

FDA-Approved Patient Labeling

Darifenacin (DAR-i-FEN-a-sin) Extended-release Tablets

Read this Patient Information leaflet about Darifenacin Extended-release Tablets 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 about your medical condition or your treatment.

What is darifenacin extended-release tablets?

Darifenacin extended-release tablets is a prescription medicine for adults used to treat the following symptoms due to a condition called overactive bladder:

- Urge urinary incontinence: a strong need to urinate with leaking or wetting accidents
- Urgency: a strong need to urinate right away
- Frequency: urinating often

It is unknown if darifenacin extended-release tablets is safe and effective in children.

Who should not take darifenacin extended-release tablets?

Do not take darifenacin extended-release tablets if you:

- are not able to empty your bladder (“urinary retention”)
- have delayed or slow emptying of your stomach (“gastric retention”)
- have an eye problem called “uncontrolled narrow-angle glaucoma”

What should I tell my healthcare provider before starting darifenacin extended-release tablets?

Before starting darifenacin extended-release tablets, tell your doctor if you:

- have trouble emptying your bladder or if you have a weak urine stream
- have any stomach or intestinal problems, or problems with constipation
- have liver problems
- have any other medical conditions
- are pregnant or are planning to become pregnant. It is not known if darifenacin extended-release tablets can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if darifenacin passes into breast milk and if it can harm your baby. Talk to your doctor about the best way to feed your baby if you take darifenacin extended-release tablets.

Tell your healthcare provider about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. Darifenacin extended-release tablets and certain other medicines may affect each other, causing side effects.

Especially tell your healthcare provider if you take a:

- antifungal medicine ketoconazole (Nizoral[®]) or itraconazole (Sporanox[®])

- antibiotic medicine clarithromycin (Biaxin[®])
- anti-HIV medicine ritonavir (Norvir[®]) or nelfinavir (Viracept[®])
- medicine to treat depression nefazadone (Serzone[®])
- medicine to treat an abnormal heartbeat flecainide (Tambocor[™])
- antipsychotic medicine thioridazine (Mellaril[®])
- medicine to treat depression 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 darifenacin extended-release tablets?

- Take darifenacin extended-release tablets exactly as prescribed. Your doctor will prescribe the dose that is right for you. Take darifenacin extended-release tablets 1 time daily with water.
- Darifenacin extended-release tablets should be swallowed whole. Do not chew, cut or crush darifenacin extended-release tablets.
- Darifenacin extended-release tablets may be taken with or without food.
- If you take too much darifenacin extended-release tablets call your doctor or go to the nearest hospital emergency room right away.

What should I avoid while taking darifenacin extended-release tablets?

Darifenacin extended-release tablets can cause blurred vision or dizziness. Do not drive or operate heavy machinery until you know how darifenacin extended-release tablets affects you.

What are the possible side effects of darifenacin extended-release tablets?

Darifenacin extended-release tablets may cause serious side effects including:

- Serious allergic reaction. Stop taking darifenacin extended-release tablets and get medical help right away if you have:
 - hives, skin rash or swelling
 - severe itching
 - swelling of your face, mouth or tongue
 - trouble breathing

The most common side effects with darifenacin extended-release tablets are:

- constipation
- dry mouth
- headache
- heartburn
- nausea
- urinary tract infection
- blurred vision
- heat exhaustion or heat-stroke. This can happen when darifenacin extended-release tablets are used in

hot environments. Symptoms of heat exhaustion may include:

- decreased sweating
- dizziness
- tiredness
- nausea
- increase body temperature

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of darifenacin extended-release tablets. 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 do I store darifenacin extended-release tablets?

Store darifenacin extended-release tablets at 20° to 25°C (68° to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) [see USP Controlled Room Temperature]. Protect from light.

Keep darifenacin extended-release tablets and all medicines out of reach of children.

General information about darifenacin extended-release tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use darifenacin extended-release tablets for a condition for which it was not prescribed. Do not give darifenacin extended-release tablets to other people, even if they have the same symptoms you have. It may harm them.

This Patient Information leaflet summarizes the most important information about darifenacin extended-release tablets. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about darifenacin extended-release tablets that is written for health professionals.

What are the ingredients in darifenacin extended-release tablets?

Active ingredient: darifenacin

Inactive ingredients: microcrystalline cellulose, colloidal silicon dioxide, talc, magnesium stearate, hypromellose (E15 LV), titanium dioxide, polyethylene glycol 400 and hypromellose (methocel K4M CR). The 15 mg tablet also contains ferric oxide red and ferric oxide yellow.

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This Patient Information has been approved by the U.S. Food and Drug Administration.



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July 2022