יוני 2020

רופא/ה רוקח/ת נכבד/ה,

חברת סאנופי-אוונטיס ישראל בע"מ מבקשת להודיע על עדכון **העלון לצרכן במתכונת עלון לרופא** של התכשיר:

AMIODACORE INJECTION, *solution for injection.*

החומר פעיל:

amiodarone hydrochloride

ההתוויה המאושרת:

Treatment should be initiated and normally monitored only under hospital or specialist supervision.
Amiodacore injection is indicated for Corronary insufficiency, arrhythmias resistant to other treatments, wolf parkinson white syndrome.
Amiodacore intravenous can be used where a rapid response is required or where oral administration is not possible.

מפורטים להלן רק תתי הסעיפים בהם נעשו העדכונים העיקריים בעלונים:

4.4 Special warnings and precautions for use

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Severe Bradycardia (see section 4.5):

Cases of severe, potentially life-threatening bradycardia and heart block have been observed when amiodarone is used in combination with sofosbuvir in combination with another hepatitis C virus (HCV) direct acting antiviral (DAA), such as daclatasvir, simeprevir, or ledipasvir. Therefore, coadministration of these agents with amiodarone is not recommended.

If concomitant use with amiodarone cannot be avoided, it is recommended that patients are closely monitored when initiating sofosbuvir in combination with other DAAs. Patients who are identified as being at high risk of bradyarrhythmia should be continuously monitored for at least 48 hours in an appropriate clinical setting after initiation of the concomitant treatment with sofosbuvir.

Due to the long half-life of amiodarone, appropriate monitoring should also be carried out for patients who have discontinued amiodarone within the past few months and are to be initiated on sofosbuvir alone or in combination with other direct DAAs.

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Patients receiving these hepatitis C medicines with amiodarone, with or without other medicines that lower heart rate, should be warned of the symptoms of bradycardia and heart block and should be advised to seek urgent medical advice if they experience them.

Primary graft dysfunction (PGD) post cardiac transplant:
In retrospective studies, amiodarone use in the transplant recipient prior to heart transplant has been associated with an increased risk of PGD.

PGD is a life-threatening complication of heart transplantation that presents as a left, right or biventricular dysfunction occurring within the first 24 hours of transplant surgery for which there is no identifiable secondary cause (see section 4.8). Severe PGD may be irreversible.

For patients who are on the heart transplant waiting list, consideration should be given to use an alternative antiarrhythmic drug as early as possible before transplant.

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Eye disorders (see section 4.8):

If blurred or decreased vision occurs, complete ophthalmologic examination including fundoscopy should be promptly performed. Appearance of optic neuropathy and/or optic neuritis requires amiodarone withdrawal due to the potential progression to blindness.

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4.5 Interaction with other medicinal products and other forms of interaction

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Digoxin

Administration of Amiodacore Injection to a patient already receiving digoxin will bring about an increase in the plasma digoxin concentration and thus precipitate symptoms and signs associated with high digoxin levels; disturbances in automaticity (excessive bradycardia), a synergistic effect on heart rate and atrioventricular conduction may occur. Clinical, ECG and biological monitoring is recommended to observe for signs of digitalis toxicity and digoxin dosage should be halved.

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Other drug interactions with amiodarone (see section 4.4)

Coadministration of amiodarone with sofosbuvir in combination with another HCV direct acting antiviral (such as daclatasvir, simeprevir, or ledipasvir) is not recommended as it may lead to serious symptomatic bradycardia. The mechanism for this bradycardia effect is unknown.

If coadministration cannot be avoided, cardiac monitoring is recommended (see section 4.4).

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4.8 Undesirable effects

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Eye disorders:

Frequency not known: optic neuropathy/neuritis that may progress to blindness (see section 4.4).

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Respiratory, thoracic and mediastinal disorders:

Very rare:

- interstitial pneumonitis or fibrosis, sometimes fatal (see section 4.4).
- severe respiratory complications (adult acute respiratory distress syndrome), sometimes fatal (see sections 4.4 and 4.5).
- bronchospasm and/or apnoea in case of severe respiratory failure, and especially in asthmatic patients.

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Skin and subcutaneous tissue disorders:

Common: eczema

Very rare: sweating.

Frequency not known: urticaria, severe skin reactions sometimes fatal including toxic epidermal necrolysis/Stevens-Johnson syndrome, bullous dermatitis and Drug Reaction with Eosinophilia and Systematic Symptoms.

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Injury, poisoning and procedural complaints:

Not known: primary graft dysfunction post cardiac transplant (see section 4.4).

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השינויים המודגשים ברקע צהוב מהווים החמרה. כמו כן, בוצעו שינויים נוספים הכוללים תוספת מידע, השמטת מידע ועדכוני נוסח שאינם מהווים החמרה.

העלונים המעודכנים נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות . בנוסף ניתן לקבלם מודפסים על ידי פנייה לבעל הרישום, סאנופי-אוונטיס ישראל בע"מ, רח' בני גאון 10 נתניה או בטלפון : 09-8633700 .להלן הקישור לאתר משרד הבריאות :
https://data.health.gov.il/drugs/index.html#!/byDrug

בברכה,

צליל גנר להב

רוקחת ממונה

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