

INFORMATION FOR PATIENTS

ENABLEX[®] (ěn-ā-blěx)

(darifenacin)

Extended-release tablets

7.5 mg or 15 mg

Rx only

Read the Patient Information that comes with ENABLEX[®] before you start taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking to your doctor or other healthcare professional about your medical condition or your treatment. Only your doctor or healthcare professional can determine if treatment with ENABLEX is right for you.

What is ENABLEX?

ENABLEX is a prescription medicine used in adults to treat the following symptoms due to a condition called overactive bladder:

- having a strong need to go to the bathroom right away (also called “urgency”)
- leaking or wetting accidents (also called “urinary incontinence”)
- having to go to the bathroom too often (also called “urinary frequency”)

What is overactive bladder?

Overactive bladder happens when you cannot control your bladder contractions. When these muscle contractions happen too often or cannot be controlled, you get symptoms of overactive bladder, which are urinary urgency, urinary incontinence (leakage) and urinary frequency.

Who should not take ENABLEX?

Do not take ENABLEX if you:

- are not able to empty your bladder (also called “urinary retention”)
- have delayed or slow emptying of your stomach (also called “gastric retention”)
- have an eye problem called “uncontrolled narrow-angle glaucoma”
- are allergic to ENABLEX or to any of its ingredients. See the end of this leaflet for a complete list of ingredients.

ENABLEX has not been studied in children.

What should I tell my doctor before starting ENABLEX?

Before starting ENABLEX, tell your doctor or healthcare professional about all of your medical conditions including if you:

- have any stomach or intestinal problems, or problems with constipation
- have trouble emptying your bladder or if you have a weak urine stream
- have an eye problem called narrow-angle glaucoma
- have liver problems
- are pregnant or are planning to become pregnant. It is not known if ENABLEX can harm your unborn baby.
- are breast-feeding. It is not known if ENABLEX passes into breast milk and if it can harm your baby.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. ENABLEX and certain other medicines can interact with each other, causing side effects. Especially tell your doctor if you take:

- ketoconazole (Nizoral[®]) or itraconazole (Sporanox[®]), antifungal medicines
- clarithromycin (Biaxin[®]), an antibiotic medicine
- ritonavir or nelfinavir (Viracept[®]), antiviral medicines
- nefazadone (Serzone[®]), a depression medicine
- flecainide (Tambocor[™]), an abnormal heartbeat (antiarrhythmia) medicine
- thioridazine (Mellaril[®]), a mental disorder (antipsychotic) medicine
- a medicine called a tricyclic antidepressant

Know all the medicines you take. Keep a list of them with you to show your doctor and pharmacist each time you get a new medicine.

How should I take ENABLEX?

Take ENABLEX exactly as prescribed. Your doctor will prescribe the dose that is right for you. Your doctor may prescribe the lowest dose if you have certain medical conditions such as liver problems.

- You should take ENABLEX once daily with liquid.
- **ENABLEX should be swallowed whole and not chewed, divided or crushed.**
- ENABLEX may be taken with or without food.
- If you miss a dose of ENABLEX, begin taking ENABLEX again the next day. Do not take two doses of ENABLEX in the same day.
- If you take too much ENABLEX, call your local Poison Control Center or emergency room right away.

What are the possible side effects of ENABLEX?

The most common side effects with ENABLEX are:

- dry mouth
- constipation

ENABLEX may cause other less common side effects that include:

- Swelling (angioedema) of the face, lips, tongue, and/or throat may occur. Stop taking ENABLEX and seek medical attention immediately if you experience swelling of the tongue or throat, or if you experience difficulty breathing.
- blurred vision. Use caution while driving or doing dangerous activities until you know how ENABLEX affects you.
- heat prostration. Heat prostration (due to decreased sweating) can occur when drugs such as ENABLEX are used in a hot environment.

These are not all the side effects with ENABLEX. For more information, ask your doctor, healthcare professional or pharmacist.

How do I store ENABLEX?

- **Keep ENABLEX and all medicines out of the reach of children.**
- Store ENABLEX at room temperature, 59 to 86°F (15 to 30°C). Protect from light.
- Safely dispose of ENABLEX that is out of date or no longer needed.

General information about ENABLEX

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not give ENABLEX to other people, even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about ENABLEX. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about ENABLEX that is written for health professionals. You can also call the product information department at 1-888-44-ENABLEX (1-888-443-6225) or visit the website at www.Enablex.com.

What are the ingredients in ENABLEX?

Active Ingredient: darifenacin

Inactive Ingredients: dibasic calcium phosphate anhydrous, hypromellose (hydroxypropyl methylcellulose), magnesium stearate, polyethylene glycol, talc, titanium dioxide. The 15 mg tablet also contains iron oxide red and iron oxide yellow.

Appearance:

The 7.5-mg tablet is round and white-colored with “DF” on one side and “7.5” on the other side.

The 15-mg tablet is round and peach-colored with “DF” on one side and “15” on the other side.

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