נובמבר 2020

רופא/ה נכבד/ה
רוקח/ת נכבד/ה,

<u>פרסום עדכון בעלון לרופא של התכשיר Fluoresceine SERB</u>
<u>Solution for Injection 10G/100ML</u>

ההתוויה הרשומה לתכשיר בישראל:
For examination of the retina by Fluorescent Angiography

חברת טרדיס גת מבקשת להודיע על עדכון העלון לרופא של התכשיר.
בהודעה זו מצויינים השינויים המהותיים בלבד שבוצעו בעלון. כמו כן בוצעו שינויים נוספים.
<u>מקרא</u>: תוספת – באדום
הסרה – מחיקה

4.2. Posology and method of administration

<u>Posology</u>

(...)

Paediatric population

The safety of Fluorescein SERB in children has not been established

~~If Fluoresceine SERB is used in children a dosage adjustment is recommended, e.g., 5 mg/kg.~~

(...)

4.4. Special warnings and precautions for use

<u>Special warnings</u>

<u>Hypersensitivity</u>

Fluorescein sodium may induce severe hypersensitivity reactions.

The benefit of Fluorescein angiography must be carefully weighed against the risk of severe hypersensitivity reactions (sometimes with a fatal outcome).

A detailed medical history of each patient must be carried out before examination including any history of allergy, history of cardiopulmonary disease, diabetes mellitus or concomitant treatments (in particular beta-blocking drugs, including eye drops solutions). Beta-blocking agents can reduce the vascular compensation reactions to anaphylactic shock and reduce the effectiveness of adrenaline in the case of cardiovascular collapse.

These hypersensitivity reactions are always unforeseeable, but they occur more frequently in patients who have poorly tolerated a previous injection of fluorescein sodium (other than by nausea and vomiting) and in patients who have displayed a history of allergy such as food-induced or drug-induced urticaria, asthma, eczemaor allergic rhinitis. These hypersensitivity reactions may not be detected by carrying out a specific intradermal skin allergy fluorescein test, whose results are unreliable and sometimes possibly dangerous. A specialised allergy consultation may provide a more precise diagnosis.

Premedication is proposed. However, it does not prevent the occurrence of severe accidents:

- premedication mainly includes H1 antihistamines administered orally,followed by corticosteroids before fluorescein injection
- it is not currently considered necessary to administer the premedication to all patients giventhe low percentage of accidents

The risk of hypersensitivity reactions to fluorescein sodium means that throughout the examination:

- fluorescein angiography must be performed only in facilities with staff trained in emergency resuscitation with the appropriate materials and equipment,
- close patient monitoring must be ensure by the ophthalmologist carrying out the examination throughout the duration of the examination and for at least 30 minutes following completion of the examination,
- the venous infusion line must be maintained for at least 5 minutes in order to treat any potential accident without delay,
- the materials required for emergency resuscitation must be available. This involves inserting a second intravenous line to enable vascular filling (polyionic solution or colloidal plasma substitute) and the intravenous injection of adrenaline at an appropriate dose.

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4.6. Fertility, pregnancy and lactation

Breast-feeding

Fluorescein sodium is excreted in breast milk. The effect of fluorescein sodium on infants/newborns is unknown.

Breast-feeding should be discontinued for 7 days after treatment with fluorescein sodium.

(…)

4.7. Effects on ability to drive and use machines

Due to the mydriasis induced by the angiography examination, patients should not drive or use machines while still experiencing visual disorders (glare, blurred vision).

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.8. Undesirable effects

Minor intolerance reactions can occur. They can be isolated or associated with others. Transient nausea and vomiting are commonly reported (>1 % and <10 %).Uncommon adverse reaction (>0.1% and <1%) include feeling of malaise and skin reactions such as pruritus, rash, urticaria. More severe adverse reactions can follow these minor signs or occur directly after the injection: rarely (>1/10,000 and<1/1,000) angioedema, hypotension, respiratory symptoms (bronchospasm, laryngeal oedema, respiratory distress) and very rarely (<1/10,000) anaphylactic shock that can lead to cardiovascular collapse, heart failure or even death.

Immune system disorders

Hypersensitivity reactions (liable to be accompanied by hypoaesthesia and dysgeusia), potentially fatal anaphylactic or anaphylactoid shock.

~~, anaphylactic shock or anaphylactic-like shock that can be fatal.~~

(…)

Respiratory, thoracic and mediastinal disorders

Respiratory arrest, pulmonary oedema, asthma, dyspnoea, laryngeal oedema, cough, feeling of throat tightness, throat irritation, sneezing

(…)

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס על ידי פניה ישירה לבעל הרישום.

בברכה,
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