

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

NICARDIPINE EQUITY 10 mg Solution for Injection

Nicardipine hydrochloride

Contains sugar: Sorbitol 500 mg

Read all of this leaflet carefully before you are given NICARDIPINE EQUITY

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

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

1. What NICARDIPINE EQUITY is and what it is used for

NICARDIPINE EQUITY contains the active substance nicardipine hydrochloride, which belongs to a group of medicines called calcium channel blockers.

NICARDIPINE EQUITY is used for the treatment of very severe high blood pressure. It may also be used to control high blood pressure after an operation.

2. What you need to know before you are given NICARDIPINE EQUITY

NICARDIPINE EQUITY should not be administered to you:

- If you are allergic to nicardipine or any of the other ingredients of this medicine (listed in section 6)
- If you have chest pain

- If your high blood pressure is because of narrowing of a heart valve or other defects in the heart
- If you have had a heart attack in the last eight days
- If you have angina (chest tightness or heaviness)
- If you have been told by your doctor that you have intolerance to some sugars.

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- If you have heart failure or other heart defects
- If your liver is not working properly, or you have had liver disease in the past
- If you have high pressure in the brain
- If you have suffered a recent stroke
- If you are taking beta-blockers (used to treat high blood pressure and heart conditions)
- If you are pregnant
- If you are under 18 years of age
- If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before you are given this medicine

If you have these conditions, your doctor may need to monitor additional tests or change the dose. If any of the above apply to you, or you are not sure, tell your doctor before receiving NICARDIPINE EQUITY.

Children and adolescents

NICARDIPINE EQUITY should only be used when high blood pressure becomes life-threatening in children or adolescents, when they are in the ICU (intensive care unit) or after an operation.

Other medicines and NICARDIPINE EQUITY

Always tell your health care provider if you are taking any other medicine.

(This includes complementary or traditional medicines.)

In particular, tell your doctor if you are taking any of the following medicines:

- dantrolene (used to treat long-term muscle stiffness)

- beta-blockers (used to treat high blood pressure and heart conditions) such as propranolol, atenolol and metoprolol
- medicines used to control seizures, such as carbamazepine, phenobarbitone, primidone and phenytoin
- baclofen (used to treat muscle spasms)
- especially tell your doctor if you are using other medicines used to control the body's immune system, such as tacrolimus, sirolimus and cyclosporin
- itraconazole (used to treat certain types of fungal infection)
- rifampicin (used to treat tuberculosis and certain other types of infection)
- alpha-blockers (used to treat high blood pressure, or prostate problems in men) such as doxazosin, prazosin and terazosin
- any other medicine for high blood pressure
- cimetidine (to treat indigestion or stomach ulcers)
- digoxin (used for heart conditions)
- amifostine (used to protect against the harmful effects of certain cancer treatments)
- medicines to treat depression, anxiety or other mental health problems
- strong painkilling medicines like morphine or codeine
- medicines used to treat inflammation such as steroids and tetracosactide
- magnesium

If you are having an operation, your anaesthetist will need to know which other medicines you are taking, as some of these can affect the way NICARDIPINE EQUITY works.

NICARDIPINE EQUITY with food and drink

Do not drink grapefruit juice or eat grapefruit whilst using this medication as it may increase blood levels of NICARDIPINE EQUITY.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Pregnancy

NICARDIPINE EQUITY should be used with caution in women in the third trimester of pregnancy as it could interfere with the spontaneous induction on labour.

NICARDIPINE EQUITY should not be used if you are having multiple children (twins or more) or if you have any issues with your heart except if no other suitable option is available.

Breast-feeding

NICARDIPINE EQUITY should not be used during breast-feeding.

Driving and using machines

It is not always possible to predict to what extent NICARDIPINE EQUITY may interfere with your daily activities. You should ensure that you do not engage in activities requiring mental alertness, judgment and/or sound coordination and vision e.g., driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which NICARDIPINE EQUITY affects you.

NICARDIPINE EQUITY contains sorbitol.

Sorbitol is a source of fructose. If you (or your child) have hereditary fructose intolerance (HFI), a rare genetic disorder, you (or your child) must not receive this medicine. Patients with HFI cannot break down fructose, which may cause serious side effects.

You must tell your doctor before receiving this medicine if you (or your child) have HFI or if your child can no longer take sweet foods or drinks because they feel sick, vomit or get unpleasant effects such as bloating, stomach cramps or diarrhoea.

3. How to use NICARDIPINE EQUITY

Intravenous Infusion

You will not be expected to give yourself NICARDIPINE EQUITY. It will be given to you by a person who is qualified to do so.

This medicine will be given to you in hospital.

Your doctor will decide on the amount of NICARDIPINE EQUITY you will be given. This will depend on how much and how fast they want to reduce your blood pressure.

The medicine will be injected slowly into a vein. Your blood pressure will be taken whilst you are receiving treatment and the dose adjusted to make sure your blood pressure falls to normal levels.

NICARDIPINE EQUITY will be given to you by a doctor, who will ensure that the correct dose is given for your condition. If you have any further questions on the use of this medicine, ask your doctor or nurse.

NICARDIPINE EQUITY may be dissolved before administration, depending on the dose requirements. This will be done by a healthcare provider.

If you are given more NICARDIPINE EQUITY than you should receive:

Since a health care provider will administer NICARDIPINE EQUITY, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to receive NICARDIPINE EQUITY

Since a health care provider will administer NICARDIPINE EQUITY, it is unlikely that the dose will be missed.

4. Possible side effects

NICARDIPINE EQUITY can have side effects.

Not all side effects reported for NICARDIPINE EQUITY are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking NICARDIPINE EQUITY, please consult your health care provider for advice.

Headache, dizziness, swollen legs or ankles and an increased heart rate are the most common side effects.

If any of the following happens, stop receiving NICARDIPINE EQUITY and tell your doctor immediately:

- feeling your heart beat (palpitations),

- feeling sick or being sick,
- flushing of the skin,
- slow heart rhythm,
- chest pain,
- heart problems leading to increased fluid in the lungs and shortness of breath,
- abdominal pain,
- inflammation of the vein where the medicine has been given,
- changes in blood tests of how your liver is working.

These are all very serious side effects. If you have them, you may have had a serious reaction to NICARDIPINE EQUITY. You may need urgent medical attention or hospitalisation.

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

- increase bleeding or bruising,
- allergic reactions.

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

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 or nurse. 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 NICARDIPINE EQUITY.

5. How to store NICARDIPINE EQUITY

Store all medicines out of reach of children.

Store at or below 25 °C.

The ampoules must be kept in the original outer carton in order to protect them from light.

Not for use undiluted.

Reconstituted solution:

The reconstituted solution may be stored up to 24 hours at temperatures at 25 °C, away from light.

6. Contents of the pack and other information

What NICARDIPINE EQUITY contains

The active substance is nicardipine hydrochloride.

The other ingredients are sorbitol, citric acid monohydrate, sodium citrate, hydrochloric acid, sodium hydroxide, water for injections and nitrogen.

What NICARDIPINE EQUITY looks like and contents of the pack

NICARDIPINE EQUITY is a clear and yellow coloured solution

NICARDIPINE EQUITY is packed in a neutral type I borosilicate coloured (brown), opaque glass ampoules with a capacity of 10 ml, the ampoules are packaged in thermoformed blisters strips or in paper racks placed inside cardboard boxes. Pack size: 5, 10 and 50 ampoules in outer carton

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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