Package leaflet: Information for the user

Ipratropiumbromide/Salbutamol Sandoz 0,5/2,5 mg per 2,5 ml, verneveloplossing
ipratropium bromide/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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What [nationally completed name] is and what it is used for

Your medicine is called [nationally completed name]. The active ingredients are ipratropium bromide and salbutamol. Ipratropium bromide and salbutamol both belong to a group of medicines called bronchodilators, which help to improve your breathing by opening up your airways. This is achieved by preventing the contraction of the smooth muscles surrounding the airways, therefore allowing the airways to remain open. Ipratropium bromide acts by blocking the nerve signals that go to the muscles surrounding the airways, and salbutamol acts by stimulating the beta$_2$ receptors in the muscles.

[Nationally completed name] is used to treat breathing problems in people with long-standing breathing difficulties (such as chronic bronchitis, emphysema). [Nationally completed name] will relieve wheezing, shortness of breath and chest tightness.

2. What you need to know before you use [nationally completed name]

Do not use [nationally completed name] if:
- You are allergic to ipratropium or salbutamol or any of the other ingredients of this medicine (listed in section 6).
- You are allergic to similar medicines which contain atropine or medicines like atropine.
- You suffer from fast heart rhythms (tachyarrhythmia).
- You have an enlarged heart or a condition known as hypertrophic obstructive cardiomyopathy.
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Warnings and precautions
Talk to your doctor or pharmacist before using [nationally completed name] if**:**

- You experience an abnormal cramping of the muscles around the trachea (paradoxical bronchospasm) after inhalation of ipratropium/salbutamol. This can be life-threatening, you must stop immediately the use of this medicine. Contact your doctor immediately so that a replacement therapy can be started.
- You have difficulties adjusting diabetes.
- You have, or recently had heart or circulation problems.
- You experience tightness of the chest.
- You have an increased thyroid function (hyperthyroidism).
- You have a rare tumor in the adrenal medulla (pheochromocytoma).
- You have glaucoma (increased pressure in the eyes), or have been told you may develop it. Your doctor may advise you to protect your eyes when using [Nationally completed name], for instance using a mouthpiece.
- You have an enlarged prostate.
- You have problems passing water (urine).
- You suffer from cystic fibrosis: you might have increased digestive complaints.

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. If you feel that your medicine is not working as well as usual and you need to use the nebuliser more than your doctor has recommended, immediately talk to a doctor.

Other medicines and [nationally completed name]
Tell your doctor if you are taking, have recently taken or might take any other medicines, in particular any of the following medicines:

- other medicines you are prescribed for respiratory diseases, including bronchodilators, such as beta2-mimetics, anticholinergics and xanthine derivatives (e.g. theophylline).
  These may increase the effect of [nationally completed name] and increase the severity of side effects.
- certain anti-hypertensive agents (beta-blockers).
- certain medicines to treat depression (such “anti-depressants” are medicines that are prescribed for patients suffering from depression and anxiety) This class of medicines includes medicines such as monoamine oxidase inhibitors (e.g. phenelzine) or tricyclic antidepressants (e.g. amitriptyline).
- digoxin (for heart problems) may cause heart rhythm problems when given with [nationally completed name]
- diuretics (“water tablets”) can potentiate urinary blockade
- steroid tablets (these are medicines that are used to reduce inflammatory processes within the body and include medicines such as prednisolone), which may increase the airway blockade
- anaesthetic agents may increase the susceptibility of the effects of salbutamol on the heart - you will be monitored closely or your doctor might decide to discontinue [nationally completed name] if you are going to have an operation. If you are going to have a general anaesthetic in hospital, please tell the anaesthetist what medicines you are taking.

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

[Nationally completed name] should only be used during pregnancy or breast feeding after consultation with your doctor.

Ask your doctor for advice before taking any medicine.

Driving and using machines
If you experience side effects such as dizziness, difficulty focusing and blurred vision during treatment with [nationally completed name] you should avoid potentially hazardous tasks such as driving or operating machinery

3. How to use [nationally completed name]

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

[Nationally completed name] is for inhalation use. The nebuliser solution is for oral inhalation after nebulisation.

The recommended dose for adults and children over 12 years of age is the contents of one ampoule, three or four times a day.

Elderly patients should take the usual adult dose.

[Nationally completed name] is **not** recommended for children under 12 years of age.

The label will tell you how much to take and how often to take it.

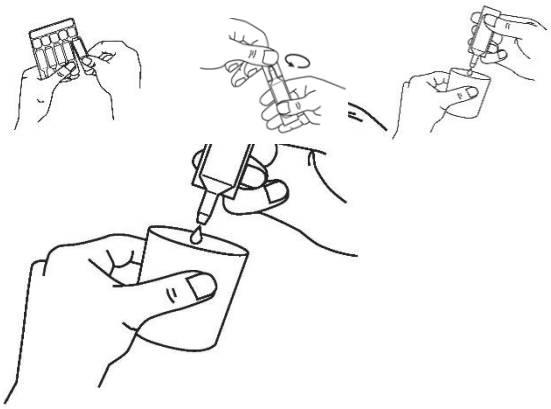
Never use more medicine than your doctor has told you to. **Tell your doctor if your breathing problems get worse** or your medicine does not provide as much relief from your breathing problems as before or if you are using your blue short-acting "reliever" inhaler more often than is usual for you.

[Nationally completed name] should be used with a suitable nebuliser, e.g. PARI LC PLUS Nebuliser, jet nebulizer. Please read the full instructions for use of the nebuliser in the leaflet provided with PARI LC PLUS before starting the inhalation.

Instructions for use
- Prepare your nebuliser for use according to the manufacturer's instructions and advice from your doctor.
- Carefully remove an ampoule from the labelled strip by twisting and pulling. Never use an ampoule that has been opened already or if the nebuliser solution is discoloured (diagram A).
- Hold the ampoule upright and twist off the cap (diagram B).
- Squeeze the contents into the reservoir of your nebuliser (diagram C).

- Follow the manufacturer's instructions and the advice from your doctor on how to assemble and how to use your nebuliser.
- After you have used your nebuliser, throw away any nebuliser solution that is left in the reservoir. Any nebuliser solution left in the ampoule should also be thrown away.
- Clean your nebuliser thoroughly according to the manufacturer's instructions. It is important that the nebuliser is kept clean.

A **B** **C**



Do not dilute the nebuliser solution or mix it with other medicines, unless your doctor tells you to.

The single dose ampoules of [nationally completed name] do not contain preservatives and therefore it is important to use the contents immediately after opening. A new ampoule must be used each time you use [nationally completed name] in your nebuliser.

Partly used, opened or damaged ampoules should be discarded. You should **never** use an ampoule, which has been opened earlier.

It is important that you follow these instructions in order to avoid any contamination of the nebuliser solution within the ampoules.

Do **not** swallow the nebuliser solution or use it in injections.

Do **not** allow the nebuliser solution or mist to enter your eyes.

If you use more [nationally completed name] than you should
If you have taken a slightly larger dose than usual, you may notice a faster heart beat (palpitations) or tremor. Other symptoms might include chest pain, changes in blood pressure, flushing, restlessness or dizziness. These effects usually wear off in a few hours. The level of potassium in your blood may fall and the doctor may want to monitor the potassium in your blood by taking a blood test to measure the levels from time to time. Tell your doctor if you are worried by any of these symptoms or if they persist.

If you have taken more medicine than you should have taken, tell your doctor immediately or go to the nearest hospital. If you need to visit a doctor or need to go into hospital then you should take all of your medicines with you, including any you may have bought without a prescription; these should be in their original packaging if at all possible. Take this leaflet with you to show the doctor.

If you forget to use [nationally completed name]
If you forget to take a dose at the right time, take it as soon as you remember. Do not take a double dose to make up for a forgotten dose.

If you stop using [nationally completed name]
You should not stop taking [nationally completed name] without prior discussion with your doctor.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

If your asthma or wheezing gets worse immediately after inhaling [nationally completed name], or your breathing becomes more difficult and you become short of breath do not take any more [nationally completed name] but use your short-acting 'reliever' inhaler straightaway. You should stop using [nationally completed name] and should contact your doctor immediately. Your doctor may prescribe alternative treatment for your condition.

If you experience eye pain or eye discomfort, blurred vision or red eyes, or if you see halos or coloured spots then you should contact your doctor straightaway as treatment for these symptoms may be required.

If you think that you may be allergic to [nationally completed name] or if you think you may be having an allergic reaction to the nebuliser solution then you should stop using [nationally completed name] straightaway and contact your doctor immediately.

A reduction in the level of potassium (hypokalaemia) in the blood due to the salbutamol component of [nationally completed name] can occur - and this may cause muscle weakness, twitching or abnormal heart rhythm. This is more likely to happen if you are taking [nationally completed name] with some other asthma treatments, with inhaled steroids or steroid tablets or with diuretics ("water tablets"). Your doctor may need to take a blood test to measure your potassium levels from time to time.

Side effects can occur with the following frequencies:

Uncommon, may affect up to 1 in 100 people
- nervousness
- headaches
- vibrations, feeling shaky (tremor)
- dizziness
- palpitations

- rapid heartbeat
- increased (upper) blood pressure
- cough
- hoarseness
- dryness of the mouth
- nausea (feeling sick)
- irritation of the throat
- changes in taste
- skin reactions

Rare, may affect up to 1 in 1,000 people
- severe, life-threatening allergic reaction to certain substances (anaphylactic reactions, including swelling, which may affect the tongue, lips and face)
- reduced potassium levels in the blood (hypokalaemia)
- mental illness
- difficulties focusing your eyes
- visual disturbances
- increased eye pressure (glaucoma)
- dilation of the pupil (mydriasis)
- blurred vision
- pain in the eyes
- red eyes
- seeing circles and colored images around light sources (halos)
- abnormal or very fast heartbeat
- heart attack
- reduced (lower) blood pressure
- dryness of the throat
- difficulty in breathing or speaking due to a brief cramping of the muscles in the airways or in the throat
- inflammation of the mouth and/or throat, and/or fluid accumulation in mouth and/or throat
- diarrhoea
- vomiting (feeling sick)
- constipation
- problems with your digestive system
- tooth decay (dental caries)
- skin rash, nettle rash
- itching
- excessive sweating
- muscle cramps, weakness and/or pain
- difficulty in passing water (urine)
- feeling weak

Frequency not known (frequency cannot be estimated from the available data)
- a condition known as lactic acidosis which may cause stomach pain, hyperventilation, shortness of breathe even though there may be improvement in your wheezing, cold feet and hands, irregular heartbeat or thirst.

Although it is not known exactly how often this happens, some people might experience chest pain (due to problems such as angina). Tell your doctor as soon as possible if you develop these symptoms whilst receiving treatment with [nationally completed name], but do not stop using this medicine unless told to do so.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly via the national reporting system listed in Appendix V*. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [nationally completed name]

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

Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.

Do not refrigerate or freeze. Do not store above 25°C.

Keep the nebuliser solution in the outer pouch or carton in order to protect from light.
After first opening the pouch, the closed ampoule should be used within 3 months.

For single use only. Use immediately after first opening the ampoule.
Discard immediately after first use.
Partly used, opened or damaged ampoules should be disposed in accordance with local requirements.

Do not use this medicine if you notice the nebuliser solution is cloudy.

Do no 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 protect the environment.

6. Contents of the pack and other information

What [nationally completed name] contains
Each 2.5 ml [nationally completed name] contains:
- The active substances are 0.5 mg of ipratropium bromide as 520 micrograms ipratropium bromide monohydrate and 2.5 mg of salbutamol as sulphate.
- The other ingredients are sodium chloride, water for injection and sulfuric acid.

What [nationally completed name] looks like and contents of the pack
The pack is a Plastic Form fill Seal (FFS) ampoule containing 2.5 ml of nebuliser solution, 5 of which are over wrapped in a triple laminated pouch and then packed into cardboard cartons.

Mutlipacks may contain 10 ampoules (2 pouches of 5 ampoules), 20 ampoules (4 pouches of 5 ampoules), 30 ampoules (6 pouches of 5 ampoules), 40 ampoules (8 pouches of 5 ampoules), 50 ampoules (10 pouches of 5 ampoules), 60 ampoules (12 pouches of 5 ampoules), 80 ampoules (16 pouches of 5 ampoules), 100 ampoules (20 pouches of 5 ampoules), 120 ampoules (24 pouches of 5 ampoules) and 150 ampoules (30 pouches of 5 ampoules).

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Houder van de vergunning voor het in de handel brengen
Sandoz B.V., Hospitaaldreef 29, 1315 RC Almere, Nederland

Fabrikant
Salutas Pharma GmbH
Otto-von-Guericke Allee 1
39179 Barleben
Duitsland

Lek Pharmaceuticals d.d
Verovškova ulica 57
1526 Ljubljana
Slovenië

Dit middel is in het register ingeschreven onder RVG 109136

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:

Denemarken	Ipratropium/Salbutamol Sandoz
Duitsland	SalbuHEXAL plus Ipratropiumbromid 2,5 mg + 0,5 mg Lösung für einen Vernebler
Nederland	Ipratropiumbromide/Salbutamol Sandoz 0,5/2,5 mg per 2,5 ml, verneveloplossing
Zweden	Ipratropium/Salbutamol Sandoz Sandoz A/S
Verenigd Koninkrijk	Copralineb 0.5/2.5 mg per 2.5 ml Nebuliser Solution

Deze bijsluiter is voor het laatst goedgekeurd in februari 2024