PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

CORDARONE X INTRAVENOUS concentrated solution for infusion/injection

Each 3 ml ampoule also contains:

organic iodine: approximately 56 mg

benzyl alcohol

Read all of this leaflet carefully before you receive CORDARONE X INTRAVENOUS:

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- CORDARONE X INTRAVENOUS has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What CORDARONE X INTRAVENOUS is and what it is used for
2. What you need to know before you receive CORDARONE X INTRAVENOUS
3. How to receive CORDARONE X INTRAVENOUS
4. Possible side effects
5. How to store CORDARONE X INTRAVENOUS
6. Contents of the pack and other information

1 WHAT CORDARONE X INTRAVENOUS IS AND WHAT IT IS USED FOR:

WHAT CORDARONE X INTRAVENOUS IS USED FOR

CORDARONE X INTRAVENOUS is an antidysrhythmic medicine and is used to control an irregular or rapid heart rate where other similar medicines do not have the expected effect.

2. WHAT YOU NEED TO KNOW BEFORE YOU RECEIVE CORDARONE X INTRAVENOUS:

CORDARONE X INTRAVENOUS should not be administered to you:

- if you are hypersensitive (allergic) to amiodarone hydrochloride, iodine or to any of the other ingredients of CORDARONE X INTRAVENOUS (see section 6)
- if you have heart block - which may cause a very slow, very fast or irregular pulse, or dizziness
- if you have a slower than usual heartbeat
- if you have any other problems with your heartbeat and do not have a pacemaker fitted
- if you have or have had thyroid problems
- if you have severe respiratory failure or very low blood pressure
- if you are being given as a single injection and you have low blood pressure, heart failure or cardiomyopathy (weakness of the heart muscle).
- if you have blood circulation problems
- if you are pregnant or likely to become pregnant. Tell your doctor about this. (see Pregnancy and Breastfeeding)
- if you are breastfeeding (see Pregnancy and Breastfeeding)
- if you are taking or have taken certain other prescription medicines: including other heart medicines (e.g. sotalol, disopyramide, quinidine, procainamide, bepridil), antibiotics (e.g. intravenous erythromycin, pentamidine injection, co-trimoxazole, ciprofloxacin or

moxifloxacin), antipsychotics, antidepressants (including lithium), antihistamines, antimalarials. Tell your doctor if you are taking or have recently taken any prescription medications. (see Other medicines and CORDARONE X INTRAVENOUS)

- if you are taking or have taken certain other non-prescription medicines including herbal supplements like St John's Wort or other nutritional supplements. Tell your doctor if you are taking or have recently taken any other non-prescription medications (see Other medicines and CORDARONE X INTRAVENOUS).

CORDARONE X INTRAVENOUS is not recommended for use in paediatric patients. The ampoules of CORDARONE X INTRAVENOUS contain benzyl alcohol (see Warnings and special precautions).

Do not receive CORDARONE X INTRAVENOUS if any of the above apply to you. If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before receiving CORDARONE X INTRAVENOUS.

Warnings and precautions:

Tell your doctor or other healthcare provider immediately if you notice any of the following during treatment, since you may require urgent medical care:

- difficulty breathing or lung (respiratory) problems
- unexplained weight loss or gain, cold intolerance, restlessness or slow or fast heartbeat. These could be signs of thyroid abnormalities (see Do not take CORDARONE X INTRAVENOUS and POSSIBLE SIDE EFFECTS)
- problems with your eyesight such as blurred or decreased vision

- worsening skin rash often with blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals, flu-like symptoms and fever (see section 4).

Tell your doctor or healthcare professional before being given the injection:

- if you have heart failure
- if you are going to have an anaesthetic, any kind of surgery (including dental) or high dose oxygen therapy
- if you are porphyric
- if you have or have had liver or kidney problems
- if you are a heart transplant patient
- if you are taking or have taken certain other prescription medicines including anti-infectives, statin medicines used to lower cholesterol, HIV-protease inhibitors, stimulant laxatives or hepatitis C treatment (see Other medicines and CORDARONE X INTRAVENOUS for a complete list).

Before and during treatment your doctor may perform tests to assess your medical condition such as blood tests, chest X-Rays and ECG (electrical tracing of your heart) examinations.

Other medicines CORDARONE X INTRAVENOUS:

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of these medicines before receive CORDARONE X INTRAVENOUS:

- other heart medicines (e.g. sotalol, quinidine, disopyramide, procainamide or bepridil);
- some antibiotics – used to treat infections (e.g. intravenous erythromycin, pentamidine injection, co-trimoxazole, fluoroquinolones such as ciprofloxacin or moxifloxacin)
- some antipsychotics (such as chlorpromazine, haloperidol)
- lithium and some antidepressants (e.g. amitriptyline)
- some antihistamines - used to treat hay fever, rashes or other allergies (such as or mizolastine)
- some antimalarials (such as quinine, mefloquine, chloroquine, halofantrine).

Examples of medicines that may cause serious undesirable interactions are:

- beta-blockers and some calcium channel inhibitors – used to treat high blood pressure and angina (e.g. verapamil, diltiazem)
- stimulant laxatives – used for constipation (such as bisacodyl or senna).
- medicines that may change the levels of potassium or magnesium in your blood e.g. diuretics (water tablets), corticosteroids or the antifungal amphotericin (when given directly into a vein)
- general anaesthetics or high dose oxygen – medicines used during surgery
- hepatitis C treatment (such as sofosbuvir, daclatasvir, simeprevir or ledispasvir.

CORDARONE X INTRAVENOUS may increase the effect of the following medicines:

- digoxin
- anticoagulants - used to thin the blood (e.g. warfarin, dabigatran)
- phenytoin

- ciclosporin and tacrolimus – used after transplant operations
- flecainide – used for uneven heartbeats
- simvastatin or other statins – used to lower cholesterol levels.
- sildenafil, tadalafil -used to treat impotence
- clonazepam, midazolam - used to relieve anxiety
- other amiodarone containing medicines
- lidocaine – used as a local anaesthetic
- colchicine – used to treat gout
- ergotamine – used for migraines
- fentanyl – used for pain relief.

The following medicines may increase the effect of CORDARONE X INTRAVENOUS :

- cimetidine
- HIV-protease inhibitors.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before receiving CORDARONE X INTRAVENOUS.

Using CORDARONE X INTRAVENOUS with food and drink and alcohol:

Do not drink grapefruit juice while receiving this medicine. This is because drinking grapefruit juice while receiving CORDARONE X INTRAVENOUS can increase your chance of getting side effects. (see Warnings and precautions).

Pregnancy and breastfeeding and fertility:

Pregnancy:

You should not be treated with CORDARONE X INTRAVENOUS during pregnancy.

Breastfeeding:

Do not breastfeed if you are being treated with CORDARONE X INTRAVENOUS.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before receiving CORDARONE X INTRAVENOUS.

Driving and using machines:

CORDARONE X may cause blurred vision and coloured halos in dazzling light in some people. Do not drive or operate machinery if you experience this side effect. Check with your doctor.

It is not always possible to predict to what extent CORDARONE X may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which CORDARONE X affects them.

CORDARONE X INTRAVENOUS contains benzyl alcohol and iodine:

- Benzyl alcohol: CORDARONE X INTRAVENOUS contains benzyl alcohol. The use of CORDARONE X INTRAVENOUS in paediatric patients is not recommended. Benzyl alcohol may cause toxic and/or allergic reactions in paediatric patients.
  High volumes should be used with caution in patients with liver or kidney impairment because of the risk of accumulation and toxicity (metabolic acidosis).
- Iodine: CORDARONE X INTRAVENOUS contains iodine. Iodine is present in amiodarone hydrochloride, the medicine your infusion contains. Iodine can cause problems to your thyroid.

3 HOW TO RECEIVE CORDARONE X INTRAVENOUS:

Do not share medicines prescribed for you with any other person.

The correct dose and dilution for you will have been decided by the doctor and will depend upon your condition.

You will not be expected to give yourself you CORDARONE X INTRAVENOUS. Your doctor or nurse will give you CORDARONE X INTRAVENOUS. This is because it needs to be given as a bolus injection or infusion into your vein in the hospital where the doctor can monitor your progress.

If you have the impression that the effect of CORDARONE X INTRAVENOUS is too strong or too weak, tell your doctor, pharmacist or other healthcare professional.

If you receive more CORDARONE X INTRAVENOUS than you should:

Since a healthcare professional will administer this CORDARONE X INTRAVENOUS, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you missed a dose of CORDARONE X INTRAVENOUS:

Since a health care provider will administer CORDARONE X INTRAVENOUS, it is unlikely that the dose will be missed.

Effects when treatment with CORDARONE X is stopped:

Your doctor will determine if you need to continue treatment with another dosage form of CORDARONE X when you are discharged from the hospital and for how long. Do not stop taking CORDARONE X just because you feel better. If you stop taking CORDARONE X the uneven heartbeats may come back and this could be dangerous.

If you are sensitive to the sun, the sensitivity may persist for some time after treatment stops and the necessary precautions need to be taken.

CORDARONE X is very slowly eliminated from the body and adverse events may only disappear several months after treatment is stopped.

POSSIBLE SIDE EFFECTS:

CORDARONE X INTRAVENOUS can have side effects.

Not all side effects reported for CORDARONE X INTRAVENOUS are included in this leaflet Should your general health worsen or if you experience any untoward effects while taking CORDARONE X INTRAVENOUS, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, tell your doctor immediately:

- you have an allergic reaction. The signs may include: swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing, rash or itching and fainting

- liver disorders
- you have blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals, flu-like symptoms and fever. This could be a condition called Stevens-Johnson syndrome
- you have a severe blistering rash in which layers of the skin may peel off to leave large areas of raw exposed skin over the body. You may also feel generally unwell, have a fever, chills and aching muscles (Toxic Epidermal Necrolysis)
- you have inflammation of the skin characterised by fluid filled blisters (bullous dermatitis)
- You have flu like symptoms and a rash on the face followed by an extended rash with a high temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes (DRESS).

These are all very serious side effects. You may need immediate medical attention.

Tell your doctor immediately if you notice any of the following:

- chest pain
- angina
- changes in the way your heart beats, for example, if you notice it beating faster
- breathing difficulties (with or without fever)
- signs of recurrent infections such as fever or sore throat
- pain in the eye.

These are all serious side effects. You may need urgent medical attention.

Frequent side effects:

- a slow pulse
- local injection site reactions including swelling, pain, redness, infection and pigmentation changes

- a decrease in blood pressure
- problem with your thyroid (see Do not take CORDARONE X and Warning and precautions):
  - feeling extremely restless or agitated, weight loss, increased sweating and being unable to stand the heat. These could be signs of an illness called hyperthyroidism (increased thyroid function)
  - feeling extremely tired, weak or 'run-down', weight gain being unable to stand the cold, constipation and aching muscles. These could be signs of an illness called hypothyroidism (decreased thyroid function).

Less frequent side effects:

- nausea (feeling sick), vomiting (being sick), taste disturbance
- headaches
- disturbed sleep patterns, nightmares and dizziness
- hot flushes, sweating
- back pain
- urticaria (hives - itchy, lumpy rash)
- increased liver enzymes
- blood disorders (you may have nose bleeds, bruising, tiredness, paleness of skin)
- confusion
- feeling unwell, confused and/or weak, feeling sick (nausea), loss of appetite and feeling irritable. This could be something called 'syndrome of inappropriate anti-diuretic hormone secretion (SIADH)'
- libido decreased.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can report side effects directly to Sanofi's Pharmacovigilance Unit at Email: za.safety@sanofi.com or Tel: 011 256 3700 or

You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**" found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of CORDARONE X INTRAVENOUS.

5. HOW TO STORE CORDARONE X INTRAVENOUS:

Protect from light and store in a cool place (at or below 25 °C). Keep the ampoule in the carton until required for use.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use after the expiry date stated on the label.

6. CONTENTS OF THE PACK AND OTHER INFORMATION:

What CORDARONE X INTRAVENOUS contains:

The active substance is amiodarone hydrochloride (150 mg/3 ml ampoule).

The other ingredients are: Benzyl alcohol (see section 4.4), polysorbate 80, water for injection and nitrogen (head space gas)

What CORDARONE X looks like and contents of the pack

Each 5 ml clear and colourless glass ampoule contains 3 ml of clear, pale yellow concentrated solution for intravenous injection/infusion. 6 ampoules are packed on a tray in with a leaflet in a unit carton.

Holder of Certificate of Registration:

sanofi-aventis south africa (pty) ltd.

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South Africa

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