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MEDICATION GUIDE

Dofetilide (Do-fee-ti-lide) capsules

Read the Medication Guide before you start taking dofetilide capsules and each time you get a refill. This information does not take the place of talking with your doctor about your condition or treatment.

What is the most important information I should know about dofetilide capsules?

Dofetilide capsules can cause serious side effects, including a type of abnormal heartbeat called Torsade de Pointes, which can lead to death.

To establish the right dose of dofetilide capsules, treatment with dofetilide capsules must be started in a hospital where your heart rate and kidney function will be checked for the first 3 days of treatment. It is important that when you go home, you take the exact dose of dofetilide capsules that your doctor prescribed for you.

While you take dofetilide capsules, always watch for signs of abnormal heartbeat.

Call your doctor and go to the hospital right away if you:

- feel faint
- become dizzy, or
- have a fast heartbeat

What is dofetilide capsules?

Dofetilide capsules is a prescription medicine that is used to treat an irregular heartbeat (atrial fibrillation or atrial flutter).

It is not known if dofetilide capsules is safe and effective in children under 18 years of age.

Who should not take dofetilide capsules?

Do not take dofetilide capsules if you:

- have an irregular heartbeat called long QT syndrome
- have kidney problems or are on kidney dialysis
- take any of these medicines:
 - cimetidine (TAGAMET, TAGAMET HB)*
 - verapamil (CALAN, CALAN SR, COVERA-HS, ISOPTIN, ISOPTIN SR, VERELAN, VERELAN PM, TARKA)*
 - ketoconazole (NIZORAL, XOLEGEL, EXTINA)*
 - trimethoprim alone (PROLOPRIM, TRIMPEX)* or the combination of trimethoprim and sulfamethoxazole (BACTRIM, SEPTRA SULFATRIM)*
 - prochlorperazine (COMPAZINE, COMPO)*
 - megestrol (MEGACE)*
 - dolutegravir (TIVICAY)*

- hydrochlorothiazide alone or in combination with other medicines (such as ES IDRIX, EZIDE, HYDRODIURIL, HYDRO-P AR, MICROZIDE, or ORETIC)*

Ask your doctor if you are not sure if any of your medicines are the kind listed above.

- are allergic to dofetilide in dofetilide capsules. See the end of this leaflet for a complete list of ingredients in dofetilide capsules.

What should I tell my doctor before taking dofetilide capsules?

Before taking dofetilide capsules, tell your doctor about all of your medical conditions including if you:

- have heart problems
- have kidney or liver problems
- are pregnant or plan to become pregnant. It is not known if dofetilide will harm your unborn baby.
- are breast-feeding or plan to breast-feed. It is not known if dofetilide passes into your breast milk. You and your doctor should decide if you will take dofetilide capsules or breast-feed. You should not do both.

Especially tell your doctor if you take medicines to treat:

- heart problems
- high blood pressure
- depression or other mental problems
- asthma
- allergies, or hay fever
- skin problems
- infections

Ask your doctor if you are not sure about the medicines you take. Tell your doctor about all prescription and non-prescription medicines, vitamins, dietary supplements, and any natural or herbal remedies. Dofetilide capsules and other medicines may affect each other, causing serious side effects. If you take dofetilide capsules with certain medicines, you will be more likely to have a different type of abnormal heartbeat. See “Who should not take dofetilide capsules?”

Know the medicines you take. Keep a list of your medicines and show it to your doctor and pharmacist when you get a new medicine.

How should I take dofetilide capsules?

- Take dofetilide capsules exactly as your doctor tells you.
- Do not change your dofetilide capsules dose unless your doctor tells you to.
- Your doctor will do tests before you start and while you take dofetilide capsules.
- Do not stop taking dofetilide capsules until your doctor tells you to stop. If you miss a dose, just take the next dose at your regular time. **Do not take 2 doses of dofetilide capsules at the same time.**
- Dofetilide capsules can be taken with or without food.
- If you take too much dofetilide capsules, call your doctor or go to the nearest hospital emergency room right away. Take your dofetilide capsules with you to show to the doctor.

What are the possible side effects of dofetilide capsules?

Dofetilide capsules can cause serious side effects, including a type of abnormal heartbeat called Torsade de Pointes, which can lead to death. See “What is the most important information I should know about dofetilide capsules?”

The most common side effects of dofetilide capsules include:

- headache
- chest pain
- dizziness

Call your doctor right away if you have signs of electrolyte imbalance:

- severe diarrhea
- unusual sweating
- vomiting
- not hungry (loss of appetite)
- increased thirst (drinking more than normal)

Tell your doctor if you have any side effects that bother you or do not go away.

These are not all the possible side effects of dofetilide capsules. For more information, ask your doctor or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store dofetilide capsules?

- Store dofetilide capsules between 68° to 77°F (20° to 25°C).
- Keep dofetilide capsules away from moisture and humidity.
- Keep dofetilide capsules in a tightly closed container.
- Keep dofetilide capsules and all medicines out of the reach of children.

General information about dofetilide capsules

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use dofetilide capsules for a condition for which it was not prescribed. Do not give dofetilide capsules to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about dofetilide capsules. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about dofetilide capsules that is written for health professionals.

For more information about Dofetilide Capsules call Granules Pharmaceuticals Inc., at 1-877-770-3183.

What are the ingredients in dofetilide capsules?

Active ingredient: dofetilide

Inactive ingredients: colloidal silicon dioxide, corn starch, gelatin, magnesium stearate, microcrystalline cellulose and titanium dioxide. The 125 mcg capsules contain FD & C Yellow # 6 and D & C yellow # 10. The 250 mcg and 500 mcg capsules contain FD & C Yellow # 6 and FD& C Red # 40. Dofetilide is supplied for oral administration in three dosage strengths: 125 mcg (0.125 mg) orange and white capsules, 250 mcg (0.25 mg) peach capsules, and 500 mcg (0.5 mg) peach and white capsules. In addition, capsule printing ink contains ammonium hydroxide, black iron oxide, propylene glycol, and shellac glaze.

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Rx only

Manufactured by:

Granules Pharmaceuticals Inc.,
Chantilly, VA 20151

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This Medication Guide has been approved by the U.S. Food and Drug Administration.