

BERODUAL N METERED DOSE INHALER

IPRATROPIUM BROMIDE/FENOTEROL HYDROBROMIDE (20mcg/50mcg)

What is in this leaflet

1. What BERODUAL N MDI is used for
2. How BERODUAL N MDI works
3. Before you use BERODUAL N MDI
4. How to use BERODUAL N MDI
5. While you are using it
6. Side effects
7. Storage and Disposal of BERODUAL N MDI
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of RiMUP revision

What BERODUAL N MDI is used for

Berodual N helps to open the airways and make breathing easier in people with asthma or long-term lung problems such as chronic bronchitis, with or without emphysema (long-term lung condition that causes shortness of breath).

People with asthma or certain types of lung and airway diseases may also need anti-inflammatory medicines as advised by their doctor.

How BERODUAL N MDI works

Berodual N MDI is a medicine that contains two active ingredients (the anticholinergic agent ipratropium bromide and the beta2-agonist fenoterol hydrobromide) in combination. Both active ingredients relax the airway muscles and thus cause the bronchi to widen and make breathing easier.

Before you use BERODUAL N MDI

- When you must not use it

Do not take this medicine if:

- you are allergic to ipratropium bromide or fenoterol hydrobromide or any other ingredients of this medicine (listed in Product Description) or to other atropine-like substances.
- you have certain serious heart conditions, such as a heart muscle disease that blocks blood flow from the heart or very fast or irregular heartbeat.

- Before you start to use it

Check with your doctor or pharmacist before taking BERODUAL N MDI if you:

- have heart problems, such as heart disease, irregular heartbeat, or chest pain
- have high blood pressure
- have diabetes that is not well controlled
- have thyroid problems
- have glaucoma (high pressure in the eyes) or eye pain
- have difficulty passing urine or an enlarged prostate
- have low potassium levels in the blood
- have cystic fibrosis

Pregnancy and lactation

Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breast-feeding before using any medicine.

Tell your doctor if you are pregnant or planning to become pregnant. Berodual should only be used during pregnancy if your doctor decides that the benefit to you is greater than any possible risk to your baby.

Berodual should be used with caution while breastfeeding, as small amounts of the medicine may pass into breast milk.

- 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.

Inform your doctor or pharmacist if you are taking:

- other inhalers or medicines used to open the airways
- medicines for high blood pressure (including beta-blockers)

- medicines for heart problems such as digoxin
- medicines for asthma such as theophylline
- steroid medicines
- water tablets (diuretics)
- medicines for depression (such as certain antidepressants)

If you are going to undergo procedures or surgery that requires anaesthesia, please inform your doctor or nurse.

How to use BERODUAL N MDI

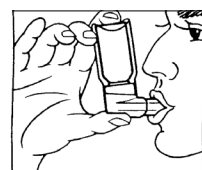
How to Use Your Inhaler

Before first use:

- Remove the protective cap.
- Press the valve twice to release medicine.

Before each use:

1. Remove the protective cap.
2. If not used for 3+ days, press the valve once.
3. Breathe out fully.
4. Hold the inhaler upright (see Fig. 1), close your lips around the mouthpiece.

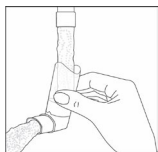


(Fig. 1)

5. Breathe in deeply while pressing the canister once to release a dose.
6. Hold your breath for a few seconds, then breathe out.
7. Repeat for a second dose if needed.
8. Replace the protective cap after use.

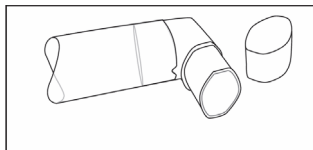
Important notes:

- The inhaler delivers 200–300 puffs. Even if you see fluid left, replace the inhaler when the labelled doses are finished.
- Clean the mouthpiece at least once a week.
- Remove the canister and dust cap.
- Rinse the mouthpiece with warm water (Fig. 2).



(Fig. 2)

- Shake out water and let it air-dry (do not use heat).
- Replace the canister and dust cap once dry (Fig. 3).



(Fig. 3)

- Only use the supplied mouthpiece with this inhaler.
- Do not use the inhaler with other mouthpieces or other aerosols.
- Keep away from heat ($>50^{\circ}\text{C}$) and do not open forcefully.

- How much to use

Your doctor will decide on the dosing based on your age, condition, and how severe your breathing problem is.

Intermittent or long-term use:

The usual dose is 1 to 2 puffs when needed. Do not use more than 8 puffs in a day unless advised by your doctor.

Acute asthma episodes

- 2 puffs usually enough for relief.
- If no improvement after 5 minutes, take 2 more puffs.
- If 4 puffs do not help, seek medical help immediately.

Use in Children: only under adult supervision and medical advice.

If your breathing does not improve or suddenly gets worse, seek medical help immediately.

- When to use it

Use as needed or as directed by your doctor or pharmacist.

- How long to use it

Use this medicine for the duration that your doctor recommends.

- 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 or anyone else may have used too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too much of this medicine may cause a higher risk of experiencing a side effect such as racing heart, palpitation, tremor, high blood pressure, low blood pressure, widening of the pulse pressure, chest pain (anginal pain), abnormal heart rhythm (arrhythmias), low potassium level in blood, flushing due to an overdose with fenoterol hydrobromide. Too much acid in the blood has also been observed with fenoterol when taken in doses higher than recommended for the approved indications of Berodual.

The following symptoms of an overdose with ipratropium bromide may occur: dry mouth and visual accommodation disorder.

While you are using BERODUAL N MDI

- Things you must do

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using BERODUAL N MDI.

Tell your doctor immediately if you become pregnant while using this medication.

Take BERODUAL N MDI only with a doctor's prescription.

- Things you must not do

Do not stop using the medicine unless advised by your doctor.

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

Do not give BERODUAL N MDI to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

This medicine may affect your ability to drive or use machines. If this medicine makes you feel dizzy, shaky, or have blurred vision, do not drive or use machines and contact your doctor immediately.

Do not let the medicine get into your eyes, as it may cause eye pain or blurred vision.

If your breathing suddenly gets worse or does not improve, seek medical help immediately.

Do not use more than the recommended dose.

If you need to use Berodual more often than usual, see your doctor — this may mean your condition is getting worse.

Side effects

Like all medicines, BERODUAL N MDI can cause side effects, although not everybody gets them.

As with all inhalation therapy, Berodual N MDI may show symptoms of local irritation.

The most frequent side effects reported in clinical trials were cough, dry mouth, headache, shivering, sore throat, sickness, dizziness, voice disturbance, irregular heartbeat, palpitations, vomiting, increased blood pressure and nervousness.

Possible side effects are:

Immune system disorders

- severe allergic reaction (anaphylactic reaction)
- hypersensitivity

Metabolism and nutritional disorders

- low level of potassium in the blood (hypokalemia)

Psychiatric disorders

- nervousness

- feeling restless, uneasy (agitation) - mental disorder	- sore oral mucosa (stomatitis) - sore tongue (glossitis) - issues with gut movement (gastrointestinal motility disorder) - diarrhoea - constipation - mouth swelling (oedema mouth)	medicines no longer required. These measures will help to protect the environment.
Nervous system disorders - headache - tremor - dizziness		Product Description - <u>What it looks like</u> Clear, colourless liquid, free from suspended particles
Eye disorders - high eye pressure (glaucoma) - high pressure inside the eye (intraocular pressure increased) - eye focusing problem (accommodation disorder) - pupil widening (mydriasis) - vision blurred - eye pain - swelling of the cornea (corneal oedema) - red eyes due to the congestion of blood in the conjunctiva (conjunctival hyperaemia) - coloured rings around sources of light (halo vision)	Skin and subcutaneous tissue disorders - urticaria - rash - Skin itch (pruritus) - Skin and tissue swelling (angioedema) - excessive sweating (hyperhidrosis)	- <u>Ingredients</u> - Active ingredient(s) The active substances are ipratropium bromide monohydrate and fenoterol hydrobromide. Dose per actuation: 21 mcg ipratropium bromide + 50 mcg fenoterol hydrobromide.
	Musculoskeletal and connective tissue disorders - muscular weakness - sudden muscle tightening (muscle spasm) - muscle pain (myalgia)	- Inactive ingredients • Anhydrous citric acid • Purified water • Absolute ethanol • Propellant HFA 134a • Nitrogen (inert gas)
Cardiac disorders - tachycardia, heart rate increased - palpitations - irregular heartbeat (arrhythmia) - irregular heartbeat (atrial fibrillation) - rapid heartbeat above the ventricles (supraventricular tachycardia) - reduced blood flow to the heart (myocardial ischaemia)	Renal and urinary disorders - urinary retention	- <u>MAL number:</u> MAL20033350AZ
	Investigations - blood pressure systolic increased - blood pressure diastolic decreased	Manufacturer Boehringer Ingelheim Pharma GmbH & Co. KG Binger Straße 173 55216 Ingelheim am Rhein Germany for Boehringer Ingelheim International GmbH Ingelheim am Rhein Germany
Respiratory, thoracic and mediastinal disorders - cough - throat inflammation (pharyngitis) - voice disturbance (dysphonia) - tightening of the airways (bronchospasm) - throat irritation - swelling in the throat (pharyngeal oedema) - sudden throat tightening (laryngospasm) - unexpected airway tightening (bronchospasm paradoxical) - dry throat	Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine. You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npdra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].	Product Registration Holder Boehringer Ingelheim (Malaysia) Sdn. Bhd. Level 23A, Mercu Aspire, No. 3, Jalan Bangsar, KL Eco City, 59200 Kuala Lumpur, Malaysia.
	Storage and Disposal of BERODUAL N MDI - <u>Storage</u> Keep out of the reach and sight of children. Store below 30°C. - <u>Disposal</u> Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of	Date of revision 13/02/2026 Serial Number NPRA(R4/1)260126/00004
Gastrointestinal disorders - vomiting - sickness (nausea) - dry mouth		

