



דצמבר 2021

## **Amiodacore Injection**

Solution for Injection

חומר פעיל: Amiodarone Hydrochloride 150mg / 3mL

ההתוויה המאושרת:

Treatment should be initiated and normally monitored only under hospital or specialist supervision.

Amiodacore injection is indicated for Coronary 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.

חברת סאנופי אוונטיס מבקשת להודיע על עדכון העלון לצרכן במתכונת עלון לרופא בספטמבר 2021.

העדכונים העיקריים הם:

## **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each 3 ml ampoule contains 150 mg amiodarone hydrochloride.

[Excipient\(s\) with known effect](#)

[Benzyl alcohol 60 mg in each 3 ml ampoule \(see section 4.4\)](#)

For excipients, see section 6.1.

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## **4.2 Posology and method of administration**

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### **Paediatric population**

The safety and efficacy of amiodarone in children has not been established.

Currently available data are described in sections 5.1 and 5.2.

~~Due to the presence of benzyl alcohol, intravenous amiodarone is contraindicated in neonates or premature babies, infants and children up to 3 years old (see section 4.3).~~



Because of the content of benzyl alcohol intravenous administration of amiodarone should be used with caution in neonates and children < 3 years (see section 4.4).

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#### 4.3 Contraindications

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- ~~• Due to the content of benzyl alcohol, Amiodacore Injection is contraindicated in newborns or premature neonates, infants and children up to 3 years old.~~

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#### 4.4 Special warnings and precautions for use

~~Amiodarone injection contains benzyl alcohol (20 mg/ml). Benzyl alcohol may cause toxic reactions and allergic reactions in infants and children up to 3 years old.~~

~~The administration of medications containing benzyl alcohol to newborns or premature neonates has been associated with a fatal "Gasping Syndrome" (symptoms include a striking onset of gasping syndrome, hypotension, bradycardia and cardio-vascular collapse). As benzyl alcohol may cross the placenta, solution for injection should be used with caution in pregnancy.~~

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##### Benzyl alcohol

This medicine contains 60 mg benzyl alcohol in each 3 ml ampoule which is equivalent to 20 mg/ml. Benzyl alcohol may cause allergic reactions.

Intravenous administration of benzyl alcohol has been associated with serious adverse events and death in neonates ("gasping syndrome"). The minimum amount of benzyl alcohol at which toxicity may occur is not known, with an increased risk in young children due to accumulation.

High volumes of benzyl alcohol should be used with caution and only if necessary, especially in subjects with liver or kidney impairment and during pregnancy and lactation, because of the risk of accumulation and toxicity (metabolic acidosis).

For the effects in pregnancy and lactation see section 4.5-6.

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#### 4.6 Pregnancy and lactation

High volumes of benzyl alcohol should be used with caution and only if necessary, during pregnancy and lactation, because of the risk of accumulation and toxicity (metabolic acidosis).

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העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס על ידי פנייה לבעל הרישום - סאנופי-אונטיס 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,

גליה הוכשטד  
רוקחת ממונה