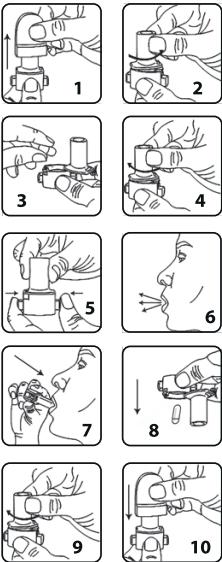


 30 gélules
Inhalateur
Voie inhalée

NE PAS AVALER LES GÉLULES





1 WHAT IS XTIOVA EASY FLOW 18 mcg, POWDER FOR ORAL INHALATION ? AND IN WHICH CASES IS IT USED ?

Composition
Active substance:
Tiotropium..... 18 micrograms
As Tiotropium bromide monohydrate22.5 micrograms
For one capsule.
Excipient :
Lactose monohydrate.
Excipients known to have a recognized action:
Lactose.

Pharmaceutical form and content:
Powder for oral inhalation in capsules.
Box of 30 capsules + an inhalation device.
Pharmacotherapeutic group:
Other drugs for obstructive airway syndromes by inhalation, anticholinergics - ATC code: R03B B04

XTIOVA Easy Flow ® is a treatment designed to help people with chronic obstructive pulmonary disease (COPD) breathe more easily. COPD is a chronic lung disease that causes breathing difficulties and cough. The term COPD is associated with conditions of chronic bronchitis and emphysema. COPD is a chronic disease and you should therefore use **XTIOVA Easy Flow** ® 18 mcg, oral inhalation powder in capsule on a daily basis, not just when you have difficulty breathing or other symptoms of COPD.
XTIOVA Easy Flow ® 18 µg, powder for oral inhalation in capsule is a long-acting bronchodilator that helps open your bronchi to facilitate air circulation in the lungs. Regular use of **XTIOVA Easy Flow** ® 18 mcg, powder for oral inhalation, can reduce the shortness of breath you experience as a result of your COPD and thus help reduce the effects of the disease on your daily life. It can help you to continue with your daily activities. Regular use of **XTIOVA Easy Flow** ® 18 mcg, powder for oral inhalation will also prevent the risk of exacerbation of COPD (sudden worsening of symptoms of COPD that can last for several days).

This medicine lasts for 24 hours, so you only need to use it once a day. For the correct use of the inhalation device of **XTIOVA Easy Flow** ® 18 mcg, powder for oral inhalation in capsule, please comply with section 3. «How to use **XTIOVA Easy Flow** ® 18 mcg, powder for oral inhalation in capsule», as well as instructions for use provided at the end of the leaflet.

2 WHAT ARE THE INFORMATION TO KNOW BEFORE USING XTIOVA EASY FLOW 18 mcg, POWDER FOR ORAL INHALATION IN CAPSULE?

Please read the following questions carefully. If you answer «Yes» to any of these questions, please tell your doctor before you start treatment with **XTIOVA Easy Flow** ® 18 mcg, powder for oral inhalation.

- Are you allergic (hypersensitive) to tiotropium, atropine or derivatives of these active substances, such as p. ex. ipratropium or oxitropium, or milk protein?
- Are you taking any other medicines containing ipratropium or oxitropium?
- Are you pregnant, think you may be pregnant, or are you breastfeeding?
- Do you have narrow-angle glaucoma, prostate problems or do you have difficulty urinating?
- Do you have kidney problems?
- Have you had a myocardial infarction in the past 6 months, or an unstable or life-threatening heart rhythm disorder or severe heart failure in the past year?

Contra-indications:
Never use **XTIOVA Easy Flow** ® 18 mcg, powder for oral inhalation in the following cases:
• If you are allergic (hypersensitive) to tiotropium or lactose (contains milk protein).
• If you are allergic (hypersensitive) to atropine or derivative substances such as p. eg, ipratropium or oxitropium.

Precautions for use; special warnings:
Take special precautions with XTIOVA Easy Flow 18 mcg, powder for oral inhalation:
• Talk to your doctor if you have narrow angle glaucoma, prostate problems or have difficulty urinating.
• If you have problems with your kidneys, please consult your doctor.
• **XTIOVA Easy Flow** ® 18 mcg, powder for oral inhalation is indicated, in regular doses, 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 taking **XTIOVA Easy Flow** ®. If this occurs, please consult your doctor immediately.

• Like any other inhaled treatments, a feeling of chest tightness, coughing, wheezing or breathlessness can occur immediately after inhalation of **XTIOVA Easy Flow** ® 18 mcg, powder for oral inhalation. In this case, do not renew the dose and 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 colored 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. If signs or symptoms appear after taking this medication or accidentally spraying the powder into the eye, you should discontinue the treatment and consult your doctor immediately (preferably an ophthalmologist).

- Dry mouth, as observed with anticholinergic treatments such as **XTIOVA Easy Flow** ® 18 mcg, powder for oral inhalation, may in the long term be associated with dental caries. You should therefore pay particular attention to maintaining good oral hygiene.
- Do not take **XTIOVA Easy Flow** ® 18 mcg, powder for oral inhalation more than once daily.

Children and adolescents:
XTIOVA Easy Flow ® 18 mcg, powder for oral inhalation is not recommended for children and adolescents under 18 years.

Interaction with other medicines:
Please talk to your doctor or pharmacist if you are taking, may take or have recently taken any other medicinal products, even medicines obtained without a prescription.

Inform your doctor or pharmacist if you are taking or have taken medicines that are similar to **XTIOVA Easy Flow** ® 18 mcg, powder for oral inhalation, such as ipratropium or oxitropium medications, to treat your breathing problems.

No specific adverse effects were reported when **XTIOVA Easy Flow** ® 18 mcg oral powder was administered with other products used to treat COPD, including inhaled symptom-relieving drugs, e.g. salbutamol, Methylnanthines, for example theophylline and / or inhaled or oral steroids, for example prednisolone.

Use during pregnancy and breastfeeding:
If you are pregnant or think you may be pregnant, or you are planning a pregnancy, or if you are breast-feeding, consult your doctor before taking this medicine.

You should not use this medication unless it has been specifically recommended to you by your doctor.

Ask your doctor or pharmacist for advice before taking any medicine.

Effects on ability to drive or use machines:

The occurrence of dizziness, blurred vision or headache can influence your ability to drive or use machines.

List of Excipients known to have a recognized action:

Please talk to your doctor or pharmacist if you are taking, may take or have recently taken any other medicinal products, even medicines obtained without a prescription.

When used correctly, one capsule (recommended daily dose) of **XTIOVA Easy Flow** ® 18 mcg contains up to 5.5 mg of lactose monohydrate.

3 HOW TO USE XTIOVA EASY FLOW 18 mcg, POWDER FOR ORAL INHALATION?

Instructions for proper use:
Follow your doctor's prescription. If you are unsure, do not hesitate to consult your doctor or seek advice from your pharmacist.

Dosage, Mode and / or route (s) of administration, Frequency of administration and Duration of treatment:

The usual adult dose is to inhale the content of one capsule (18 micrograms of XTIOVA) once daily with the appropriate inhalation device.
Treatment should be administered at the same time each day because **XTIOVA Easy Flow** ® 18 mcg, powder for oral inhalation acts for 24 hours.
Do not exceed the prescribed dose of 1 capsule per day.
XTIOVA Easy Flow ® 18 mcg, powder for oral inhalation is not recommended for children and adolescents under 18 years.

The capsules of **XTIOVA Easy Flow** ® 18 mcg, powder for oral inhalation must be used only for inhalation of the powder they contain.
The inhalation device supplied with this medicine, in which the **XTIOVA Easy Flow** ® 18 mcg capsule is placed, punctures the capsule allowing you to inhale the powder.
Make sure you have the inhalation device that came with this medicine and that you know how to use it correctly.

Instructions for using the **XTIOVA Easy Flow** ® 18 mcg inhalation device are provided in this section and at the end of this leaflet.

Make sure to not breath or blow into the inhaler.

If you have any difficulty using the **XTIOVA Easy Flow** ® 18 mcg inhalation device, ask your doctor, nurse or pharmacist for the necessary explanations.

You should clean your **XTIOVA Easy Flow** ® 18 mcg inhalation device at least once a month. Instructions for cleaning **XTIOVA Easy Flow** ® 18 mcg inhalation device are provided in this section and at the end of this section.

When taking **XTIOVA Easy Flow** ® 18 mcg, be careful not to get the powder in your eyes. If powder gets into your eyes, you may experience blurred vision, eye pain and / or redness. Immediately flush your eyes with warm water. Then consult your doctor immediately for advice.

If you feel your breathing is deteriorating, consult your doctor immediately.

Mode of administration:

Inhalation device with mouthpiece inhaled route only.

THE CAPSULES MUST NOT BE SWALLOWED

Their contents should be inhaled using the appropriate inhaler device reserved for this purpose.

The effectiveness of this drug is partly dependent on the proper use of the inhaler device.

You should read the instructions carefully. If necessary, do not hesitate to ask your doctor or pharmacist to provide you with detailed explanations.

The handling steps are illustrated at the end of this leaflet.

Step 1: Pull off the protection cap.

Step 2: Open the capsule compartment: Hold the base of the inhaler firmly and turn the mouthpiece in the direction of the arrow on the bottom of the mouthpiece to open as indicated in the corresponding diagram in the end of this leaflet.

Step 3: Make sure that your fingers are dry and place one capsule in the capsule-shaped compartment in the base of the inhaler. (Do not put it in the mouthpiece!)

BEWARE: Remove the capsule from the pillbox only immediately before you use it.

Step 4: Twist the mouthpiece to the dosed position until it clicks.

Step 5: To release the powder, keep the inhaler upright and firmly squeeze the two buttons once only.

Step 6: Breathe out fully.

Step 7: Place the mouthpiece in your mouth and tilt your head slightly backwards. Close your lips around the mouthpiece and breathe in as quickly and as deeply as you can. As you breathe in, you will inhale the medicine into your lungs.

Note: You should hear the capsule spinning in the inhaler. If you do not hear this whirring noise, check that the capsule is in place.

Step 8: Remove the inhaler from the mouth holding your breath as long as possible. Then, breathe normally. Open the inhaler to make sure it is no more powder. If there is powder, renew inhalation.

After use, tip out the empty capsule.

Step 9: Twist the mouthpiece to the closed position until it clicks.

Step 10: Replace the cap.

Care instructions: After each use, wipe the mouthpiece and capsule compartment of the inhalation device with a dry cloth or a clean soft brush.

WARNING: Do not wash the inhaler with water.

Symptoms and instructions for Overdose:

If you used more **XTIOVA Easy Flow** ® 18 mcg powder for oral inhalation than you should: If you have inhaled more than one **XTIOVA Easy Flow** 18 mcg capsule in one day, consult your doctor immediately.

You may be more likely to have side effects such as dry mouth, constipation, difficulty passing urine, increased heartbeat or blurred vision.

Instructions for omission of one or more doses:

If you forget to take **XTIOVA Easy Flow** ® 18 mcg, powder for oral inhalation:

Do not take a double dose to make up for the missed dose.

If you forget to take your daily dose, take it as soon as you remember, but do not take two doses at the same time or on the same day. Take your next dose according to your usual schedule.

Risk of withdrawal syndrome:

If you stop using **XTIOVA Easy Flow** ® 18 mcg, powder for oral inhalation:

Ask your doctor or pharmacist before stopping taking **XTIOVA Easy Flow** ® 18 mcg.

If you stop taking **XTIOVA Easy Flow** ® 18 mcg, powder for oral inhalation, the signs and symptoms of COPD may worsen.

IF YOU HAVE ANY FURTHER QUESTIONS ON THE USE OF THIS MEDICATION, ASK YOUR DOCTOR OR PHARMACIST.

4 WHAT ARE POSSIBLE SIDE EFFECTS?

Like all medicines, **XTIOVA Easy Flow** 18 mcg, powder for oral inhalation, is likely to induce undesirable effects, although not everyone gets them.

The frequency of adverse events is assessed as follows:

• **Common:** may occur in up to 1 in 10 people.

• **Uncommon:** may occur in up to 1 in 100 people.

• **Rare:** may occur in up to 1 in 1,000 people.

• **Not determined:** the frequency of occurrence cannot be estimated from the available data.

The side effects described below have been observed in patients taking this medication and are listed according to frequency of occurrence: common, uncommon, rare, or with an undefined frequency.

Common:

• Dry mouth: this is usually mild.

Uncommon:

• Dizziness

• Headache,

• Taste disorders,

• Blurred vision,

• Irregular heart beat (atrial fibrillation),

• Inflammation of the throat (pharyngitis),

• Hoarseness (dysphonia),

• Cough,

• Heart burn (gastro-oesophageal reflux disease),

• Constipation,

• Fungal infections of the mouth and throat (oropharyngeal candidiasis),

• Skin rash,

• Difficulty urinating (urinary retention)

• Painful urination (dysuria)

Rare:

• Difficulty in sleeping (insomnia),

• Seeing luminous halos around lights or colored images (not real), with red eyes (glaucoma),

• Increased pressure inside the eye (glaucoma)

• Irregular heart beat (supraventricular tachycardia),

• Accelerated heart beat (tachycardia),

• Abnormal perception of heart beats in the chest (palpitations),

• Tightness of the chest associated with coughing, wheezing or breathlessness occurring immediately after inhalation of the product (bronchospasm),

• Nosebleed (epistaxis),

• Inflammation of the larynx (laryngitis),

• Inflammation of the sinus (sinusitis),

• Blockage of intestinal transit or absence of intestinal movements (intestinal obstruction or paralytic ileus),

• Inflammation of the gums (gingivitis),

• Inflammation of the tongue (glossitis),

• Difficulties swallowing (dysphagia),

• Inflammation of the mouth (stomatitis),

• Nausea,

• Immediate allergic reactions (hypersensitivity),

• Serious allergic reactions which cause swelling of the face or throat (Angioedema),

• Urticaria,

• Itching (pruritus),

• Urinary tract infections.

Not determined frequency:

• Dehydration,

• Dental caries,

• Severe allergic reaction (anaphylactic reaction)

• Infections or ulcerations of the skin,

• Dry skin,

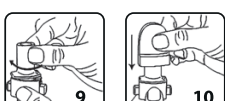
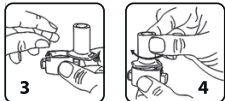
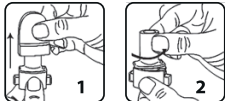
• Swelling of the joints.

Serious side effects include allergic reactions causing swelling of the face or throat (angioedema) or other allergic reactions (such as sudden reduction in blood pressure or dizziness). These reactions can occur individually or in the context of a severe allergic reaction (anaphylactic reaction) after administration of **XTIOVA Easy Flow** ® 18 mcg, powder for oral inhalation. As with all inhaled medicines, some patients may experience unexpected tightness in the chest associated with coughing, wheezing or difficulty breathing (bronchospasm) occurring immediately after inhalation.

If any of these effects occur, seek medical advice immediately.

If you get any side effects talk to your doctor or pharmacist.

This also applies to any side effects not mentioned in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.



XTIOVA® Easy flow
Tiotropium 18 µg

THIS IS A MEDICINE

- A medicine is a product, but not a product as others.
- A medicine is a product which affects your health, and its consumption contrary to instructions is dangerous.
- Comply strictly with the prescription and instruction of use as prescribed by your doctor.
- Follow the advice of your pharmacist.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not interrupt by your self the period of treatment prescribed for you.
- Neither repeat the prescription nor increase the dose without consulting your doctor.

Keep medicines out of the reach of children

Poudre pour inhalation buccale

30 gélules +

Inhalateur

Voie inhalée

NE PAS AVALER LES GÉLULES

AC1971/VI

