1.3.2.1 APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

ADCO NEBRAFEN inhalant solution

Each 4 ml solution per ampoule of ADCO NEBRAFEN contains fenoterol hydrobromide 1,25 mg and ipratropium bromide 0,5 mg.

Sugar free

Read all of this leaflet carefully before you start using ADCO NEBRAFEN

- 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.
- ADCO NEBRAFEN 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

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1. What ADCO NEBRAFEN is and what it is used for

The active ingredients fenoterol hydrobromide and ipratropium bromide both belong to the group of medicines known as bronchodilators. ADCO NEBRAFEN is used to open up the airways to make breathing easier for patients with bronchial asthma, chronic bronchitis and emphysema (all lung disorders) and any condition that obstructs the airways. This medicine is for inhalation only.

2. What you need to know before you use ADCO NEBRAFEN

Do not use ADCO NEBRAFEN:

- If you are hypersensitive (allergic) to fenoterol hydrobromide and/or ipratropium bromide or any of the other ingredients of ADCO NEBRAFEN (listed in section 6)
- If you have hypertrophic obstructive cardiomyopathy and tachyarrhythmia (heart conditions)
- If you are about to give birth due to the uterine relaxant effect of fenoterol
- If you are under the age of 18 years.

Warnings and precautions

Special care should be taken with ADCO NEBRAFEN and your doctor informed if you have:

- Diabetes (high blood sugar levels)
- Any heart disorders or conditions
- High blood pressure
- Glaucoma (pressure in the eye)

- An enlarged prostrate
- Urinary retention (difficulty emptying your bladder)
- Any type of bowel or intestine obstruction or inflammation
- Diarrhoea and/or fever
- Down's syndrome or albinism
- Parkinsonism.

It is important not to exceed the maximum dose. High doses may increase the risk of serious side effects affecting your heart. The risk is further increased if you are taking other medicines that cause low potassium levels and an abnormal heartbeat, or if you have low oxygen levels or have too much acid in your body.

Ensure you have been instructed on the correct administration of ADCO NEBRAFEN inhalation solution. Care must be taken not to allow the solution or mist to enter into the eyes. It is recommended that the nebulised solution be administered via a mouth piece. If this is not available and a nebuliser mask is used, it must fit properly. If the solution or mist does enter your eyes, it may cause certain eye conditions and symptoms. If this does happen, consult your doctor.

Children and adolescents

Do not use this medicine if you are under the age of 18 years.

Other medicines and ADCO NEBRAFEN

Always tell your health care provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

In particular, tell your doctor, pharmacist or health care provider if you are taking any other medicine:

- Used to open up the airways to make breathing easier,
- Used for asthma or any lung conditions
- Used for depression.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Do not use this medicine if you are pregnant or breastfeeding.

Driving and using machines

It is not always possible to predict to what extent ADCO NEBRAFEN may interfere with your daily activities. You should ensure that you do not engage in activities requiring mental alertness, judgement and/or sound coordination and vision e.g. driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which ADCO NEBRAFEN affects you.

3. How to use ADCO NEBRAFEN

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

For oral inhalation only, administered via a ventilator or a nebuliser. The solution is ready for

use and requires no dilution.

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

The usual dose for adults is:

Treatment of attacks: If you are experiencing an attack of difficult breathing, use one ampoule of ADCO NEBRAFEN. This should be sufficient for prompt symptom relief in most cases. If in very severe cases, two unit dose vials are required for symptom relief, this should be administered under medical supervision.

Long-term treatment: One ampoule of ADCO NEBRAFEN three to four times daily.

On demand treatment (symptom oriented) is preferable to regular use.

DO NOT EXCEED THE RECOMMENDED DOSE.

Instructions for use:

1. Prepare the nebuliser for filling, according to the instructions provided by the manufacturer or your doctor.
2. Remove one ampoule by detaching from the adjacent one.
3. Flick the top of the ampoule to dispel any fluid in the neck.
4. Detach top portion by twisting.
5. Squeeze the contents of the ampoule into the reservoir of the nebuliser.
6. Assemble the nebuliser and use as directed. After use throw away any solution left in the reservoir and clean the nebuliser, following the manufacturer's instructions.

Since the ampoules do not contain a preservative, it is important that the contents of each ampoule are used up immediately after opening and that a fresh ampoule is used for each administration to avoid microbial contamination. Partly used, opened or damaged ampoules should be discarded.

Your doctor will tell you how long your treatment with ADCO NEBRAFEN will last. If you have the impression that the effect of ADCO NEBRAFEN is too strong or too weak, tell your doctor or pharmacist.

If you use more ADCO NEBRAFEN than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Symptoms of overdosage include**:** Feeling hot, trembling or shaking, nausea, restlessness, fast heartbeat, dizziness, headache and a feeling of pressure in the chest,

4. Possible side effects

ADCO NEBRAFEN can have side effects.

Not all side effects reported for ADCO NEBRAFEN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ADCO NEBRAFEN, please consult your healthcare provider for advice.

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

- Hypersensitivity reactions: swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing; rash or itching; fainting.
- Tremor, shaking or restlessness
- Difficulty seeing or sensitivity to light
- Changes in the way your heart beats, for example, if you notice it beating faster,

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

Tell your doctor if you notice any of the following:

- Muscle cramps and tension
- Dizziness
- Fatigue
- Sweating
- Headache
- Dryness of the mouth and difficulty swallowing
- Thirst
- Dryness of the skin
- Throat irritation
- Cough
- Difficulty urinating
- Constipation

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc-org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ADCO NEBRAFEN.

For reporting of side effects directly to the Holder of the Certificate of Registration, contact +27 11 635 0134 or email Adcock.aereports@adcock.com

5. How to store ADCO NEBRAFEN

Store the ampoules in the outer packaging, at or below 25 °C, until required for use. Protect from light. Store all medicines out of reach of children.

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 ADCO NEBRAFEN contains

The active substances: Each 4 ml solution per ampoule of ADCO NEBRAFEN contains fenoterol hydrobromide 1,25 mg and ipratropium bromide 0,5 mg.

The other ingredients are: sodium chloride, sodium hydroxide (pH adjuster), hydrochloric acid (pH adjuster) and water for injections.

The solution is isotonic and preservative free.

What ADCO NEBRAFEN looks like and contents of the pack

ADCO NEBRAFEN is a clear, colourless to pale yellow solution in clear, colourless polyethylene ampoules.

ADCO NEBRAFEN is available in 5 ml polyethylene ampoules containing 4 ml of solution. Sixty ampoules are packed in a foil pouch and then in a carton.

Holder of Certificate of Registration

Adcock Ingram Critical Care (Pty) Ltd.

1 Sabax Road

Aeroton

Johannesburg

2013

Tel: +27 11 494 8000

This leaflet was last revised in

Date of registration: 15 November 2002

Date amended: 01 July 2025

Registration number

35/10.2.1/0004

Namibia: NS2 04/10.2.1/1030

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Botswana: S2 BOT1502799

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