

PACKAGE LEAFLET

Package leaflet: Information for the patient
Sirkava 18 microgram, inhalation powder, hard capsule
tiotropium

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, or 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Sirkava is and what it is used for
2. What you need to know before you use Sirkava 18 microgram
3. How to use Sirkava 18 microgram
4. Possible side effects
5. How to store Sirkava 18 microgram
6. Contents of the pack and other information

1. What Sirkava is and what it is used for

Sirkava 18 microgram helps people who have chronic obstructive pulmonary disease (COPD) to breathe more easily. COPD is a chronic lung disease that causes shortness of breath and coughing. The term COPD is associated with the conditions chronic bronchitis and emphysema. As COPD is a chronic disease you should take Sirkava 18 microgram every day and not only when you have breathing problems or other symptoms of COPD.

Sirkava 18 microgram is a long-acting bronchodilator that helps to open your airways and makes it easier to get air in and out of the lungs. Regular use of Sirkava 18 microgram can also help you when you have on-going shortness of breath related to your disease and will help you to minimise the effects of the disease on your everyday life. It also helps you to be active longer. Daily use of Sirkava 18 microgram will also help to prevent sudden, short-term worsening of your COPD symptoms which may last for several days. The effect of this medicine lasts for 24 hours, so you only need to use it once a day. For correct dosing of Sirkava 18 microgram please see section 3. How to use Sirkava 18 microgram and the instructions for use provided on the other side of the leaflet.

2. What you need to know before you use Sirkava 18 microgram

Do not use Sirkava 18 microgram

- if you are allergic (hypersensitive) to tiotropium, its active ingredient, or to any other ingredients of this medicine (listed in section 6).
- if you are allergic (hypersensitive) to atropine or substances related to it, e.g. ipratropium or oxitropium.

Warnings and precautions

Talk to your doctor or pharmacist before using Sirkava 18 microgram

- Talk to your doctor if you suffer from narrow angle glaucoma, prostate problems or have difficulty passing urine.
- If you have problems with your kidneys, please consult your doctor.
- Sirkava 18 microgram is indicated for maintenance treatment of your chronic obstructive pulmonary disease, it should not be used to treat a sudden attack of breathlessness or wheezing.
- Immediate allergic reactions such as rash, swelling, itching, wheezing or breathlessness may occur after administration of Sirkava 18 microgram. If this occurs, please consult your doctor immediately.
- Inhaled medicines such as Sirkava 18 microgram may cause tightness of the chest, coughing, wheezing or breathlessness immediately after inhalation. If this occurs, please consult your doctor immediately.
- Take care not to let the inhalation powder enter your eye as this may result in precipitation or worsening of narrow-angle glaucoma, which is a disease of the eyes. Eye pain or discomfort, blurred vision, seeing halos around lights or coloured images in association with red eyes may be signs of an acute attack of narrow-angle glaucoma. Eye symptoms may be accompanied by headache, nausea or vomiting. You should stop using tiotropium bromide and immediately consult your doctor, preferably an eye specialist, when signs and symptoms of narrow-angle glaucoma appear.
- Dry mouth, which has been observed with anti-cholinergic treatment, may in the long term be associated with dental caries. Therefore, please remember to pay attention to oral hygiene.
- In case you have suffered from a myocardial infarction during the last 6 months or from any unstable or life threatening irregular heart beat or severe heart failure within the past year, please, inform your doctor. This is important to decide if Sirkava is the right medicine for you to take.
- Do not use Sirkava 18 microgram more frequently than once daily.

Children and adolescents

Sirkava 18 microgram is not recommended for children and adolescents under 18 years.

Other medicines and Sirkava 18 microgram

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, including medicines available without prescription.

Please tell your doctor or pharmacist if you are using/have used similar medicines for your lung disease, such as ipratropium or oxitropium.

No specific side effects have been reported when Sirkava 18 microgram has been used together with other products used to treat COPD such as reliever inhalers, e.g. salbutamol, methylxanthines, e.g. theophylline and/or oral and inhaled steroids e.g. prednisolone.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding or think you may be pregnant, or you are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. You should not use this medicine unless specifically recommended by your doctor.

Driving and using machines

The occurrence of dizziness, blurred vision, or headache may influence the ability to drive and use machinery.

Sirkava 18 microgram contains lactose anhydrous.

When taken according to dosage recommendations, one capsule once a day, each dose supplies up to 5.5 mg lactose anhydrous. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to use Sirkava

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

The recommended dose is to inhale the contents of 1 capsule (18 micrograms of tiotropium) once a day. Do not use more than the recommended dose.

Sirkava 18 microgram is not recommended for children and adolescents under 18 years.

You should try to use the capsule at the same time every day. This is important because Sirkava 18 microgram is effective over 24 hours.

The capsules are only for inhalation and not for oral intake.

Do not swallow the capsules.

The NeumoHaler device, which you should put the Sirkava capsule into, makes holes in the capsule and allows you to breathe in the powder.

Make sure that you have a NeumoHaler and that you can use it properly. The instructions for use of the NeumoHaler are provided at the end of this leaflet.

Make sure that you do not blow into the NeumoHaler.

If you have any problems using the NeumoHaler, ask your doctor, nurse or pharmacist to show you how it works.

You should clean your NeumoHaler once a month. Cleaning instructions for the NeumoHaler are provided at the end of this leaflet.

When taking Sirkava 18 microgram, take care not to let any of the powder enter your eyes. If any powder does get into your eyes you may get blurred vision, eye pain and/or red eyes, you should wash your eyes in warm water immediately. Then talk to your doctor immediately for further advice.

If you feel that your breathing is worsening, you should tell your doctor as soon as possible

If you use more Sirkava 18 microgram than you should

If you inhale from more than 1 capsule of Sirkava 18 microgram in a day, you should talk to your doctor immediately. You may be at a higher risk of experiencing a side effect such as dry mouth, constipation, difficulties passing urine, increased heart beat, or blurred vision.

If you forget to use Sirkava 18 microgram

If you forget to take a dose, take one as soon as you remember but do not take two doses at the same time or on the same day. Then take your next dose as usual.

If you stop using Sirkava 18 microgram

Before you stop using Sirkava 18 microgram, you should talk to your doctor or your pharmacist. If you stop using Sirkava 18 microgram the signs and symptoms of COPD may worsen.

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.

The side effects described below have been experienced by people taking this medicine and they are listed according to frequency as either common, uncommon, rare or not known.

Common (may affect up to 1 in 10 people):

- dry mouth: this is usually mild

Uncommon (may affect up to 1 in 100 people):

- dizziness
- headache
- taste disorders
- blurred vision
- irregular heart beat (atrial fibrillation)
- inflammation of the throat (pharyngitis)
- hoarseness (dysphonia)
- cough
- heart burn (gastrooesophageal reflux disease)
- constipation
- fungal infections of the oral cavity and throat (oropharyngeal candidiasis)
- rash
- difficulties passing urine (urinary retention)
- painful urination (dysuria)

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

- difficulty in sleeping (insomnia)
- seeing halos around lights or coloured images in association with red eyes (glaucoma)
- increase of the measured eye pressure
- irregular heart beat (supraventricular tachycardia)
- faster heart beat (tachycardia)
- feeling your heart beat (palpitations)

- tightness of the chest, associated with coughing, wheezing or breathlessness immediately after inhalation (bronchospasm)
- nosebleed (epistaxis)
- inflammation of the larynx (laryngitis)
- inflammation of the sinuses (sinusitis)
- blockage of intestines or absence of bowel movements (intestinal obstruction including ileus paralytic)
- inflammation of the gums (gingivitis)
- inflammation of the tongue (glossitis)
- difficulties swallowing (dysphagia)
- inflammation of the mouth (stomatitis)
- feeling sick (nausea)
- hypersensitivity, including immediate reactions
- serious allergic reaction which causes swelling of the face or throat (angioedema)
- nettle rash (urticaria)
- itching (pruritus)
- infections of the urinary tract

Not known (frequency cannot be estimated from the available data):

- depletion of body water (dehydration)
- dental caries
- severe allergic reaction (anaphylactic reaction)
- infections or ulcerations of the skin
- dryness of the skin
- swelling of joints

Serious side effects include allergic reactions which cause swelling of the face or throat (angioedema) or other hypersensitivity reactions (such as sudden reduction of your blood pressure or dizziness) may occur individually or as part of severe allergic reaction (anaphylactic reaction) after administration of Sirkava 18 microgram. In addition, in common with all inhaled medicines, some patients may experience an unexpected tightness of the chest, coughing, wheezing or breathlessness immediately after inhalation (bronchospasm). If any of these occur, please consult your doctor immediately.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the **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 Sirkava

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 the blister foil. The expiry date refers to the last day of that month.

You can use your NeumoHaler until you have finalized the medicine contained in this box (maximum for up to 3 months).

Do not store above 30°C.

Store in the original package to protect from moisture.

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 protect the environment.

6. Contents of the pack and other information

What Sirkava contains The active substance is tiotropium. Each capsule contains 18 microgram of the active ingredient tiotropium (as bromide anhydrous). During inhalation, 12 microgram tiotropium are delivered from the mouthpiece of the NeumoHaler.

- The other ingredients are lactose, hypromellose, titanium dioxide (E171), black ink.

What Sirkava looks like and contents of the pack

Inhalation powder, hard capsule.

White or almost white capsules marked with T18 in black ink on the cap containing white or almost white powder.

Aluminium / Aluminium-PVC peelable blister.

The NeumoHaler is a single dose inhalation device with a green body and cap and a white push button made from plastic materials (ABS) and stainless steel.

Package sizes and devices supplied:

- Cardboard box containing 30 capsules
- Cardboard box containing 60 capsules
- Cardboard box containing 90 capsules

The NeumoHaler device is packed/available in each cardboard box.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

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

[To be completed nationally]

This leaflet was last revised in 15 June 2020.

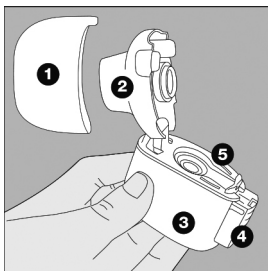
NeumoHaler Instructions for use

Dear Patient,

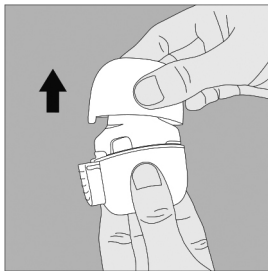
The NeumoHaler enables you to inhale the medicine contained in the Sirkava capsule – that your physician has prescribed for your breathing problems.

Remember to carefully follow your doctor's instructions for using Sirkava. The NeumoHaler is especially designed for Sirkava. You must not use it to take any other medicine. You can use your NeumoHaler until you have finalized the medicine contained in this box (maximum for up to 3 months). The NeumoHaler has a dust cap (curved top lid), mouthpiece (located under the dust cap), base, piercing button (on the side of the NeumoHaler) and centre chamber (located under the mouthpiece).

The NeumoHaler



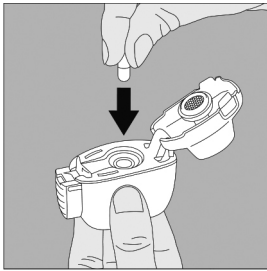
- 1 Dust cap
- 2 Mouthpiece
- 3 Base
- 4 Piercing button
- 5 Centre chamber



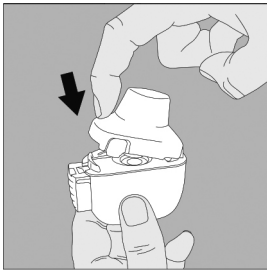
1. Remove the dust cap. Check that no foreign object is present in the inhalation channel



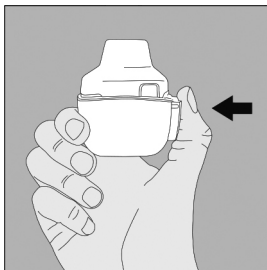
2. Open the mouthpiece by pulling it upwards while pressing two indents.



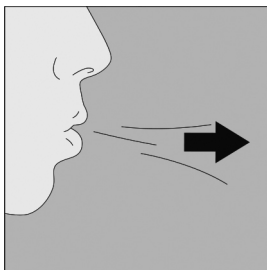
3. Remove a Sirkava capsule from the blister (only immediately before use, see blister handling at the end of the instructions) and place it in the center chamber of the NeumoHaler, as illustrated. It does not matter which way the capsule is placed in the chamber. Never place the capsule directly into the mouthpiece.



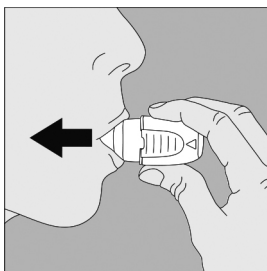
4. Close the mouthpiece firmly until you hear a click.



5. Hold the NeumoHaler with the mouthpiece upwards and press the piercing button completely in only once, and then release. This makes holes in the capsule and allows the medication to be released when you breathe in.

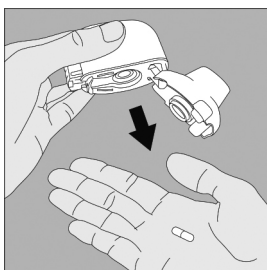


6. Breathe out completely. Important: Please avoid breathing into the mouthpiece at any time.



7. Raise the NeumoHaler to your mouth and close your lips tightly around the mouthpiece. Keep your head in an upright position and breathe in slowly and deeply but at a rate sufficient to hear or feel the capsule vibrate. Breathe in until your lungs are full; then hold your breath as long as comfortable and at the same time take the NeumoHaler out of your mouth.

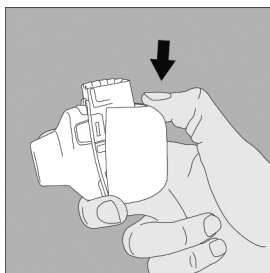
Repeat steps 6 and 7 once, in order to empty the capsule completely.



8. Open the mouthpiece again. Tip out the used capsule and dispose. Close the mouthpiece and replace the dust cap. Ensure the dust cap is properly closed.

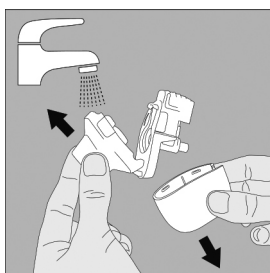
Cleaning your NeumoHaler:

Clean the NeumoHaler once a month.



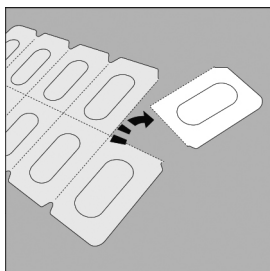
1. Open the dust cap and mouthpiece.

Then open the base by pressing down with your thumb the triangle engraved below the piercing button as shown in the picture.

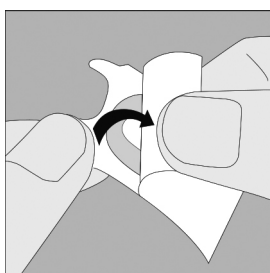


2. Rinse the complete inhaler with warm water to remove any powder. Dry the NeumoHaler thoroughly by tipping excess of water out on a paper towel and air-dry afterwards, without reassembling these components. It takes 24 hours to air dry, so clean it right after you have used it and it will be ready for your next dose. If needed, the outside of the mouthpiece may be cleaned with a moist but not wet tissue.

Blister handling:

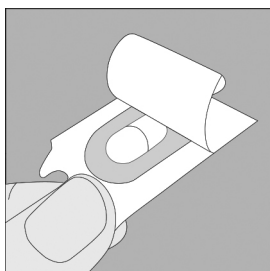


1. Separate one of the blisters from the blister card by tearing along the perforation.



2. Take the separated blister and peel away the protective backing to expose the capsule.

Do not push capsule through foil.



3. Capsules should always be stored in the blister and only removed immediately before use. With dry hands, remove capsule from the blister.

Do not swallow the capsule.

Sirkava capsules contain only a small amount of powder so that the capsule is only partially filled.

Manufacturer of the NeumoHaler device:
Ferrer Internacional, S.A
Joan Buscallà 1-9
08173 Sant Cugat del Vallès
Spain

