
PATIENT INFORMATION LEAFLET

Read 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.

Scheduling status of CORDARONE X INTRAVENOUS:

The scheduling status is schedule 4.

Name of the medicinal product and what CORDARONE X INTRAVENOUS contains:

The medicine is named: CORDARONE X INTRAVENOUS.

Each ampoule contains 150 mg amiodarone hydrochloride in 3 ml.

Each ampoule also contains benzyl alcohol, polysorbate and water for injections.

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

CORDARONE X INTRAVENOUS is an antidysrhythmic medicine and is used to control an irregular or rapid heart rate.

BEFORE YOU RECEIVE CORDARONE X INTRAVENOUS:

You should not receive CORDARONE X INTRAVENOUS if:

- You have heart block - which may cause a very slow, very fast or irregular pulse, or dizziness.
- You have or have had thyroid problems.
- You have an allergy to the active ingredient amiodarone, to iodine or to any of the other ingredients (see Name of the medicinal product and what CORDARONE X INTRAVENOUS contains).
- You have severe respiratory failure or very low blood pressure.

- It is being given as a single injection and you have low blood pressure, heart failure or cardiomyopathy (weakness of the heart muscle).
- You are pregnant or likely to become pregnant. Tell your doctor about this.
- You are breastfeeding.
- You are taking or have taken certain other prescription medicines: including other heart medicines (e.g. sotalol), antibiotics, antipsychotics, antidepressants (including lithium), antihistamines, antimalarials, anti-infectives or stimulant laxatives. Tell your doctor if you are taking or have recently taken any of these medications.
- 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 medication.
- CORDARONE X INTRAVENOUS is not recommended for use in paediatric patients.

Inform your doctor if you:

- have heart failure
- are going to have an anaesthetic, any kind of surgery (including dental) or high dose oxygen therapy
- are asthmatic
- are porphyric
- have or have had liver or kidney problems.

Take special care:

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.

Pregnancy:

You should not be treated with CORDARONE X INTRAVENOUS during pregnancy. If no alternate therapy is available and dysrhythmias are life-threatening, CORDARONE X

INTRAVENOUS may be considered. Under these circumstances you must be counselled regarding harmful effects of CORDARONE X INTRAVENOUS on your unborn baby, and you must provide a written consent.

Breastfeeding:

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

Important information about some of the ingredients of CORDARONE X INTRAVENOUS:

CORDARONE X INTRAVENOUS contains benzyl alcohol.

Taking other medicines:

If you are taking, or have recently taken, other medicines (including complementary or traditional medicines, medicines available without a prescription or prescription medicines), the use of CORDARONE X INTRAVENOUS may cause undesirable interactions. It is very important you check with your doctor or pharmacist or other healthcare professional before taking CORDARONE X INTRAVENOUS.

Examples of medicines that may cause undesirable interactions are:

- other heart medicines (e.g. sotalol); digoxin; some calcium channel inhibitors – used to treat high blood pressure and angina (e.g. verapamil, diltiazem)
- some antibiotics (e.g. intravenous erythromycin, co-trimoxazole or moxifloxacin)
- some antipsychotics
- lithium and some antidepressants (e.g. amitriptyline)
- some antihistamines
- some antimalarials
- anti-infectives
- stimulant laxatives
- anticoagulants - used to thin the blood (e.g. warfarin)
- phenytoin
- ciclosporin – used after transplant operations
- flecainide

- fluoroquinolones e.g. ciprofloxacin
- simvastatin or other statins (used to lower cholesterol levels)
- 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)
- cimetidine
- clonazepam.

HOW CORDARONE X INTRAVENOUS IS GIVEN:

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

POSSIBLE SIDE EFFECTS:

CORDARONE X INTRAVENOUS can have side effects. The most commonly reported side effects include:

- a slow pulse
- local injection site reactions including swelling, pain, redness, infection and pigmentation changes
- a decrease in blood pressure.

Other side effects reported with CORDARONE X INTRAVENOUS include:

- chest pain or palpitations, or abnormal heart rhythm
- nausea
- liver disorders
- generalised allergic reactions such as swelling of the face, lips and/or tongue, shortness of breath
- headaches
- breathing difficulties (with or without fever)
- hot flushes, sweating.

Not all side effects reported for CORDARONE X INTRAVENOUS are included in this leaflet.

Should your general health worsen while taking CORDARONE X INTRAVENOUS, please immediately consult your doctor, pharmacist or other healthcare professional.

STORING CORDARONE X INTRAVENOUS:

Protect from light and store in a cool place (25 °C).

KEEP OUT OF REACH OF CHILDREN.

PRESENTATION OF CORDARONE X INTRAVENOUS:

Ampoules for intravenous injection containing 150 mg amiodarone hydrochloride in 3 ml. Packs of 6 x 3 ml ampoules.

IDENTIFICATION OF CORDARONE X INTRAVENOUS:

Clear, pale yellow solution for intravenous administration.

REGISTRATION NUMBER:

S/6.2/384

NAME AND ADDRESS OF REGISTRATION HOLDER:

sanofi-aventis south africa (pty) ltd.

2 Bond Street,

Midrand, 1685,

South Africa.

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