

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986
THE DISPENSING OF THE MEDICINE REQUIRES A DOCTOR'S PRESCRIPTION
Read this package insert carefully in its entirety before using this medicine
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Quinidine Sulfate 200mg TABLETS

Composition: Quinidine sulfate 200 mg

Inactive ingredients: Starch, Talc, Gelatin, Acacia, Magnesium stearate, Lactose DC. Each tablet contains 31 mg of lactose.

Therapeutic activity: This medicine is intended for regulate cardiac arrhythmias.

Therapeutic group: Antiarrhythmic.

When should the preparation not be used?

Do not use this medicine if you are sensitive to Quinidine, or to any of its ingredients.

If in the past you have developed - thrombocytopenic purpura disease manifested by subcutaneous bleeding causes like rash or bruises use Quinidine or Quinine.

If you suffer from heart failure or other defects in heart function (in addition to irregular heart rhythm), especially in the absence of an artificial pacemaker implantation.

If you suffer from severe muscle weakness, (Myasthenia Gravis). Patients may suffer from anti-cholinergic drugs.

Do not take this medicine without consulting a doctor before starting treatment:

If you are pregnant, planning a pregnancy or breastfeeding. This medicine passes into breast milk, do not breastfeed while using this medicine.

If you are suffering, or have suffered in the past, from impaired function of: the respiratory system (e.g. asthma), the heart (e.g. heart failure, heart block, QT prolongation or other heart problems), Liver, Kidney/ urinary tract, Thyroid gland, Circulatory system (eg coagulation, Thrombocytopenia - (Decrease of platelet number), Hypotension, Bradycardia, Acute infections, Low and high calcium levels, Digitalis poisoning.

How will this medicine affect your daily life?

Use of this medicine may impair alertness, blurring of vision and dizziness and therefore caution should be exercised when engaging in activities such as driving a car, operating dangerous machinery and in any other activity which requires alertness. Children should be cautioned against engaging in activities such as bicycle riding, playing near roads and the like.

This medicine may cause sensitization upon exposure to the sun, therefore avoid exposure to the sun or tanning salons treatment and care appropriate precautions (long sleeve clothes, hat, sunscreen, etc.). Do not drink wine or other alcoholic beverages while under treatment with this medicine.

Warnings:

Use of this medicine may cause blurring of vision.

Do not use this medicine frequently, or for a long period, without consulting a doctor. If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine.

If you need surgery of any kind (including dental surgery) or emergency treatment, inform your doctor that you are taking this medicine.

Be careful during the transition from a lying/ sitting to standing, because of risk of dizziness.

Consult your doctor if you need a grapefruit or grapefruit juice simultaneously with this medicine, as this combination may affect the level of the medicine in the blood.

You may need blood tests and heart function during the use of this medicine.

The tablets contains lactose. Do not use if you are allergic to lactose.

Drug interactions: If you are taking another medicine or if you have just finished treatment with another medicine including over the counter drugs and dietary additives inform the attending doctor, in order to prevent hazards or lack of efficacy arising from drug interactions. This is especially important for medicines belonging to the following groups:

- Drugs that affect the central nervous system (e.g sedatives, drugs for epilepsy, pimozide (psychosis), barbiturates (e.g phenobarbital), hydantoin (e.g phenytoin).
- Anticoagulants (e.g warfarin).
- Rifampicin and rifampin (Tuberculosis).
- Digoxin or other drugs that affect the heart.
- Amiodarone (heart rhythm disorders) and verapamil (to treat the treatment of angina pectoris, cardiac arrhythmias and hypertension).
- Beta-blockers (eg Propranolol).
- Cimetidine (ulcer), antacids.
- Antibiotics of macrolide family e.g erythromycin (antibiotic).
- Mefloquine.
- Carbonic anhydrase enzyme inhibitor (acetazolamide).
- Ketoconazole, Voriconazole and Itraconazole (antifungal).
- Sodium bicarbonate.
- Diuretics from thiazide group (e.g Hydrochlorothiazide to treat the hypertension or chronic heart failure).
- Analgesic from opiates family (e.g codeine).
- Antibiotics from Quinolones family (e.g Ciprofloxacin).
- Antibiotics from Ketolidones family (e.g Telithromycin).
- Terfenadine (hay fever).
- Drugs from phosphodiesterase inhibitors family such as sildenafil -5 (for erectile dysfunction).
- Drugs from phenothiazine family (e.g chlorpromazine- antipsychotic).
- Pancuronium.

- Succinylcholine (anesthetic purposes).
- Nifedipine (for heart disease and hypertension).
- Amiloride (a diuretic).
- Astemizole (Antihistamine).
- Cisapride (for digestion).
- Dofetilide (for heart).
- Droperidol, Haloperidol (Antipsychotic).
- HIV protease inhibitors e.g Indinavir (AIDS treatment).
- Quinolone (antibiotics), Streptogramin (antibiotics such as Pristinamycin).
- Risperidone (Antipsychotic).
- Aripiprazole (Antipsychotic).
- Digitoxin (heart).
- Norepinephrine reuptake inhibitor.
- Procainamide (heart).
- Propafenone (heart).
- Anticholinesterase (e.g Pyridostigmine - Muscle weakness Treatment).

Side effects: In addition to the desired effect of the medicine, adverse reactions may occur during the course of taking this medicine, for example: Bitter taste, redness with itching, nausea or vomiting, diarrhea, abdominal pain, loss of appetite, indigestion, sensitivity to sunlight.

In the event that the side effect continues or worsens, consult your doctor immediately.

Effects that require special attention: If you develop severe allergic reaction, including: rash, itching skin, difficulty breathing, chest tightness, swelling of the lips, face or tongue - Stop treatment and contact your doctor immediately.

Contact your doctor immediately if you develop:

Dark urine, dizziness or faintness, fainting, vision changes, changes in heart rate (slowing down, up or irregular heartbeat).

Changes in hearing or hearing loss, mental changes mental or mood change, pale feces, severe or persistent stomach pain, Headache, buzzing in the ears, yellowing of the skin or eyes, fatigue or weakness, fever, hypotension, bleeding (from the nose and gums), chest pain, joint pain and swelling, subcutaneous bleeding or bruising thrombocytopenia (decrease of platelet count), trembling.

In the event that the side effect worsens, or if you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult your doctor immediately.

Possible signs of overdose: diarrhea, vertigo (rotational dizziness), tinnitus, (ringing in the ears), visual disturbances and blurred vision, fainting, increased or decreased heart rate, decreased blood pressure, difficulty breathing, difficulty walking, Hearing loss, while-light (photophobia), confusion, double vision, delirium (disturbed), headaches, heartbeat, ventricular tachycardia (rapid heart rate that originates in one of the heart), stop the treatment and contact your doctor immediately.

Adverse reactions and drug interactions in children: Parent must inform the attending doctor about any side effects, as well as any additional medicine being taken by the child. See above for the details of side effects and drug interactions.

Dosage: Dosage is according to doctor's instructions only.

Do not exceed the recommended dosage.

Do not stop taking the drug suddenly without consulting your doctor. It is advisable to take the medicine on an empty stomach: an hour before eating or two hours after, unless developing abdominal discomfort, then you can take the medicine with food to reduce stomach irritation.

Take with a glass of water.

Do not sleep during the 30 minutes after taking the medication.

Consult doctor if you need a grapefruit or grapefruit juice simultaneously with this medicine, because this combination may affect the level of drug in the blood.

If you forget to take this medicine at the specified time and remember in two hours, take the dose, if remember later, skip the dose you missed. Do not take a double dose!

This medication is usually not intended for children and infants.

How to use:

Do not chew! Swallow the medicine with a full glass of water on an empty stomach one hour before or two hours after a meal.

Prevention of gastric disorders, your doctor may recommend taking with food or milk.

You can not cross / crushed tablets.

Even if there is an improvement in your health, do not stop taking this medicine without consulting your doctor.

Avoid poisoning! This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning. If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you. (For overdose symptoms, see side effects).

Do not induce vomiting unless explicitly instructed to do so by a doctor!

This medicine has been prescribed for the treatment of your ailment; in another patient it may cause harm. **Do not give this medicine to your relatives, neighbours or acquaintances.**

Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.

Storage: Store in a dry place below 25°C.

Even if kept in their original container and stored as recommended, medicines may be kept for a limited period only. Please note the expiry date of the medicine! In case of doubt, consult the pharmacist who dispensed the medicine to you. Do not store different medications in the same package.

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Manufacturer:

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