PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

Boehringer Ingelheim

Forvent® 18 microgram
Capsules for inhalation

tiotropium

Contains sugar: 5,5 mg lactose monohydrate per capsule

Read all of this leaflet carefully before you start using FORVENT.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- FORVENT 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

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

1. What FORVENT is and what it is used for

FORVENT is an inhalation powder, enclosed in a hard gelatine capsule.
The powder from the capsules must be inhaled using the HandiHaler® device.

FORVENT helps people who have chronic obstructive pulmonary disease (COPD) to breathe more easily. Chronic obstructive pulmonary disease (COPD) is a long-term lung disease that causes shortness of breath and coughing. The term COPD is associated with the condition - chronic bronchitis.

FORVENT is a long-acting bronchodilator that helps to open your airways and makes it easier to get air in and out of the lungs.

The effect of FORVENT lasts for 24 hours, so you only need to take it once a day.
For the correct use of FORVENT, please see section **3. How to use FORVENT** and the **HandiHaler® instructions for use** (at the end of this leaflet).

As COPD is a long-term disease you should take FORVENT every day and not only when you have breathing problems or other symptoms of COPD.

2. What you need to know before you use FORVENT

Do not use FORVENT

- if you are hypersensitive (allergic) to tiotropium or to any of the other ingredients contained in FORVENT (listed in section 6).
- if you are hypersensitive or allergic to atropine or substances related to it, e.g. ipratropium or oxitropium.

Do not use FORVENT in children.

Warnings and precautions

FORVENT 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 (rescue therapy).

Immediate allergic reactions such as rash, swelling, itching, wheezing or breathlessness may occur after administration of FORVENT. If this occurs, please consult your doctor immediately.

If your breathing gets worse directly after using your inhaler, stop using it and tell your doctor immediately.
You should also contact your doctor if you feel that your breathing is worsening.

Tell 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.

When using FORVENT take care not to let any of the spray enter your eyes. If any of the spray does get into your eyes, you must wash your eyes with warm water. If you experience any blurred vision, eye pain and/or red eyes you must contact your doctor immediately.

Do not use FORVENT more frequently than once daily.

Children and adolescents

Do not use FORVENT in children and adolescents under 18 years.

Other medicines and FORVENT

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

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

Pregnancy and breastfeeding
You should not use FORVENT if you are pregnant or are breastfeeding.

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

Driving and using machines
Taking FORVENT should not affect your ability to drive or use machines. However, if you experience side effects which affect your alertness (e.g. dizziness or blurred vision) do not drive or operate machinery.

It is not always possible to predict to what extent FORVENT may interfere with your daily activities. You should not engage in the above activities until you are aware if FORVENT affects you.

FORVENT contains lactose monohydrate
FORVENT capsules contain 5,5 mg lactose monohydrate (milk sugar).
If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking FORVENT.

3. How to use FORVENT
Do not share medicines prescribed for you with any other person.

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

FORVENT is for inhalation use only. The FORVENT capsules must not be swallowed.

Inhale the contents of one capsule once daily, at the same time each day, using the HandiHaler® device.

Take note of the following
After you have inhaled once with the aid of the HandiHaler® device, the capsule is still not completely empty. Therefore, you must ***inhale a second time from the same capsule.***
Make sure that you know how to use your HandiHaler® properly. Please refer to the HandiHaler® instructions for use (at the end of this leaflet).
If you have any problems using your HandiHaler®, ask your doctor or pharmacist to show you how it works.

As COPD is a long-term disease use FORVENT every day and not only when you experience breathing problems.

Your doctor will tell you how long your treatment with FORVENT will last. Do not stop treatment with FORVENT early because this may interfere with the management of your COPD.

If you have the impression that FORVENT is too strong or too weak, tell your doctor or pharmacist.

If you use more FORVENT than you should

If you inhale too many puffs you may experience the following: dry mouth and/or rapid heart rate and/or blurred vision.

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

If you forget to use FORVENT

If you forget to take your daily dose don't worry. Take it 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.

4. Possible side effects

FORVENT can have side effects.
The most common side effect with FORVENT is dry mouth, which is usually mild.

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

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

- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- unexpected tightness of the chest, coughing, wheezing or breathlessness immediately after using FORVENT
- rash, itching or hives on the skin and other hypersensitivity reactions

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

The following side effects are reported less frequently:

- dizziness
- headache
- taste disorder
- inability to sleep
- blurred vision
- seeing halos around lights or coloured images in association with red eyes (glaucoma)
- increase in the measured eye pressure



- fast or irregular heartbeat
- palpitations (feeling your heartbeat)
- sore throat
- hoarseness
- cough
- nose bleeds
- loss of voice
- fullness of the nose, cheeks and behind your eyes, sometimes with a throbbing ache
- heartburn
- constipation
- fungal infection of the mouth (thrush)
- blockage of the intestine, absence of bowel movements or severe pain in the stomach with bloating, cramps and vomiting
- swollen, sore gums
- swollen, sore tongue
- difficulty in swallowing
- sore mouth
- nausea
- skin rash
- difficulty in passing urine
- pain when passing urine
- urinary tract infections

Other side effects reported are:
- excessive loss of body water
- tooth decay
- skin infection
- skin ulcers
- dry skin
- joint swelling

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 the South African Health Products Regulatory Authority (SAHPRA), via the Med Safety App (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website. Suspected adverse reactions can also be reported directly to the holder of the certificate of registration using the email address pv_local_south_africa@boehringer-ingelheim.com.
By reporting side effects, you can help provide more information on the safety of FORVENT.

5. How to store FORVENT



Store at or below 25 °C.
Do not freeze.
Prior to use, the blister strip must be torn along the perforation into two halves, each containing five capsules. (Please refer to the HandiHaler® device instructions for use, blister handling section). Once the foil has been peeled back from the half blister strip and the first capsule exposed to air, the contents of the capsules in this half of the blister strip must be inhaled within 4 to 5 days.
Store all medicines out of reach of children.
Do not use FORVENT after the expiry date printed on the pack.
Return all unused medicine to your pharmacist.

6. Contents of the pack and other information

What FORVENT contains

The active substance is tiotropium.
Each hard gelatine capsule contains 18 micrograms of tiotropium.
Other ingredient: Lactose (which contains milk protein).

What FORVENT looks like and contents of the pack

Light green, opaque, hard gelatine capsules, containing a white powder, with "TI 01" and the Boehringer Ingelheim company logo printed in black on the capsule.
Cartons containing 30 capsules for inhalation.
Cartons containing a HandiHaler® device and 30 capsules for inhalation.
The capsules are packaged in aluminium blister strips containing 10 capsules per strip.

Holder of Certificate of Registration

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This leaflet was last revised on

05 May 2026

Registration number

36/10.2.1/0045

0251-08-09

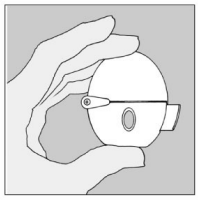


HandiHaler®

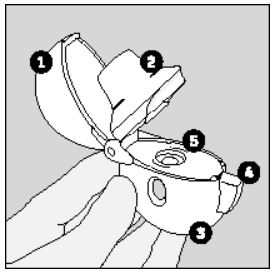
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INSTRUCTIONS FOR USE

The HandiHaler® is an inhalation device especially designed for FORVENT capsules for inhalation. It must not be used to take any other medication.

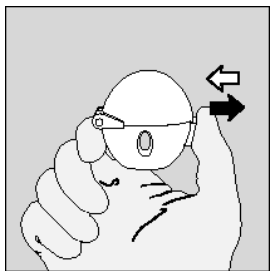


Remember to follow your doctor's instructions carefully when using FORVENT capsules for inhalation. After first use, you can use your HandiHaler® device for up to one year before you need to replace it with a new one.

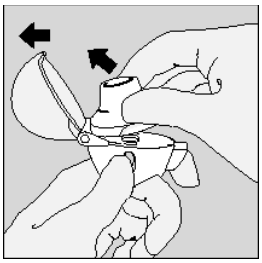


The HandiHaler® device

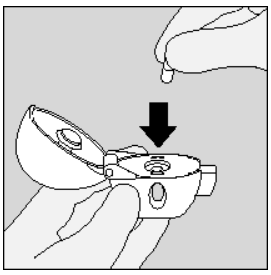
1 dust cap
2 mouthpiece
3 base
4 piercing button
5 centre chamber



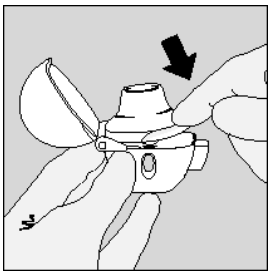
1. To release the dust cap press the piercing button completely in and let go.



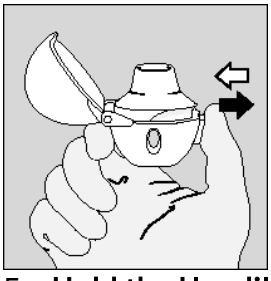
2. Open the dust cap completely by pulling it upwards.
Then open the mouthpiece by pulling it upwards.



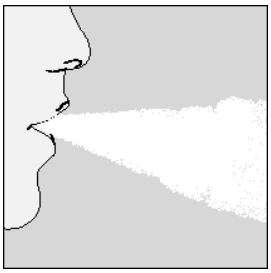
3. Remove a FORVENT capsule from the blister (only immediately before use) and place it in the centre chamber, as illustrated. It does not matter which way up the capsule is placed in the chamber.



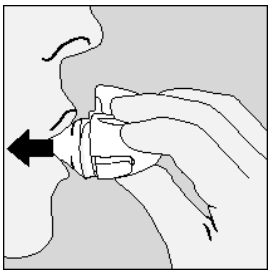
4. Close the mouthpiece **firmly** until you hear a click. Leave the dust cap open.



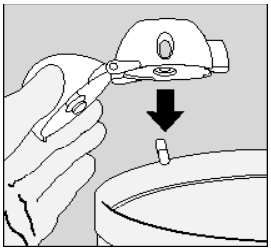
5. **Hold the HandiHaler® device with the mouthpiece facing upwards and press the light green piercing button completely in only once, and release.** This makes holes in the capsule and allows the medication to be released when you breathe in.



6. **Breathe out completely. Important:** do not breathe into the mouthpiece at any time.

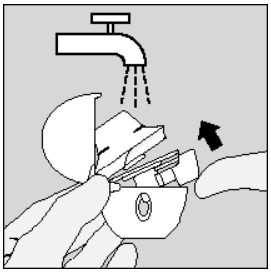


7. Raise the HandiHaler® device to your mouth and close your lips tightly around the mouthpiece. Keep your head in an upright position and breathe in slowly and deeply but at a rate sufficient to hear or feel the capsule vibrate.
   Breathe in until your lungs are full; then hold your breath for as long as is comfortable and take the HandiHaler® device out of your mouth at the same time. Resume normal breathing.
   Repeat steps 6 and 7 once, this will empty the capsule completely.



8. Open the mouthpiece again. Tip out and dispose of the used capsule. Close the mouthpiece and dust cap.

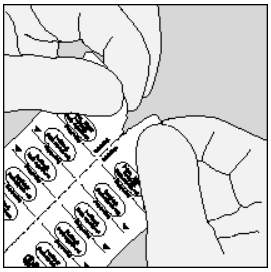
CLEANING THE HANDIHALER® DEVICE:



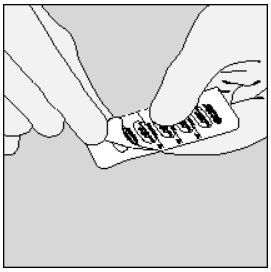
Clean the HandiHaler® device once a month.
Open the dust cap and mouthpiece, then open the base by lifting the piercing button. Rinse the complete inhaler with warm water to remove any powder. Dry the HandiHaler® device thoroughly by tipping excess water out on a paper towel and air dry afterwards,

leaving the dust cap, mouthpiece and base open. It takes 24 hours to air dry the HandiHaler® device, so clean it immediately after use so that it will be ready for your next dose.
The outside of the mouthpiece may be cleaned with a moist but not wet tissue or clean cloth, if needed.

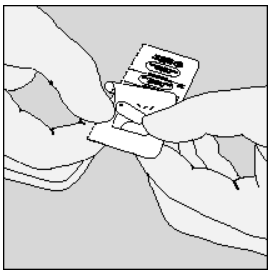
BLISTER HANDLING:



A. Separate the FORVENT blister strips by tearing along the perforation.



B. Peel back the foil (only immediately before use) using the tab until one capsule is completely visible. After first opening of the half blister, use within 4 to 5 days.
In case a second capsule is exposed to air inadvertently this capsule has to be discarded.



C. Remove the capsule.

The capsules should not be packed or stored in the HandiHaler® device nor should they be exposed to extreme temperatures i.e. sunlight or heat.

FORVENT capsules contain only a tiny amount of powder so that the capsule is only partially filled.