

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S4**

FENRI 175 µg/3 ml Inhalation solution

Revefenacin

Sugar free

Read all of this leaflet carefully before you start using FENRI

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- FENRI has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What FENRI is and what it is used for
2. What you need to know before you use FENRI
3. How to use FENRI
4. Possible side effects
5. How to store FENRI
6. Contents of the pack and other information

1. What FENRI is and what it is used for

FENRI is a prescription medicine used to treat chronic obstructive pulmonary disease (COPD). COPD is a long-term (chronic) lung disease that includes chronic bronchitis, emphysema, or both.

FENRI is an anticholinergic medicine. Anticholinergic medicines help the muscles around the airways in your lungs stay relaxed to prevent symptoms such as wheezing, cough, chest tightness, and shortness of breath.

FENRI is used long-term as 1 vial of FENRI, 1 time each day inhaled through your nebulizer to improve symptoms of COPD for better breathing.

FENRI is not used to relieve sudden breathing problems and will not replace an inhaled rescue medicine.

Use in children

FENRI should not be used in children. It is not known if FENRI is safe and effective in children.

What you need to know before you use FENRI

Do not use FENRI:

- if you are allergic (hypersensitive) to revefenacin or any other ingredients of FENRI (listed in section 6).

Warnings and precautions

Take special care with FENRI:

- if you have eye problems such as glaucoma. FENRI may make your glaucoma worse.
- if you have prostate or bladder problems, or problems passing urine. FENRI may make these problems worse.
- if you have liver problems.

Other medicines and FENRI

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Especially tell your healthcare provider if you take:

- other anticholinergic medicines (including tiotropium, ipratropium, aclidinium,

umeclidinium, glycopyrrolate)

- atropine

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby while using FENRI, please consult your doctor, pharmacist or other healthcare professional for advice before using FENRI.

Pregnancy

Do not use FENRI if you are pregnant. It is not known if FENRI may harm your unborn baby.

Breast-feeding

Mothers taking FENRI are advised to not breastfeed their babies.

It is not known if the medicine in FENRI passes into your breast milk and if it can harm your baby.

Driving and using machines

FENRI should not affect your ability to drive or to use machines.

3. How to use FENRI

Do not share medicines prescribed for you with any other person.

Always use FENRI exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Read the step-by-step instructions below, for using FENRI.

FENRI is only for use with a nebuliser.

INSTRUCTIONS FOR USE

FENRI is used only in a standard jet nebuliser machine with a mouthpiece connected to an air compressor. Make sure you know how to use your nebulizer machine before you use it to breathe in FENRI.

Important Information:

- Do not mix FENRI with other medicines in your nebuliser.
- FENRI comes in a vial that is sealed in a foil pouch. Do not open the sealed pouch until you are ready to use a dose of FENRI.
- Use your FENRI right away after opening.

Using FENRI:

Read the following Steps before using FENRI. If you have any questions, ask your healthcare provider or pharmacist.

Step 1. Open Pouch: Open the foil pouch by tearing along the seam of the pouch. Remove the vial of FENRI from the foil pouch (Figure 1).

Remove vial from pouch.

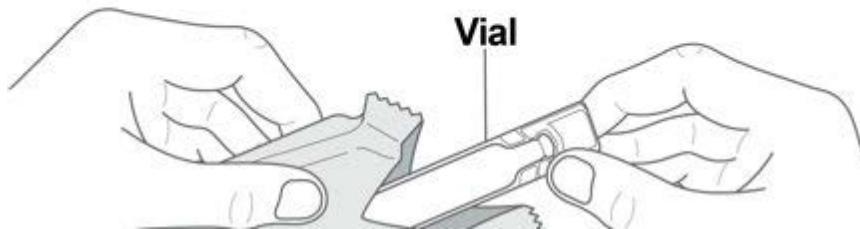


Figure 1

Step 2. Open Vial: Carefully twist open the top of the vial and use it right away (Figure 2).

Twist open the top of vial.

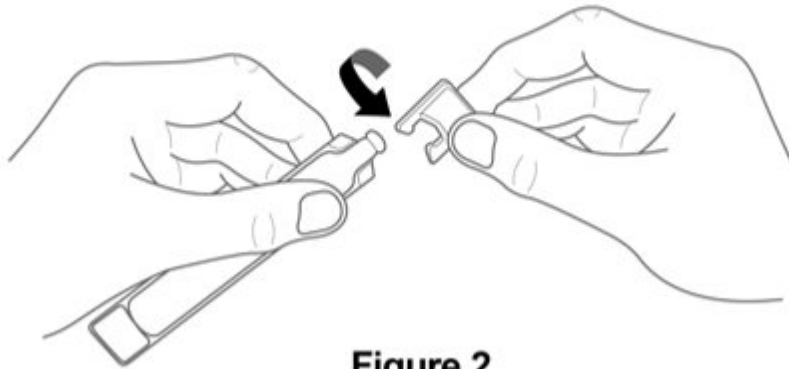


Figure 2

Step 3. Add Medicine: Squeeze all of the medicine from the vial into the nebulizer cup (reservoir) (Figure 3).

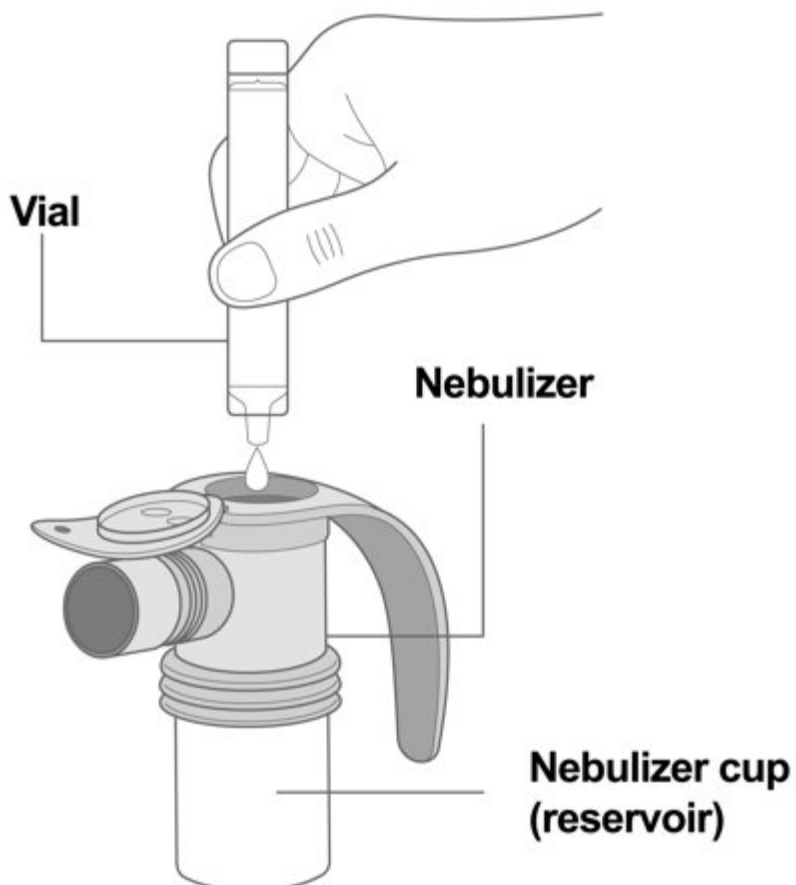


Figure 3

Step 4. Attach Mouthpiece: Connect the mouthpiece to the nebulizer cup (reservoir) with the expiratory valve facing up (Figure 4).

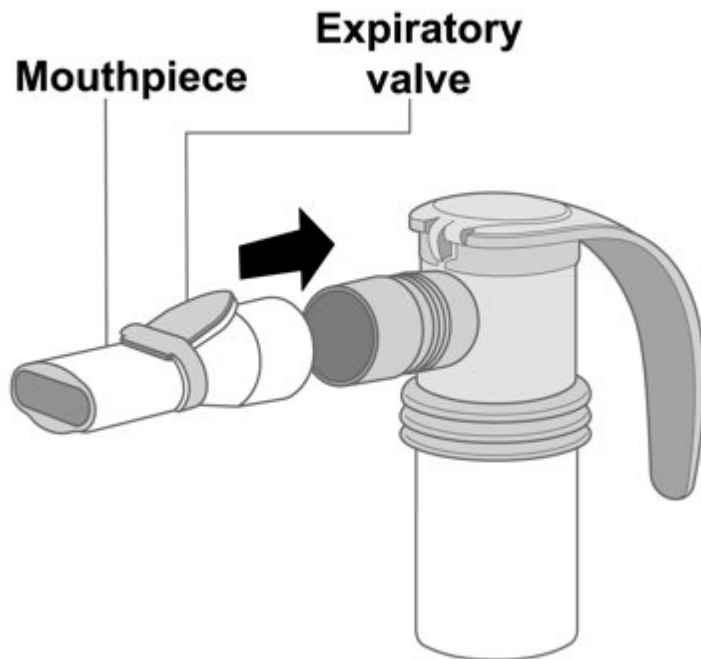


Figure 4

Step 5. Connect the Nebulizer to the Compressor: Firmly insert one end of the tubing to the compressor. Insert the other end of the tubing to the bottom of the nebulizer cup (reservoir) (Figure 5).

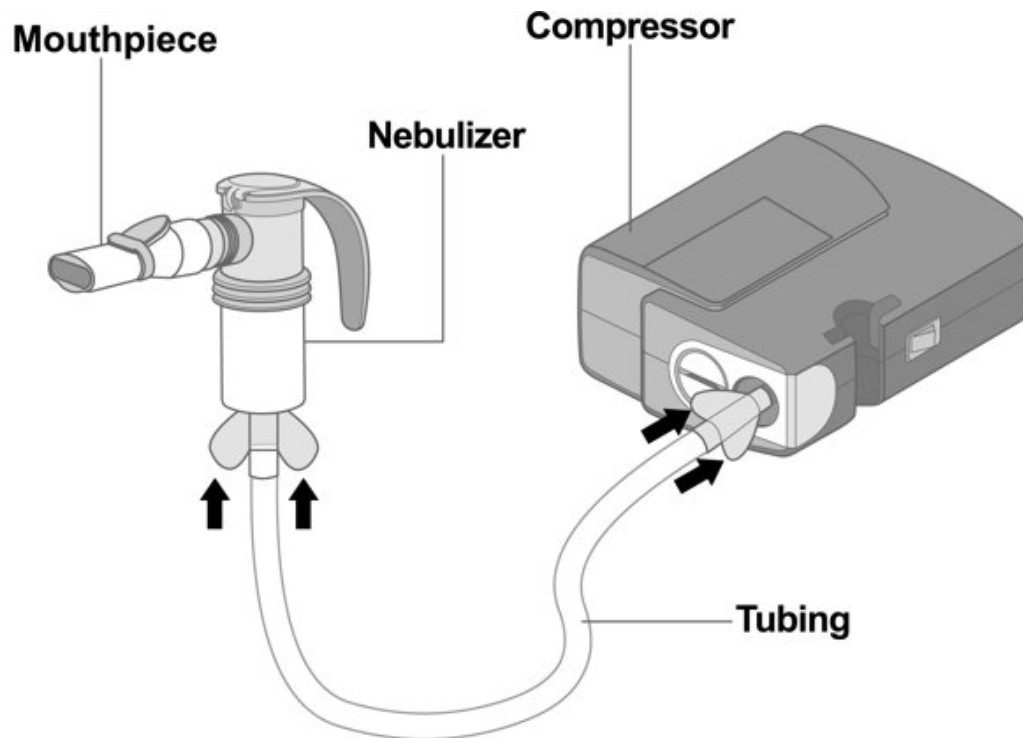


Figure 5

Step 6. Prepare for Treatment: Sit in a comfortable, upright position. Place the mouthpiece in your mouth and close your lips around the mouthpiece.

Step 7. Begin Treatment: Turn on the compressor to begin your treatment (Figure 6).

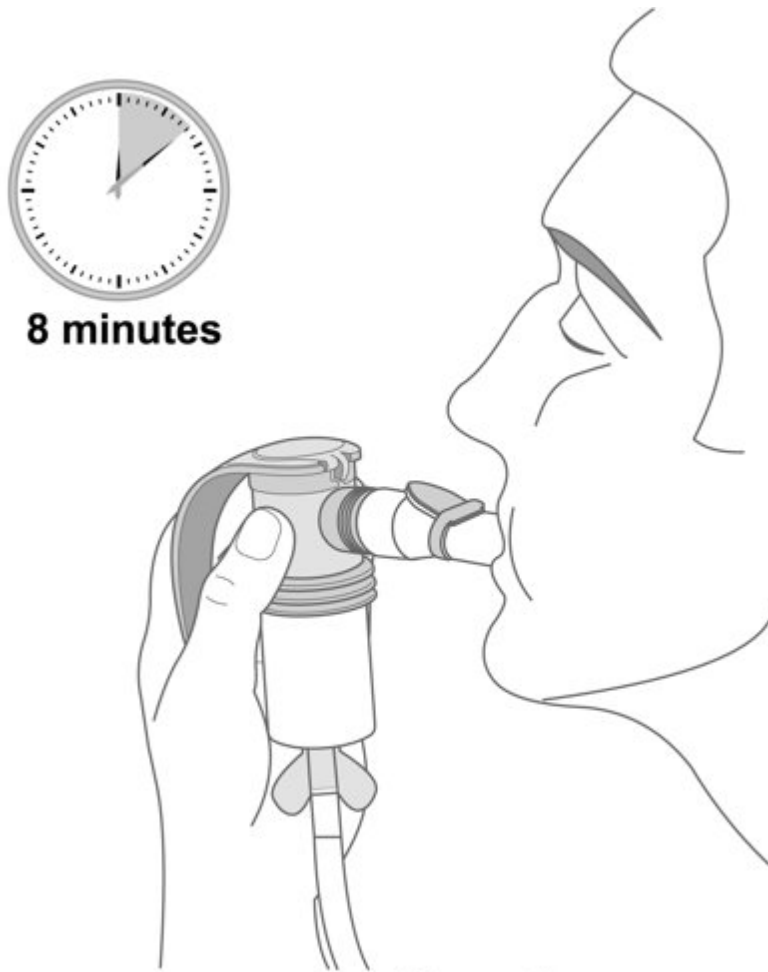


Figure 6

Step 8. Breathe in Medicine: Breathe as calmly, deeply, and evenly as possible until no more mist is seen in the nebulizer reservoir. Your treatment will take about 8 minutes. When you do not see any mist in the nebulizer, your treatment is finished. Turn the compressor off.

Step 9. Clean Nebulizer: Clean and store your nebulizer. See the manufacturer's instructions that come with your nebulizer for how to clean and store your nebulizer.

Do not use FENRI unless your doctor has taught you how to use it with your nebulizer and you understand how to use it correctly.

FENRI is taken as a breathing treatment (by oral inhalation) and should be used with a standard jet nebuliser with a mouthpiece connected to an air compressor.

Do not mix FENRI with other medicines in your nebuliser.

The usual dose is 1 vial of FENRI, 1 time each day. Do not use more than 1 vial of FENRI a day.

Use FENRI at the same time each day.

Do not use other medicines that contain an anticholinergic for any reason. Ask your healthcare provider or pharmacist if any of your other medicines are anticholinergic medicines.

FENRI does not relieve sudden symptoms of COPD and you should not use extra doses of FENRI to relieve these sudden symptoms. Always have an inhaled rescue medicine with you to treat sudden symptoms. If you do not have an inhaled rescue medicine, call your healthcare provider to have one prescribed for you.

Call your healthcare provider or get emergency medical care right away if:

- your breathing problems get worse.
- you need to use your inhaled rescue medicine more often than usual.
- your inhaled rescue medicine does not relieve your symptoms.

If you have the impression that the effect of FENRI is too strong or too weak, tell your doctor or pharmacist.

If you use more FENRI than you should:

In the event of overdosage consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. If you use too much FENRI, you may experience symptoms, such as worsening shortness of breath, chest pain, or increased heart rate.

If you missed a dose of FENRI:

Do not use a double dose to make up for forgotten individual doses.

Effects when treatment with FENRI is stopped

Do not stop using FENRI, even if you are feeling better, unless your doctor tells you to because your symptoms might get worse.

4. Possible side effects

FENRI can have side effects.

Not all side effects reported for FENRI are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using FENRI, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using FENRI and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, tongue and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to FENRI. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- sudden breathing problems immediately after inhaling FENRI,
- new or worsened eye problems including acute narrow-angle glaucoma.
Acute narrow-angle glaucoma can cause permanent loss of vision if not treated. Symptoms of acute narrow-angle glaucoma may include: red eyes, blurred vision, seeing halos or bright colours around lights, eye pain or discomfort, nausea or vomiting,
- urinary retention. People who use FENRI may develop new or worse urinary

retention. Symptoms of urinary retention may include: difficulty urinating, urinating frequently, urination in a weak stream or drips, painful urination.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- cough,
- runny nose,
- upper respiratory tract infection,
- headache,
- back pain.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse.

You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of FENRI.

How to store FENRI

Store all medicines out of reach of children.

- Store at or below 25 °C. Protect from direct sunlight and excessive heat.
- Store FENRI in the unopened protective foil pouch and only open the foil pouch right before you are ready to use FENRI.

- Discard any solution that is not clear and colourless.
- FENRI should only be administered via a standard jet nebuliser connected to an air compressor with an adequate airflow and equipped with a mouthpiece.
- Do not swallow or inject FENRI.
- Do not use after the expiry date stated on the bottle / carton label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Contents of the pack and other information

What FENRI contains

The active substance is revefenacin. Each FENRI vial contains 175 µg of revefenacin in 3 ml of aqueous solution.

The other ingredients are: citric acid, sodium chloride, sodium citrate, and water for injection.

What FENRI looks like and contents of the pack

FENRI inhalation solution is supplied as a sterile, clear, colourless, aqueous solution for nebulisation in low-density polyethylene unit-dose vials.

FENRI is supplied as 3 ml of revefenacin solution packaged in a unit-dose low-density polyethylene vial overwrapped in a foil pouch. Each vial contains 175 µg of revefenacin in 3 ml of an isotonic, sterile aqueous solution containing sodium chloride, citric acid, sodium citrate, and water for injection at pH 5,0.

Pack size:

Each vial is overwrapped in a foil pouch and supplied in cartons containing either 30 individually pouched unit-dose vials or 7 individually pouched unit-dose vials

Holder of Certificate of Registration

MYLAN (PTY) LTD

**Mylan (Pty) Ltd
FENRI**

**Inhalation solution, 175 µg/ 3 ml
(Revefenacin)**

4 Brewery Street

Isando, Gauteng, 1609

Republic of South Africa

This leaflet was last revised in

Registration numbers

55/5.4/0036

Access to the corresponding Professional Information

Refer to the SAHPRA website at www.sahpra.org.za