

# ENABLEX PROLONGED-RELEASE TABLETS

Darifenacin hydrobromide (7.5mg, 15mg)

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## What Enablex is used for

Enablex is used to treat the following symptoms due to a condition called overactive bladder:

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

## How Enablex works

Enablex contains the active ingredient called darifenacin hydrobromide.

Enablex works by relaxing the bladder smooth muscle and helps to decrease muscle spasm. This delays the initial desire and the urge to urinate.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription. It is not addictive.

Enablex is not recommended for use in children because there have been no studies of its effects in this age group.

## Before you use Enablex

### - When you must not use it

Do not take this medicine if you have an allergy to:

- darifenacin, the active ingredient
- any of the other ingredients listed at the end of this leaflet

Do not take Enablex if you have any of the following medical conditions:

- a disorder of eye related to eye pressure called narrow angle glaucoma that is not being controlled with medicine
- delayed in stomach emptying
- urinary retention
- abnormal weakness of certain muscles.
- severe liver impairment
- severe inflammation and ulcer of large intestine
- a very dilated colon (megacolon), accompanied by abdominal bloating

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

### - Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or intend to become pregnant.

There is no information on the use of this medicine during pregnancy.

Your doctor will discuss the possible risks and benefits involved.

Tell your doctor if you are breastfeeding or plan to breast-feed.

It is not known if the active ingredient of Enablex passes into breast milk and could affect your baby. Your doctor will discuss the possible risks and benefits of breastfeeding while taking Enablex.

Tell your doctor if you have or have had any medical conditions, especially the following:

- heart problems
- stomach, intestinal or large bowel problems, including severe constipation.
- nerve problems
- kidney disease

- Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Enablex may interfere with each other.

These include:

- some medicines used to treat fungal infections, such as ketoconazole, itraconazole and fluconazole
- some medicines used to treat depression called tricyclic antidepressants
- some medicines used to treat heart problems, such as digoxin, flecainide and verapamil
- cimetidine, a medicine used to treat stomach ulcers
- ritonavir, a medicine used to treat HIV/AIDS
- thioridazine, a medicine used to treat mental illness
- a variety of other medicines that work in a similar way to Enablex.
- Some medicine used to treat bacterial infections, such as erythromycin and clarithromycin
- Midazolam, a medicine used for anesthesia
- St. John's wort for depression treatment

These medicines may be affected by Enablex or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

If you not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

**How to use Enablex**

Follow all directions given to you by your doctor and pharmacist carefully.

These directions may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

- How much to use

The usual starting dose is one 7.5mg tablet once a day.

If necessary, your doctor may increase your dose to one 15mg tablet once a day, as early as two weeks after starting therapy.

If you have a problem with your liver or are taking certain medicines, your doctor may limit your dose to one 7.5mg tablet once a day.

- When to use it

Take Enablex at about the same time each day.

Taking Enablex at the same time each day will have the best effect. It will also help you to remember when to take the medicine.

Swallow the tablet whole with a glass of water. Do not chew, crush or divide the tablet.

You can take the tablet with or without food.

- How long to use it

Continue taking Enablex for as long as your doctor recommends.

Enablex helps control your condition, but does not cure it. Therefore, you must take this medicine every day.

- If you forget to use it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

- If you use too much (overdose)

Immediately telephone your doctor for advice or go to Emergency Department of your nearest hospital if you think that you or anyone else may have taken too much Enablex.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause dry mouth, constipation and blurred vision.

**While you are using it**

- Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Enablex.

If you become pregnant while taking Enablex, tell your doctor.

If you are about to start taking any new medicine tell your doctor and pharmacist that you are taking Enablex.

- Things you must not do

Do not take grapefruit juice at the same time as Enablex.

Do not take Enablex to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

- Things to be careful of

Be careful driving or operating machinery until you know how Enablex affects you.

This medicine may cause dizziness or blurred vision in some people.

Discontinue Enablex and seek immediate medical attention if you experience swelling of the tongue or throat, or difficulty breathing

**Side effects**

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Ask for the advice of your doctor or pharmacist if you have any concerns about the effects of taking this medicine.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Some of the very common and common side effects include:

- constipation
- stomach ache
- nausea
- nasal dryness
- dry eyes
- headache
- dryness of the mouth
- indigestion

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people. You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Monitoring by calling Tel: 03-78835550, or visiting the website [npra.moh.gov.my](http://npra.moh.gov.my) (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

**Storage and Disposal of Enablex**

- Storage

Keep your medicine in its original packaging until it is time to take them.

If you take the tablets out of the pack, they may not keep well.

Do not keep your medicine in a place where the temperature will stay above 30°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink.

Keep it where children cannot reach it.

- Disposal

Medicines should not be disposed of via wastewater or household waste. If your doctor or pharmacist tells you to stop taking this medicine or it has passed its expiry date, ask your pharmacist what to do with any medicine that is left over. These measures will help to protect the environment.

**Product Description**

- What it looks like

*Enablex 7.5mg Prolonged-Release Tablets*

- Round, shallow, convex, white tablets and are identified with “DF” on one side and “7.5” on the other.

*Enablex 15mg Prolonged-Release Tablets*

- Round, shallow, convex light-peach-coloured tablets and are identified with ‘DF’ on one side and ‘15’ on the reverse.

- Ingredients

Active ingredient:

- Darifenacin (as hydrobromide)

Inactive ingredients:

- Hypromellose
- Opadry white
- Magnesium stearate
- Calcium hydrogen phosphate (Dibasic)

- MAL number

*Enablex 7.5mg Prolonged-Release Tablets*

MAL20081778AZ

*Enablex 15mg Prolonged-Release Tablets*

MAL20081779AZ

**Manufacturer**

Aspen Bad Oldesloe GmbH  
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**Product Registration Holder**

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