12.2020

MYOVIEW

מיוויו

Active ingredient and strength:
TETROFOSMIN 0.23 MG/VIAL

חומר פעיל וכמותו:
טטרופוסמין 0.23 מ"ג לוייל

רופא/ה, רוקח/ת נכבד/ה,

- העלון לרופא של המוצר עודכן בדצמבר 2020.
- **<u>בהודעה זו מתוארים רק השינויים העיקריים המהווים החמרה או תוספת מידע.</u>**
- טקסט שנוסף מופיע על רקע אפור, טקסט שנמחק מופיע עם קו חוצה על רקע אפור.

להלן נוסח ההתוויה המאושר לתכשיר:

Indicated as an adjunct in the diagnosis and localization of myocardial ischaemia or infarction. Myoview is indicated as an adjunct to the initial assessments (e.g. palpation mammography or alternative imaging modalities and/or cytology) in characterisation of malignancy of suspected breast lesions where all these other recommended tests were inconclusive.

העדכונים העיקריים בעלון לרופא נעשו בסעיפים הבאים:

4.4 Special warnings and precautions for use

(...)

<u>Renal impairment and hepatic impairment</u>

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

<u>Patient preparation</u>

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.

(...)

<u>Specific warnings</u>

This medicinal product contains 0.08-0.16mg/ml sodium. This needs to be taken into consideration for patients on a controlled sodium diet.

4.8 Undesirable effects

(...)

Since the administered substance quantity is very low, the major risk is caused by the radiation. Exposure to ~~Ionised~~ ionising radiation ~~can cause~~ is linked with cancer induction and a potential for developing hereditary defects ~~genetic changes~~.

(...)

~~As most diagnostic nuclear medicine investigations are carried out with low radiation doses of less than 20 mSv~~

(...)

5.2 Pharmacokinetic properties

(…)

Renal/hepatic impairment

The pharmacokinetics in patients with renal or hepatic impairment has not been characterized.

(…)

8. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)

(…)

Withdrawals should be performed under aseptic conditions. The vials must not be opened before disinfecting the stopper, the solution should be withdrawn via the stopper using a single dose syringe fitted with suitable protective shielding and a disposable sterile needle or using an authorised automated application system.

If the integrity of this vial is compromised, the product should not be used.

(…)

Simplified Chromatographic Procedure for Rapid Quality Control (method 2):

Equipment and eluent

(1) Solid Phase Extraction (SPE) C18 cartridge (360 mg Sorbent, 55 – 105 µm particle size), e.g. Waters Sep-Pak® or equivalent)
(2) 3 x 10ml vials and caps, Labelled “A”, “B” and C
(3) Lead pots
(4) 0.9% Sodium chloride
(5) Ethanol
(6) Dose calibrator

Method

Note: all loading steps (sample and solvents) must be performed using a slow flow rate (i.e. drop by drop application of the mobile phase). If the flow is too high, components may not interact sufficiently with the stationary phase which will give an inaccurate result for radiochemical purity.

(1) Place the cartridge in the correct orientation (short end facing upwards) in a clamp stand and place behind a suitable lead shield
(2) Place the vial labelled ‘A’ under the cartridge as a collection vial.
(3) Condition the stationary phase by flushing with 2ml 0.9% Sodium Chloride collecting in vial ‘A’.
(4) Carefully load 25 - 50µL of the preparation onto the cartridge.
(5) Elute the cartridge with 2ml 0.9% Sodium chloride, collecting the eluate in vial ‘A’.
(6) Cap vial ‘A’ and place in a shielded container. Cap and retain for measurement.
(7) Place vial ‘B’ under the cartridge as a collection vial.
(8) Elute the cartridge with 5ml ethanol, collecting the eluate in vial ‘B’.
(9) Cap vial ‘B’ and place in a shielded container. Cap and retain for measurement.
(10) Remove the SPE cartridge using tweezers and place into vial ‘C’ and place in a shielded container. Cap and retain for measurement.

(11) Measure the activity of each of the vials labelled A to C using a dose calibrator.
Under the test conditions employed:

- Free $^{99m}Tc\ O_4^-$ (pertechnetate) is eluted from the cartridge with 2ml 0.9% Sodium Chloride (Vial A)
- ^{99m}Tc - tetrofosmin is retained on the stationary phase and is eluted with 5ml ethanol (Vial B)
- Reduced hydrolysed ^{99m}Tc (RHT) and hydrophilic impurities remain on the cartridge (Vial C)

(12) Calculate the % 99mTc-tetrofosmin as follows:

$$\%\ RCP\ (^{99m}Tc\ tetrofosmin) = \frac{\text{Activity in vial B}}{\text{Sum of activity in vial A + B + C}} \times 100$$

(13) Do not use material if the radiochemical purity is less than 90%.

- העלון לרופא נשלחו 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, רח' השילוח 6, ת.ד. 7641, פתח תקווה 4917001, טלפון: 03-9371111.

בברכה, כיאן בסול,

רוקחת ממונה עבור בעל הרישום אלדן ציוד אלקטרוני בע"מ