

CORZYNA™

Ranolazine 500 mg and 1000 mg
Extended-release Tablets

PATIENT SAFETY INFORMATION LEAFLET

(download additional copies at www.kyepharma.com)

See also the full Patient Information Leaflet at www.kyepharma.com.

PATIENT ALERT

Important safety information that you need to know before and during your treatment with CORZYNA™ is provided below (See also 'Before you Take CORZYNA™' in this leaflet).

- CORZYNA™ can cause **QT prolongation** (changes in the electrical activity of your heart). Symptoms could include dizziness, feeling faint or lightheaded, heart beating irregularly or fast, or seizures. If you experience any of these symptoms, stop taking CORZYNA™ and talk to your doctor right away.
- If you have **severe kidney problems**, do NOT take CORZYNA™. CORZYNA™ can make your condition worse and can cause kidney failure. Symptoms could include pain, difficulty breathing, fatigue, confusion, nausea, swelling in your ankles or feet, chest pain or pressure, or weakness. Talk to your doctor if you experience any of these symptoms or go to the nearest emergency room if the symptoms are severe.
- CORZYNA™ can interact with certain **other medicines** you may be taking. Tell your doctor about all the medicines (including any drugs, vitamins, minerals, natural supplements or alternative medicines) that you are taking. Make sure you read 'Before you Take CORZYNA™' in this leaflet and know what medicines you should not use CORZYNA™ with.
- If you have **moderate or severe liver problems** do not take CORZYNA™.
- CORZYNA™ should not be used if you are **pregnant or are breastfeeding**.

Tell your doctor if you have ever had an abnormal electrocardiogram (ECG), feel dizzy or sick, become sick or experience any unexpected side effects after starting CORZYNA™.

SERIOUS WARNINGS AND PRECAUTIONS

CORZYNA™ can change the electrical activity (prolong the QT interval) of your heart. You should not take more than 1000 mg of CORZYNA™ twice a day.

WHAT IS CORZYNA™ USED FOR?

CORZYNA™ is a medicine used to treat chest pain (stable angina) in adults. It is used with other medicines in patients:

- Who cannot tolerate other antianginal therapies or for whom other antianginal therapies do not work to control their chest pain (this includes beta-blockers and calcium channel blockers)

BEFORE YOU TAKE CORZYNA™

Do not use CORZYNA™ if you:

- are allergic to ranolazine or to any of the other ingredients in CORZYNA™
- have severe kidney disease
- have moderate to severe liver disease
- take any of the following medicines. These can have serious interactions with CORZYNA™.
 - for arrhythmias: quinidine, procainamide, disopyramide, sotalol, ibutilide, amiodarone, dronedarone
 - for a fungal infection: ketoconazole, itraconazole, voriconazole, posaconazole
 - for an infection: clarithromycin
 - for depression: nefazodone
 - for HIV: nelfinavir, ritonavir, lopinavir, saquinavir
 - for tuberculosis (TB): rifampicin, rifabutin, rifapentine
 - for seizures: phenobarbital, phenytoin, carbamazepine
 - St. John's wort
- eat grapefruit, drink grapefruit juice or take products that contain grapefruit

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take CORZYNA™. Talk about any health conditions or problems you may have, including:

- all of the medicines you take (prescription, over-the-counter and natural health products)
- if you have or have a family history of a heart problem, called 'QT prolongation' or 'long QT syndrome'
- if you have low electrolyte levels (such as low potassium, magnesium or calcium), conditions that can cause low electrolyte levels (such as persistent vomiting and eating disorders) or are taking medicines that can affect your electrolyte levels such as diuretics, laxative, enemas, high dose corticosteroids and medicines for acid reflux or gastroesophageal reflux disease (GERD)
- if you have liver problems
- if you have kidney problems
- if you are pregnant or plan to become pregnant. It is not known if CORZYNA™ will harm your unborn baby.
- If you are breastfeeding or plan to breastfeed. It is not known if CORZYNA™ passes into your breast milk. Your doctor will decide if you should breastfeed or if you should stop treatment with CORZYNA™

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

If you want more information about CORZYNA™:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website www.kyepharma.com, or by calling 1-888-822-7126.

Other warnings you should know about:

Patients over 75 years of age: You may be more sensitive to experiencing side effects.

Monitoring and Laboratory tests: Before you start treatment with CORZYNA™ and periodically during treatment your doctor should:

- perform electrocardiograms (ECGs) to monitor your heart
- do blood tests to check your electrolyte levels
- check your kidney and liver function

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may also interact with CORZYNA™:

- medicines for heart problems including arrhythmias: such as digoxin, propafenone, flecainide
- medicines for bacterial, viral or fungal infection: such as erythromycin, rifampicin, rifabutin, rifapentine, fluconazole
- medicines to prevent organ rejection after a transplant: such as cyclosporine, sirolimus, everolimus
- medicines used to lower your cholesterol: such as simvastatin, lovastatin, atorvastatin
- medicines for high blood pressure: such as metoprolol, diltiazem, verapamil
- medicines for depression: such as imipramine, doxepin, amitriptyline
- metformin – used to treat high blood sugar (diabetes)
- tacrolimus – used to treat eczema

HOW TO TAKE CORZYNA™

Take CORZYNA™:

- exactly as your doctor tells you
- **do not** crush, break or chew the tablet. Swallow it whole.
- **do not** take more than 1000 mg twice a day

Usual adult dose: 500 or 1000 mg twice a day.

Missed dose: If you miss a dose, wait and take the next dose at your regular time. Do not double your dose to make up for the missed dose.