

1.3.2 PROPOSED CLEAN PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S4**

REFENA 175 µg/3 ml Inhalation solution

Revefenacin

Sugar free

Read all of this leaflet carefully before you start using REFENA

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

1. What REFENA is and what it is used for

REFENA 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.

REFENA 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.

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

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

Use in children

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

2. What you need to know before you use REFENA

Do not use REFENA:

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

Warnings and precautions

Take special care with REFENA:

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

Other medicines and REFENA

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 REFENA, please consult your doctor, pharmacist or other healthcare professional for advice before using REFENA.

Pregnancy

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

Breast-feeding

Mothers taking REFENA are advised to not breastfeed their babies.

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

Driving and using machines

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

3. How to use REFENA

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

Always use REFENA 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 REFENA.

REFENA is only for use with a nebuliser.

INSTRUCTIONS FOR USE

REFENA 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 REFENA.

Important Information:

- Do not mix REFENA with other medicines in your nebuliser.
- REFENA 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 REFENA.
- Use your REFENA right away after opening.

Using REFENA:

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

Remove vial from pouch.

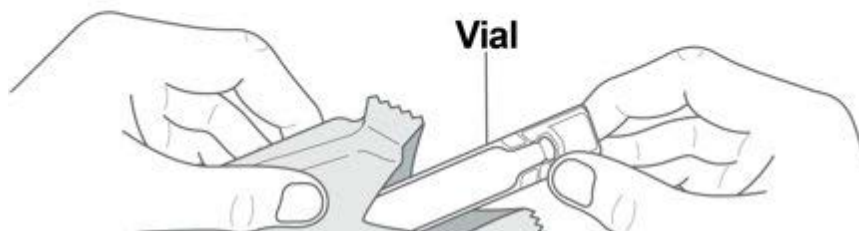


Figure 1

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.

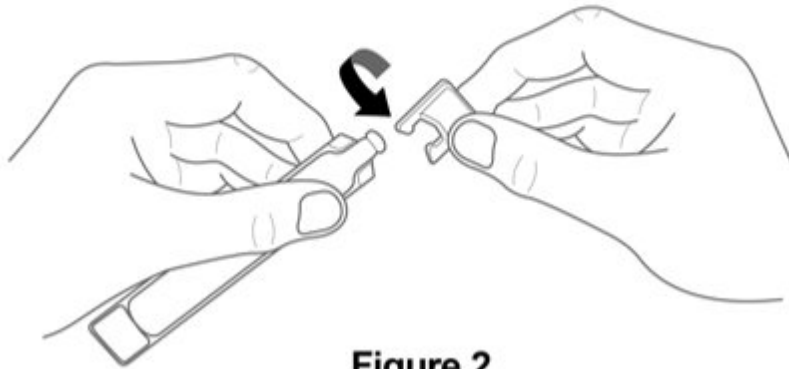


Figure 2

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

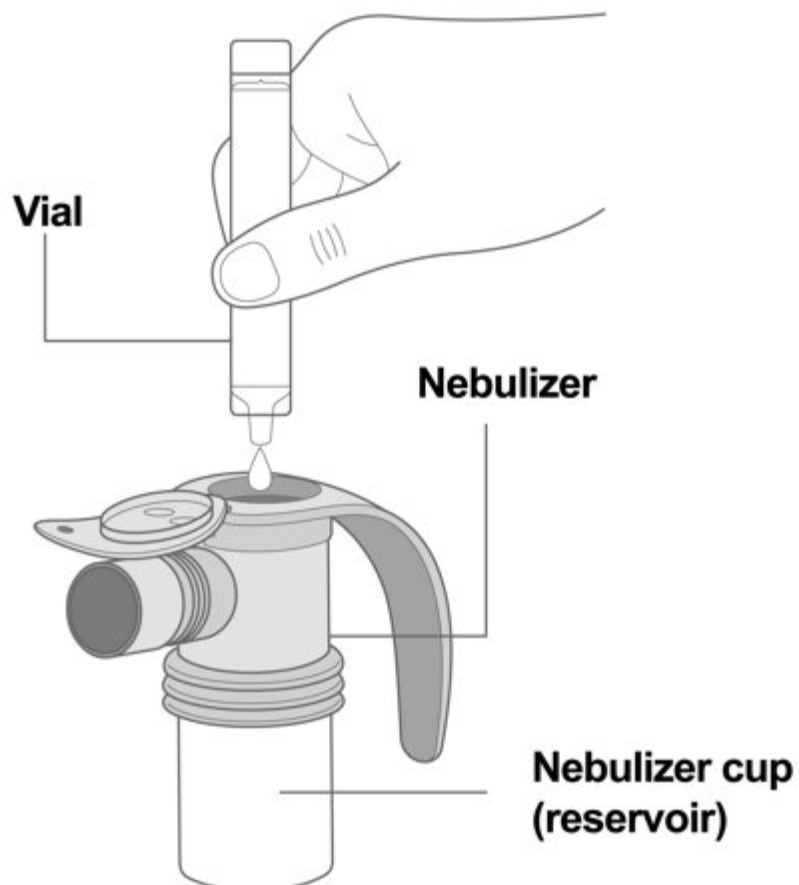


Figure 3

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

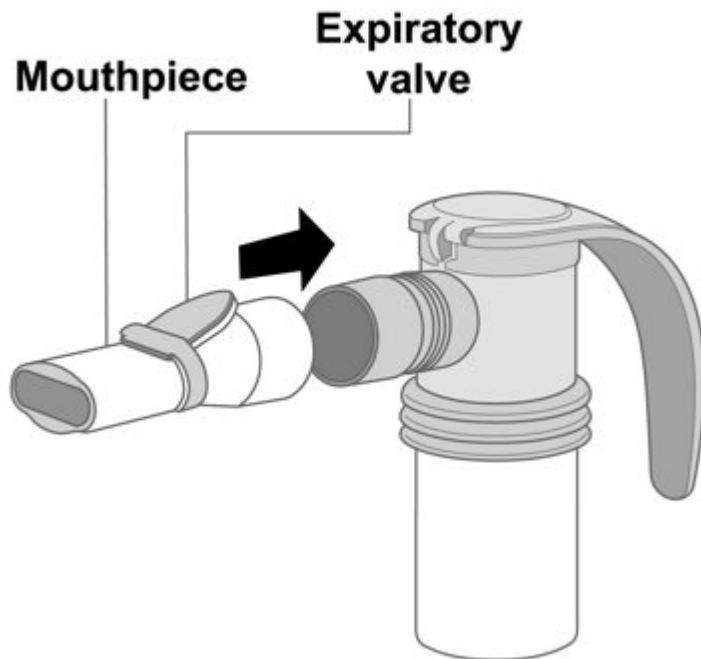


Figure 4

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).

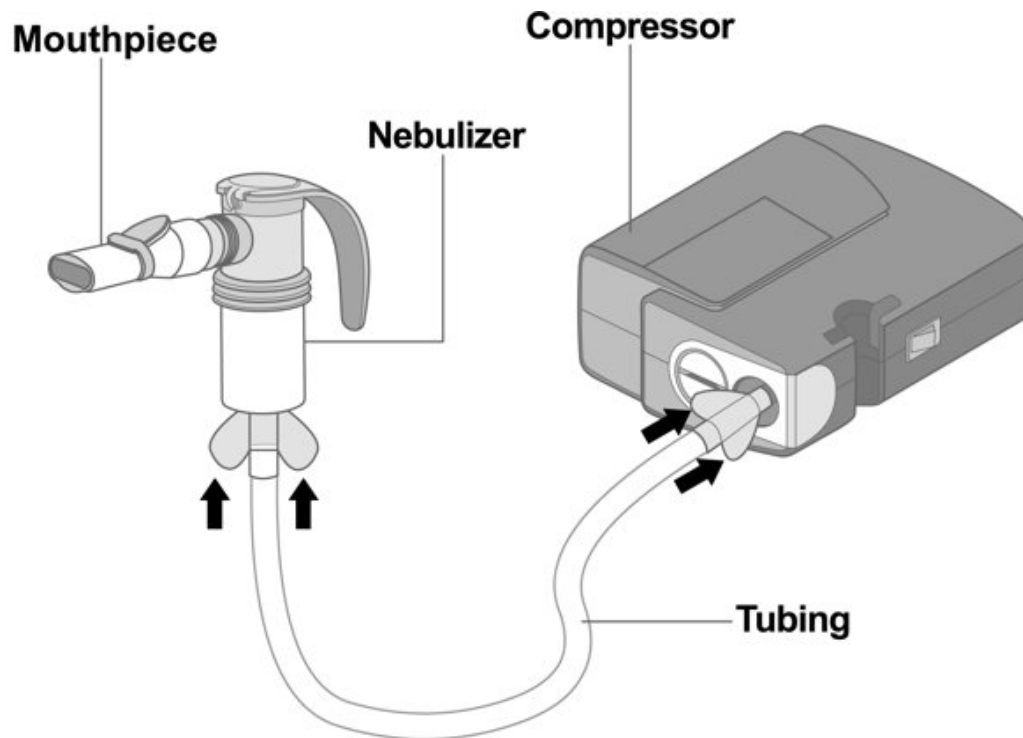


Figure 5

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).

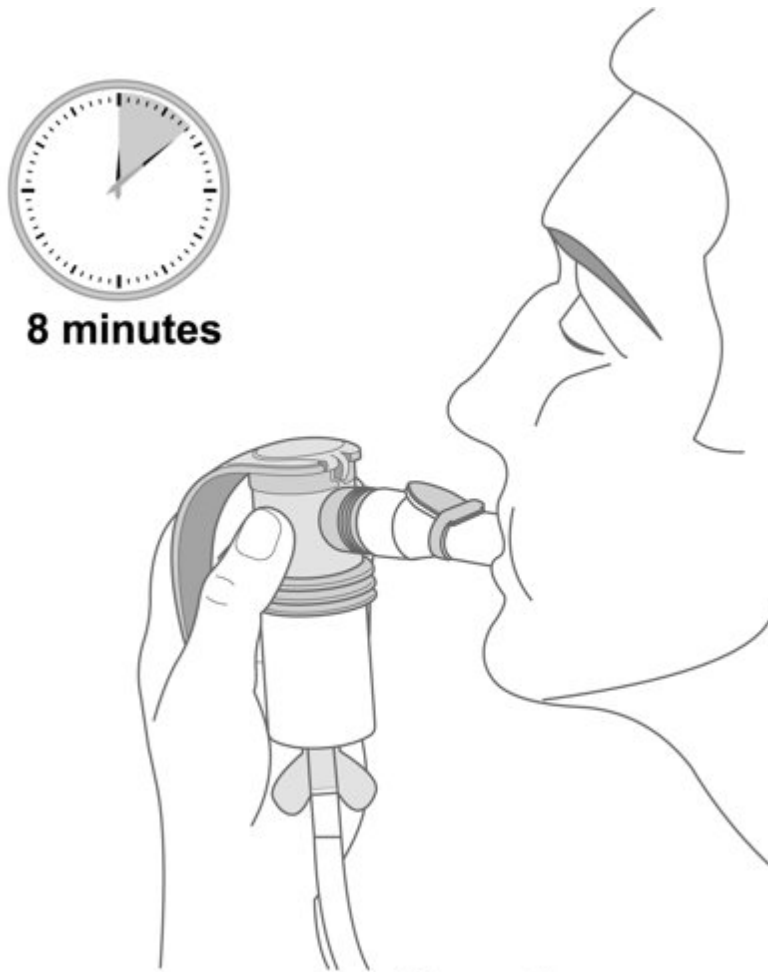


Figure 6

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 REFENA unless your doctor has taught you how to use it with your nebulizer and you understand how to use it correctly.

REFENA 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 REFENA with other medicines in your nebuliser.

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

Use REFENA 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.

REFENA does not relieve sudden symptoms of COPD and you should not use extra doses of REFENA 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 REFENA is too strong or too weak, tell your doctor or pharmacist.

If you use more REFENA 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 REFENA, you may experience symptoms, such as worsening shortness of breath, chest pain, or increased heart rate.

If you missed a dose of REFENA:

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

Effects when treatment with REFENA is stopped

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

4. Possible side effects

REFENA can have side effects.

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

If any of the following happens, stop using REFENA 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 REFENA. 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 REFENA,
- 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 REFENA 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 REFENA.

5. How to store REFENA

Store all medicines out of reach of children.

- Store at or below 25 °C. Protect from direct sunlight and excessive heat.
- Store REFENA in the unopened protective foil pouch and only open the foil pouch right

before you are ready to use REFENA.

- Discard any solution that is not clear and colourless.
- REFENA 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 REFENA.
- 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).

6. Contents of the pack and other information

What REFENA contains

The active substance is revefenacin. Each REFENA 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 REFENA looks like and contents of the pack

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

REFENA 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
REFENA**

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

MYLAN (PTY) LTD

4 Brewery Street

Isando, Gauteng, 1609

Republic of South Africa

This leaflet was last revised in

Registration numbers

55/5.4/0037.036

Access to the corresponding Professional Information

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