity reactions.

#### Individual benefit/risk justification:

For each patient, the radiation exposure must be justifiable by the likely benefit. The activity administered should in every case be as low as reasonably achievable to obtain the required diagnostic information.

#### Renal impairment and hepatic impairment:

Careful consideration of the benefit risk ratio in these patients is required since an increased radiation exposure is possible.

#### Paediatric population

Paediatric population, see section 4.2



### Patient preparation

The patient should be well hydrated before the start of the examination and urged to void as often as possible during the first hours after the examination in order to reduce radiation.

### Specific warnings

Depending on the time when you administer the injection the content of sodium given to the patient may in some cases be greater than 1 mmol. This should be taken into account in patients on low sodium diet.

### וכן עדכון פרק 4.8 שכותרתו **Undesirable effects** : (הוספה)

The frequencies of undesirable effects are defined as follows: Very common ( $\geq 1/10$ ), common ( $\geq 1/100$  to  $< 1/10$ ), uncommon ( $\geq 1/1,000$  to  $< 1/100$ ), very rare ( $< 1/10,000$ ) and not known (cannot be estimated from the available data).

#### **Immune system disorders**

Not known: Hypersensitivity including rash, erythema, urticaria, angioedema, pruritus. Re-injected Ceretec labelled leukocytes only:

Not known: Hypersensitivity including rash, erythema, urticaria, angioedema, pruritus, anaphylactoid reaction or anaphylactoid shock.

#### **Nervous system disorders**

Not known: Headache, dizziness, paraesthesia

#### **Vascular disorders**

Not known: Flushing

#### **Gastrointestinal disorders**

Not known: Nausea, vomiting

#### **General disorders and administration site conditions**

Not known: Asthenic conditions (e.g., malaise, fatigue)

Exposure to ionising radiation is linked with cancer induction and a potential for developing hereditary defects. As the effective dose is 5.2 mSv when the maximal recommended activity of 555 MBq is administered, these adverse events are expected to occur with a low probability.

העלון לצרכן במתכונת עלון לרופא נשלח למשרד הבריאות לצורך העלאתו למאגר התרופות שבאתר משרד הבריאות.

ניתן לקבל עלון זה מודפס על ידי פניה ישירה לבעל הרישום:  
אלדן ציוד אלקטרוני בע"מ, השילוח 6, ת.ד. 7063, פתח תקווה 4917001.  
טלפון: 03-9373737  
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בברכה,

כיאן בסול - רוקחת ממונה עבור בעל הרישום