

YUPELRI® INHALATION SOLUTION

175 MCG/3ML

Revefenacin (175mcg/3ml)

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What Yupelri® is used for

Yupelri® is used for the maintenance treatment of patients with chronic obstructive pulmonari disease (COPD). COPD is a long-term (chronic) lung disease that includes chronic bronchitis, emphysema, or both.

How Yupelri® works

Yupelri® inhalation solution contains revefenacin, 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.

Before you use Yupelri®

- When you must not use it

Do not take Yupelri® in case of:

- hypersensitivity to revefenacin or any other ingredients of this medicine (listed in Product Description).

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

Pregnancy and lactation

Ask your doctor or pharmacist for advice before taking Yupelri® if you are pregnant, trying to get pregnant or think you may be pregnant. It is not known if Yupelri® may harm your unborn baby.

It is not known if the medicine in Yupelri® passes into your breast milk and if it can harm your baby. Ask your doctor

or pharmacist for advice before taking any medicine.

- Before you start use it

Please know that Yupelri® is not used to relieve sudden breathing problems and will not replace an inhaled rescue medicine.

If breathing difficulty occurs, Yupelri® should be discontinued immediately and alternative therapy should be instituted.

Tell your doctor or pharmacist if you have:

- eye problems such as glaucoma
- prostate or bladder problems, or problems passing urine
- liver problems

- Taking other medicines

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

Some medicines may interfere with Yupelri®.

These include:

- other anticholinergic-containing drugs (e.g. tiotropium, ipratropium, aclidinium, umeclidinium, glycopyrrolate)
- atropine

How to use Yupelri®

- How much to use

One 175 mcg unit-dose vial administered once daily by nebulizer using a mouthpiece.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Yupelri® for the duration that your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Using too much Yupelri® may cause worsening shortness of breath, chest pain, or increased heart rate, nausea, vomiting, dizziness, lightheadedness, blurred vision, eye pain, reddening of the eye, severe constipation or difficulties emptying your bladder.

While you are using it

- Things you must do

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

Use Yupelri® at the same time each day.

The Yupelri® unit-dose vial should only be removed from the foil pouch and opened immediately before use.

Throw away the vial of Yupelri® and any leftover medicine after use.

Throw away the vial of Yupelri® if the solution is not clear and colorless.

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Yupelri®, including if you:

- have eye problems such as glaucoma.
- have prostate or bladder problems, or problems passing urine.
- have liver problems
- are allergic to any of the ingredients in YUPELRI or any other medicines.

Tell your doctor immediately if you become pregnant or breastfeeding while taking this medication.

- Things you must not do

Do not mix Yupelri® with other medicines in your nebulizer.

Do not use more than 1 vial of Yupelri® a day.

Yupelri® does not relieve sudden symptoms of COPD and you should not use extra doses of Yupelri® 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, please inform your doctor to have one prescribed for you.

Do not stop taking Yupelri® even if you are feeling better unless advised by your doctor because your symptoms might get worse.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give Yupelri® to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Contact your doctor or get emergency medical care right away if:

- your breathing problem worsens
- your need to use your inhaled rescue medicine more than usual
- your inhaled rescue medicine does not relieve your symptoms

Driving and using machines

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

Side effects

Like all medicines, Yupelri® can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Serious side effects include:

- sudden breathing problems immediately after inhaling Yupelri®
- new or worsened eye problems including acute narrow-angle glaucoma, its symptoms include:
 - red eyes
 - blurred vision
 - seeing halos or bright colors around lights
 - eye pain or discomfort
 - nausea or vomiting
- new or worsened urinary retention, its symptom include:
 - difficulty urinating
 - urinating frequently
 - urination in a weak stream or drips
 - painful urination
- serious allergic reaction, its symptoms include:
 - rash
 - hives
 - severe itching

- swelling of your face, mouth and tongue
- difficulty breathing or swallowing
- inflammation of the lining of bronchial tubes

Common side effects include:

- cough
- common cold
- upper respiratory tract infection
- headache
- back pain
- dizziness/ lightheadedness
- hypertension
- dry mouth
- Severe Constipation

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Yupelri®

- Storage

Keep out of the reach and sight of children.

Store at room temperature below 30°C.

Store Yupelri® in the unopened protective foil pouch and only open the foil pouch right before you are ready to use Yupelri®.

Protect from direct sunlight and excessive heat.

Throw away the vial of Yupelri® if the solution is not clear and colorless.

- Disposal

Throw away the vial of Yupelri® and any leftover medicine after use.

Product Description

- What it looks like

Yupelri® inhalation solution is supplied as a 175 mcg/3 mL sterile, clear, colorless, aqueous solution in unit-dose low-density polyethylene vials.

Each vial is overwrapped in a foil pouch and supplied in cartons containing either 30 individually pouched unitdose vials (NDC 49502-806-93) or 7 individually pouched unit-dose vials (NDC 49502-806-77).

- Ingredients

- Active ingredient
Revefenacin

- Inactive ingredients
Sodium chloride, citric acid, sodium citrate and water for injection
Hydrochloric acid or sodium hydroxide may be used to adjust pH.

- MAL number:

MAL *****

Manufacturer

The Ritedose Corporation
1 Technology Circle
Columbia,
South Carolina (SC) 29203
United States

Product Registration Holder

Viatrix Sdn Bhd
15-03 & 15-04, Level 15, Imazium,
No. 8, Jalan SS 21/37,
Damansara Uptown,
47400, Petaling Jaya, Selangor,
Malaysia.

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10/06/2025

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Instruction for use

YUPELRI is used only in a standard jet nebulizer 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 YUPELRI or other medicines.

Important Information:

- Do not mix YUPELRI with other medicines in your nebulizer.
- YUPELRI 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 YUPELRI.
- Use your YUPELRI right away after opening.

Using YUPELRI:

Read the following Steps before using YUPELRI. 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 YUPELRI from the foil pouch (Figure 1).

Remove vial from pouch.

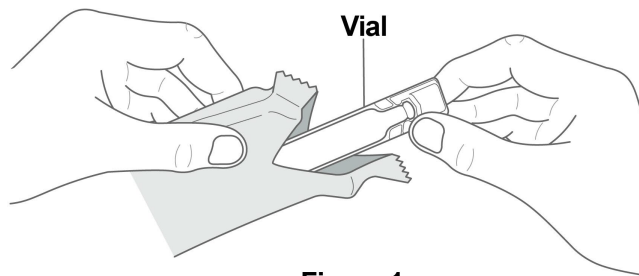


Figure 1

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.

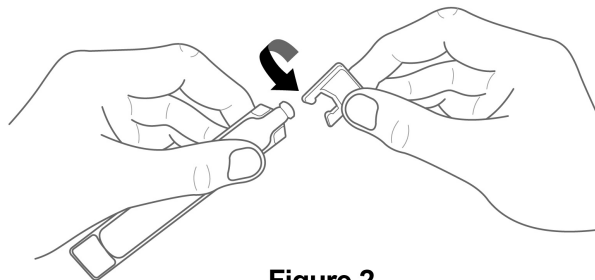


Figure 2

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

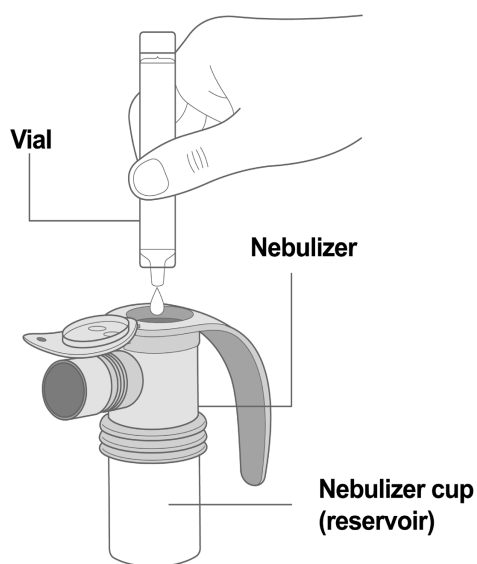


Figure 3

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

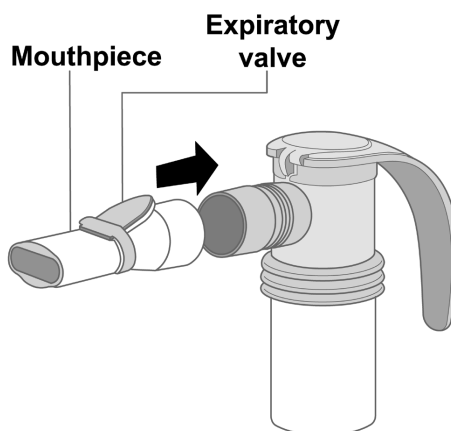


Figure 4

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).

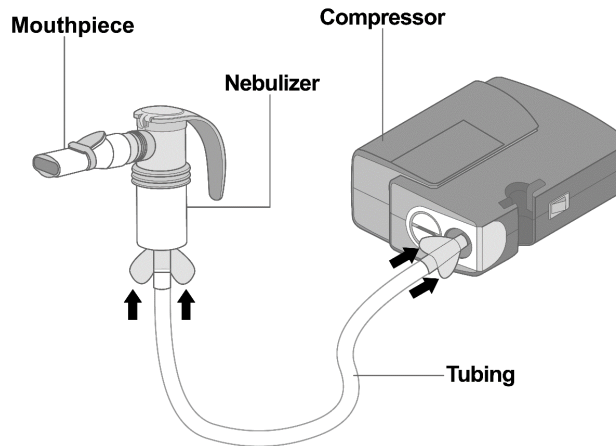


Figure 5

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).

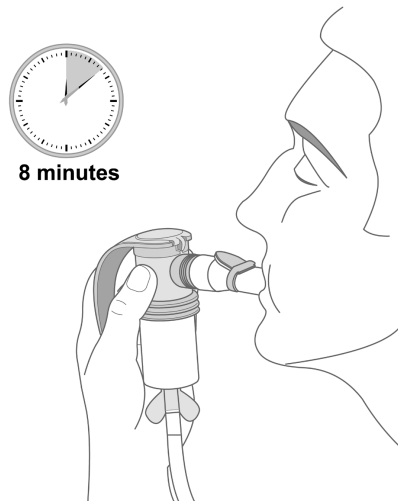


Figure 6

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.