

PACKAGE LEAFLET

Package leaflet: Information for the user

Brodilaten 1.25 mg / 2.5 mL nebuliser solution
Brodilaten 2.5 mg / 2.5 mL nebuliser solution
Brodilaten 5.0 mg / 2.5 mL nebuliser solution
salbutamol

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is the following:

- Brodilaten 1.25 mg / 2.5 mL Nebuliser solution
- Brodilaten 2.5 mg / 2.5 mL Nebuliser solution
- Brodilaten 5.0 mg / 2.5 mL Nebuliser solution

In the rest of this leaflet your medicine is called Brodilaten.

What is in this leaflet

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

1. What Brodilaten is and what it is used for

Brodilaten contains a medicine called salbutamol. This belongs to a group of medicines called fast-acting bronchodilators.

- Bronchodilators help the airways in your lungs to stay open. This makes it easier for air to get in and out.
- They help to relieve chest tightness, wheezing and cough.

Brodilaten 1.25 mg/2.5 mL: This low dose is adapted for use in children and infants only to treat severe asthma attacks, where inhalation of high doses of salbutamol is required.

Brodilaten is used to treat breathing problems in people with asthma and other chest illnesses. It is usually given to people who suffer quite badly from these conditions. Brodilaten is also given to treat severe attacks of asthma.

Brodilaten is a liquid contained in an ampoule. The liquid is put into a machine called a nebuliser. This machine makes a fine mist for you to breathe in through a face mask.

Depending on the severity of asthma, your doctor may prescribe Brodilaten alone or in addition to continuous background treatment with one or more other medications, such as inhaled corticosteroids.

2. What you need to know before you use Brodilaten

Do not use Brodilaten:

- if you are allergic to salbutamol sulfate (the active substance) or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Brodilaten if:

- your asthma is active (for example you have frequent symptoms or flare ups, such as breathlessness that makes speaking, eating or sleeping difficult, cough, wheezing, tight chest or limited physical ability), you should tell your doctor right away who may start or increase a medicine to control your asthma such as an inhaled corticosteroid.
- you have high blood pressure.
- you are diabetic.
- you have an overactive thyroid gland.
- you have a history of heart problems such as an irregular or fast heartbeat, severe heart failure or chest pain (angina).
- you use another nebuliser solution such as ipratropium bromide, make sure the mist does not get in your eyes. This can be prevented by using a mouthpiece instead of a face mask or goggles.
- you are taking xanthine derivatives (such as theophylline) or steroids to treat asthma
- you are taking water tablets (diuretics), sometimes used to treat high blood pressure or a heart condition
- if you have taken other drugs used to relieve stuffy nose (such as ephedrine or pseudoephedrine) or other medicines used to treat asthma

A condition known as lactic acidosis has been reported in association with high therapeutic doses of salbutamol, mainly in patients being treated for an acute bronchospasm (see Section 3 and 4). Increase in lactate levels may lead to shortness of breath and hyperventilation even though there may be improvement in your wheezing. Tell your doctor as soon as possible if you feel that your medicine is not working as well as usual (for example you need higher doses to relieve your breathing problems or your inhaler fails to give relief for at least 3 hours) and you need to use the nebuliser more than your doctor has recommended.

If you use Brodilaten more than twice a week to treat your asthma symptoms, not including preventive use before exercise, this indicates poorly controlled asthma and may increase the risk of severe asthma attacks (worsening of asthma) that can have serious complications and may be life-threatening or even fatal. You should contact your doctor as soon as possible to review your asthma treatment.

If you use a medicine against inflammation of your lungs daily, e.g., “inhaled corticosteroid”, it is important to continue using it regularly, even if you feel better.

Use of salbutamol can sometimes cause lowering of potassium levels in the blood, particularly if you are taking certain other medicines at the same time. If you are at risk of this happening, your doctor might recommend further tests to monitor your blood more closely.

If your breathing or wheezing gets worse straight after taking this medicine, stop using it immediately and tell your doctor as soon as possible.

Other medicines and Brodilaten

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription. This includes herbal medicines.

In particular tell your doctor, nurse or pharmacist if you are taking:

- medicines for an irregular or fast heartbeat.
- other medicines for your asthma.
- medicines that decrease blood glucose (antidiabetics).

Remember to take this medicine with you if you go to hospital.

Brodilaten with food and drink

You can use Brodilaten at any time of day, with or without food.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before using this medicine.

Brodilaten can be used during pregnancy when considered necessary by your doctor.

Athletes

The use of salbutamol may cause a positive outcome in anti-doping control tests.

Driving and using machines

Brodilaten is not likely to affect you being able to drive or use any tools or machines.

You should not drive or use machinery while using the nebuliser as this makes the mist for you to inhale.

Brodilaten contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per ampoule, that is to say essentially 'sodium-free'.

3. How to use Brodilaten

Brodilaten should be used as required rather than regularly.

Always use this medicine exactly as your doctor has told you. Check with your doctor, nurse or pharmacist if you are not sure.

Using this medicine

- **do not inject or swallow the liquid.** Brodilaten should only be inhaled using your nebuliser
- **do not let the liquid, or the mist produced by the nebuliser get into your eyes.** You can wear glasses or goggles to protect them.
- your doctor, nurse or pharmacist should show you how to use your medicine.
- each small plastic container (ampoule) contains some liquid.
- the liquid is put into a nebuliser. This makes a fine mist for you to breathe in through a face mask or mouthpiece.
- use your nebuliser in a well-ventilated room as some of the mist will be released into the air and may be breathed in by others.

Adults, adolescents aged 12 years and over and children 4 to 11 years of age

- The usual starting dose is 2.5 mg up to four times daily. Increased to 5 mg up to four times daily if required.

Brodilaten 1.25 mg/2.5 mL: This low-dose presentation is not suitable for treating adults but is suitable for children and infants.

Infants and children: 50 to 150 micrograms of salbutamol / kg (i.e. 0.1 to 0.3 mL/kg of Brodilaten 1.25 mg in nebulized form) without generally exceeding 5 mg of salbutamol in nebulised form for toddlers over 18 months up to 2 years old (i.e. four single doses of Brodilaten 1.25 mg or one single dose of Brodilaten 5.0 mg in nebulised form) and 2.5 mg of salbutamol for infants and toddlers under 18 months (i.e. two single doses of Brodilaten 1.25 mg or one single dose of Brodilaten 2.5 mg in nebulised form).

Using your ampoules

1. Your ampoules are overwrapped in a non-transparent protective pouch. Do not open the protective pouch until you need to use them.
2. Open the protective pouch. Hold the strip of ampoules in one hand, with your other hand hold the last ampoule in the row.
3. Twist the ampoule downwards and away from you.

4. Return the remaining ampoules to the protective pouch. Write the discard date, in the space provided on the pouch as a reminder. The discard date is 3 months from the date you opened the protective pouch. Return the opened pouch to the box.
5. Hold the top of the ampoule you have just removed. Open the ampoule.
6. Put the open end of the ampoule into the nebuliser bowl and squeeze slowly. Make sure that all the contents are emptied into the nebuliser.
7. Assemble the nebuliser and use it as directed.

Diluting your ampoules

- **do not dilute the contents of an ampoule unless you are told to by your doctor.**
- if your doctor has told you to dilute the solution, empty the contents of the ampoule into the nebuliser bowl.
- add the amount of sterile normal saline your doctor has told you to use.
- put the top on the nebuliser bowl and shake gently to mix the contents.

If dilution is necessary then only sterile normal saline should be used.

Nebulization should generally not exceed 10 to 20 minutes.

The technique used by the patient should be verified regularly.

After use

After nebulization, the unused solution remaining in the device tank must be discarded.

Cleaning and maintenance of the equipment will be performed according to the recommendations of the manufacturer.

The single-dose containers do not contain any preservatives; they must be used immediately after opening.

A new single-dose container must be used for each nebulization. The content of partially opened or damaged single-dose containers should not be administered.

If you use more Brodilaten than you should

If you use more medicine than you should, talk to a doctor as soon as possible.

The following effects may happen:

- your heart is beating faster than usual
- you feel shaky
- hyperactivity

These effects usually wear off in a few hours.

If you forget to use Brodilaten

- If you forget a dose, take it as soon as you remember it.
- However, if it is time for the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

If you stop using Brodilaten

Do not stop using Brodilaten without talking to your doctor.

If you think this medicine is not working well enough for you

If your medicine does not seem to be working as well as usual, talk to your doctor as soon as possible.

Your chest problem may be getting worse and you may need a different medicine. Do not take extra Brodilaten unless your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

If your breathing difficulty (wheezing) gets worse straight after taking this medicine, stop using it immediately, and tell your doctor as soon as possible.

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Allergic reactions (may affect up to 1 in 10,000 people)

If you have an allergic reaction, stop taking Brodilaten and see a doctor straight away. Signs of an allergic reaction include: swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, itchy rash, feeling faint and light headed, and collapse.

If you suffer from heart disease, tell your doctor or go to the casualty department at your nearest hospital IMMEDIATELY if you experience chest pain or any symptoms of your heart disease worsening.

Talk to your doctor as soon as possible if:

- you feel your heart is beating faster or stronger than usual (palpitations). This is usually harmless, and usually stops after you have used the medicine for a while.
- you may feel your heartbeat is uneven or it gives an extra beat.

If any of these happen to you, talk to your doctor as soon as possible. **Do not stop using this medicine unless told to do so.**

Lactic acidosis (frequency: very rare)

- increased level of lactic acid in the blood (manifested by rapid breathing, shortness of breath, although you feel an improvement in wheezing, feeling cold, stomach pain, nausea and vomiting). In such a case, stop treatment with Brodilaten and contact your doctor immediately.

Tell your doctor if you have any of the following side effects which may also happen with this medicine:

Common (may affect up to 1 in 10 people)

- tremors of the extremities (feet and hands),
- increased heart rate,
- headache.

Uncommon (may affect up to 1 in 100 people)

- mouth and throat irritation
- muscle cramps.

Rare (may affect up to 1 in 1,000 people)

- a low level of potassium in your blood
- increased blood flow to your extremities (peripheral dilatation)

Very rare (may affect up to 1 in 10,000 people)

- nervousness
- agitation
- cardiac arrhythmias
- as with other products administered by inhalation, coughing or increased difficulty breathing could occur following inhalation of the product. In this case, stop treatment and contact your doctor to consider another treatment.

Additional side effects in children and adolescents

In addition, very rare adverse events of psychiatric / behavioral disorders regarding nervousness and agitation, as well as pruritus have been reported in children.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie.

5. How to store Brodilaten

Keep this medicine out of the sight and reach of children.

Store below 25°C.

Store the ampoules in the outer carton and pouch, in order to protect from light.

When you open the protective pouch:

- note the date of opening.
- add 3 months to this date. This will be the 'discard after' date.
- write the 'discard after' date in the space provided on the pouch
- do not use any unused ampoules remaining from that pouch after the 'discard after' date, return them to your pharmacist for destruction.

If the pouch has not been opened, do not use this medicine after the expiry date, which is stated on the carton, labels and pouch after 'EXP'. The expiry date refers to the last day of that month.

If you are told to stop taking this medicine return any unused Brodilaten to your pharmacist to be destroyed.

Discard any partly used opened or damaged single dose containers.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Brodilaten contains

- 1.25 mg / 2.5 mL: The active substance is salbutamol sulfate. Each 2.5 mL ampoule contains 1.25 mg of salbutamol (as salbutamol sulfate).
- 2.5 mg / 2.5 mL: The active substance is salbutamol sulfate. Each 2.5 mL ampoule contains 2.5 mg of salbutamol (as salbutamol sulfate).
- 5.0 mg / 2.5 mL: The active substance is salbutamol sulfate. Each 2.5 mL ampoule contains 5 mg of salbutamol (as salbutamol sulfate).
- The other ingredients are sodium chloride, water for injections and sulfuric acid (for pH adjustment).

What Brodilaten looks like and contents of the pack

Brodilaten 1.25 mg / 2.5 mL Nebuliser solution is packed in strips of 5 or 6 ampoules, depending on the pack size, overwrapped in non-transparent aluminium protective pouch. Each carton contains 30 or 60 ampoules.

Brodilaten 2.5 mg / 2.5 mL Nebuliser solution is packed in strips of 5 or 6 ampoules, depending on the pack size, overwrapped in non-transparent aluminium protective pouch. Each carton contains 30 or 60 ampoules.

Brodilaten 5.0 mg / 2.5 mL Nebuliser solution is packed in strips of 5 or 6 ampoules, depending on the pack size, overwrapped in non-transparent aluminium protective pouch. Each carton contains 30 or 60 ampoules.

Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer

Marketing Authorisation Holder: Noridem Enterprises Limited, Evagorou & Makariou, Mitsi Building 3, Office 115, 1065 Nicosia, Cyprus

Manufacturer:

DEMO S.A. PHARMACEUTICAL INDUSTRY, 21st km National Road Athens-Lamia, 14568 Krioneri, Attiki, Greece, **T:** +30 210 8161802, **F:** +30 210 8161587

This medicinal product is authorised in the Member States of the EEA under the following names:

Greece	Brodilaten 1,25 mg / 2,5 mL διάλυμα για εισπνοή με εκνεφωτή Brodilaten 2,5 mg / 2,5 mL διάλυμα για εισπνοή με εκνεφωτή Brodilaten 5,0 mg / 2,5 mL διάλυμα για εισπνοή με εκνεφωτή
Germany	Salbutamol Noridem 1,25 mg Lösung für einen Vernebler Salbutamol Noridem 2,5 mg Lösung für einen Vernebler Salbutamol Noridem 5 mg Lösung für einen Vernebler
Ireland	Brodilaten 1.25 mg / 2.5 mL nebuliser solution Brodilaten 2.5 mg / 2.5 mL nebuliser solution Brodilaten 5.0 mg / 2.5 mL nebuliser solution
France	SALBUTAMOL NORIDEM 1,25 mg/2,5 mL, solution pour inhalation par nébuliseur SALBUTAMOL NORIDEM 2,5 mg/2,5 mL, solution pour inhalation par nébuliseur SALBUTAMOL NORIDEM 5,0 mg/2,5 mL, solution pour inhalation par nébuliseur

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