

ENABLEX tablets

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ENABLEX?

ENABLEX contains the active ingredient darifenacin (as darifenacin hydrobromide). ENABLEX is used to decrease the urgency and the frequency of urination.

For more information, see Section [1. Why am I using ENABLEX?](#) in the full CMI.

2. What should I know before I use ENABLEX?

Do not use if you have ever had an allergic reaction to darifenacin or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use ENABLEX?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ENABLEX and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use ENABLEX?

- The usual starting dose is 7.5mg once a day. This may be increased to 15 mg once a day if necessary.
- Swallow the tablet whole with a glass of water. Do not chew, crush, or divide the tablet.

More instructions can be found in Section [4. How do I use ENABLEX?](#) in the full CMI.

5. What should I know while using ENABLEX?

Things you should do	<ul style="list-style-type: none">• If you become pregnant while taking ENABLEX, tell your doctor.• Remind any doctor, dentist or pharmacist you visit that you are using ENABLEX.
Things you should not do	<ul style="list-style-type: none">• Do not give this medicine to anyone else, even if their condition seems like yours.• Do not take it to treat any other complaints unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how ENABLEX affects you.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in the pack protected from light until it is time to take them.• Keep in a cool dry place, away from moisture or heat where the temperature stays below 25°C.

For more information, see Section [5. What should I know while using ENABLEX?](#) in the full CMI.

6. Are there any side effects?

Common side effects of ENABLEX include constipation; diarrhoea; stomach ache or indigestion; nausea or vomiting; nasal dryness; flatulence; dry or itchy skin; dry eyes; blurred or changed vision; dryness of the mouth, nose, and throat; sore throat or cough; change in taste; mouth ulcers; swelling of the hands, ankles or feet; unusual tiredness, confusion, or weakness; difficulty sleeping; dizziness; pain in the joints; discharge or itching in the vagina; signs of a possible urinary tract infection, such as pain on urination; urinary retention; fast or irregular heart beats; weight gain; excessive sweating; and impotence.

Serious side effects of ENABLEX include sudden signs of allergy such as rash, itching, or hives on the skin; swelling of the face, lips, tongue, or other parts of the body; and shortness of breath, wheezing or trouble breathing.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ENABLEX tablets

Active ingredient: *darifenacin (as darifenacin hydrobromide)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ENABLEX.

You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ENABLEX.

Where to find information in this leaflet:

- [1. Why am I using ENABLEX?](#)
- [2. What should I know before I use ENABLEX?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ENABLEX?](#)
- [5. What should I know while using ENABLEX?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using ENABLEX?

ENABLEX contains the active ingredient darifenacin (as darifenacin hydrobromide). ENABLEX is used to decrease the urgency and the frequency of urination.

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 not addictive.

2. What should I know before I use ENABLEX?

Warnings

Do not use ENABLEX if:

- you are allergic to darifenacin or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue, or any other parts of the body; rash, itching or hives on the skin.
- you have any of the following health conditions:**
 - a disorder of the eye called narrow angle glaucoma that is not being controlled with medicine.
 - a blockage in the stomach or intestine.
 - urinary tract blockage.
- the expiry date printed on the pack has passed.**
- the packaging is torn or shows signs of tampering.**

Check with your doctor if you:

- have any other medical conditions, especially the following:**
 - heart problems
 - liver problems
 - narrow-angle glaucoma that is controlled with medicine.
 - stomach, intestinal or large bowel problems, including chronic constipation.
- have had any allergy to any other medicines, or any other substances, such as foods, preservatives, or dyes.**

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with 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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

Use in children

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

3. What if I am taking other medicines?

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

Some medicines may interfere with ENABLEX and affect how it works. These include:

- medicines used to treat fungal infections, such as ketoconazole, itraconazole and miconazole
- medicines used to treat depression, such as paroxetine, fluoxetine, nefazodone and tricyclic antidepressants
- medicines used to treat heart problems, such as digoxin and flecainide
- cimetidine, a medicine used to treat stomach ulcers
- ritonavir, a medicine used to treat HIV/AIDS
- thioridazine, a medicine used to treat schizophrenia

- other medicines that work in a similar way to ENABLEX.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ENABLEX.

4. How do I use ENABLEX?

How much to take

- The usual starting dose is one 7.5 mg tablet once a day.
- If necessary, your doctor may increase your dose to one 15 mg 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 7.5 mg tablet once a day.

When to take it

Take ENABLEX at about the same time each day.

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

How to take it

- **Swallow the tablet whole with a glass of water. Do not chew, crush, or divide the tablet.**
- It can be taken with or without food.

How long to take it for

Continue taking this medicine for as long as your doctor tells you to.

ENABLEX helps control your condition, but does not cure it.

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 medicine as you would normally.

Do not take a double dose to make up for the dose you missed.

This may increase the chance of you getting an unwanted side effect.

If you're not sure what to do, ask your doctor or pharmacist.

If you take too much ENABLEX

If you think that you have taken too many ENABLEX tablets, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using ENABLEX?

Things you should do

- **If you become pregnant while taking ENABLEX, tell your doctor.**
Your doctor can discuss with you the risks of taking it while you are pregnant.
- **Remind any doctor, dentist or pharmacist you visit that you are using ENABLEX.**
- **If you are about to be started on any new medicine, tell your doctor, dentist, or pharmacist that you are taking ENABLEX.**

Things you should not do

- **Do not give this medicine to anyone else, even if their condition seems like yours.**
- **Do not take it to treat any other complaints unless your doctor tells you to.**

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ENABLEX affects you.

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

Looking after your medicine

- **Keep your tablets in the pack protected from light until it is time to take them.**
- **Keep ENABLEX tablets in a cool dry place, away from moisture or heat where the temperature stays below 25°C. For example, do not store it:**
 - in the bathroom or near a sink, or
 - in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Some side effects such as raised blood pressure may not give you any symptoms and can only be found when tests are done.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• constipation• diarrhoea• stomach ache or indigestion• nausea or vomiting• nasal dryness• flatulence• dry or itchy skin• dry eyes• blurred or changed vision• dryness of the mouth, nose and throat• sore throat or cough• change in taste• mouth ulcers• swelling of the hands, ankles or feet• unusual tiredness, confusion or weakness• difficulty sleeping• dizziness• pain in the joints• discharge or itching in the vagina• signs of a possible urinary tract infection, such as pain on urination• urinary retention• fast or irregular heart beats• weight gain• excessive sweating• impotence.	<p>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.	<p>Stop taking ENABLEX and tell your doctor immediately or go to Accident and Emergency at your nearest hospital.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ENABLEX contains

Active ingredient (main ingredient)	<ul style="list-style-type: none">• Each modified release tablet contains either darifenacin 7.5 mg or 15 mg (as darifenacin hydrobromide).
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• calcium hydrogen phosphate• hypromellose• magnesium stearate• opadry complete film coating system OOF18296 white <p>In addition, ENABLEX 15 mg tablets contain:</p> <ul style="list-style-type: none">• opadry complete film coating system OOF12951 yellow• opadry complete film coating system OOF15613 red.

Do not take this medicine if you are allergic to any of these ingredients.

What ENABLEX tablets look like

ENABLEX 7.5 mg tablets are round, white film coated, modified release tablets marked with "DF" on one side and "7.5" on the other side. Available in blister packs of 28 tablets.

ENABLEX 15 mg tablets are round, light peach film coated, modified release tablets marked with "DF" on one side and "15" on the other side. Available in blister packs of 28 tablets.

Australian Registration numbers:

ENABLEX 7.5 mg: AUST R 99418

ENABLEX 15 mg: AUST R 99439

Who distributes ENABLEX

Aspen Pharmacare Australia Pty Ltd
34-36 Chandos St
St Leonards NSW 2065
Australia

This leaflet was revised in October 2025.