

09/2023

## מיווי

## MYOVIEV

מרכיבים פעילים:  
TETROFOSMIN 0.23 MG/VIAL

צורת מינון:  
LYOPHILIZED POWDER FOR SOLUTION FOR INJECTION

רופא/ה, רוקח/ת נכבד/ה,  
חברת אלדן ציוד אלקטרוני בע"מ מבקשת להודיע על עדכון העלון לרופא של התכשיר שבנדון.  
העלון עודכן בתאריך מאי 2023.

**ההתוויה הרשומה לתכשיר בישראל:**  
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.

בהודעה זו מצוינים השינויים המהותיים בלבד.

**מקראה לעדכונים המסומנים:**  
מידע שהוסר - מסומן בקו אדום חוצה **XXX**  
תוספת - כתב **כחול**

עדכונים מהותיים נעשו בסעיפים הבאים בעלון לרופא:

### 4.6 Fertility, pregnancy and lactation

(...)

#### **Pregnancy**

Myoview is contraindicated in pregnancy (see section 4.3). **Animal reproductive toxicity studies have not been performed with this product.** Radionuclide procedures carried out on pregnant women also involve radiation doses to the foetus. Administration of 250 MBq tetrofosmin (99mTc) at exercise, followed by 750 MBq at rest results in an absorbed dose to the uterus of 8.1 mGy. A radiation dose above 0.5 mGy (equivalent to the exposure from annual background radiation) would be regarded as a potential risk to the foetus.

#### **Breast feeding**

Before administering a radiopharmaceutical to a mother who is breast feeding consideration should be given to the possibility of delaying the administration of a radionuclide until the mother has ceased breast feeding and to what is the most appropriate choice of radiopharmaceutical, bearing in mind the secretion of activity in breast milk. **Tchnetium Tc99m tetrofosmin is present in human milk in small amounts (<1% of maternal dose). If the administration is considered necessary, breastfeeding should be interrupted for 3 to 6 hours and the expressed feeds discarded. It is not known whether tetrofosmin (99mTc) is secreted in human milk, therefore if administration is considered necessary, formula feeding should be substituted for breast feeding for at least 12 hours.**



## Fertility

Animal reproductive toxicity studies have not been conducted with MYOVIEW.

### 4.8 Undesirable effects

(...)

#### Immune system disorders

**Not known:** ~~Face oedema~~, ~~H~~ypersensitivity reaction, ~~allergic reaction~~, including anaphylactoid or anaphylactic reaction **and anaphylactic or anaphylactoid shock.**

#### Nervous system disorders

**Uncommon:** Taste metallic

**Rare:** Disturbances of smell ~~and taste~~

**Not known:** Headache, dizziness

#### Eye disorders

**Rare:** Abnormal vision

#### Cardiac disorders

**Not known:** Tachycardia, chest pain

#### Vascular disorders

**Uncommon:** Flushing

**Not known:** ~~H~~ypotension

#### Respiratory, thoracic and mediastinal disorders

**Not known:** Dyspnoea, bronchospasm, throat tightness, cough

#### Gastrointestinal disorders

**Uncommon:** Vomiting ,

**Rare:** Abdominal pain, nausea, burning mouth

#### Skin and subcutaneous tissue disorder

**Rare:** Rash

**Not known:** Urticaria, pruritus, erythema, angioedema ~~itching, erythematous rash~~

#### General disorders and administration site condition

**Uncommon:** Feeling of warmth

**Not known:** Local swelling, Face oedema, fever

#### Investigations

**Not known:** White blood cell count increased.

(...)

קיימים עדכונים נוספים . למידע נוסף יש לעיין בעלון לרופא המעודכן.

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על ידי פניה לבעל הרישום אלדן ציוד אלקטרוני בע"מ, בנין ניאופרם, רח' השילוח 6 ת.ד. 7641 פתח תקוה 4917001, טלפון: 03-9371111, פקס: 03-9371100.

בברכה,

עוז וולך

רוקח ממונה



מכון התקנים הישראלי