





INHALATION ROUTE



RESPYVA® 18 µg
Tiotropium

LEAFLET: USER INFORMATION


30 CAPSULES
& 1 inhaler



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Tiotropium

LEAFLET: USER INFORMATION

30 CAPSULES
& 1 inhaler



NON00016 / VO0

Read this leaflet carefully before taking this medicine as 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 for more information.
- This medicine has been prescribed only for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious or if you notice any side effects not listed in this leaflet, talk to your doctor or pharmacist. See section 4.

What is in this leaflet?

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

1. What RESPYVA 18 micrograms is and what it is used for ?

RESPYVA 18 micrograms 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 RESPYVA 18 micrograms every day and not only when you have breathing problems or other symptoms of COPD. RESPYVA 18 micrograms is a long-acting bronchodilator that helps open your bronchial tubes and makes it easier to get air in and out of your lungs. Regular use of RESPYVA 18 micrograms 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 be active longer. Daily use of RESPYVA 18 micrograms will also prevent sudden short-term worsening of your COPD symptoms which may last for several days. The effect of RESPYVA 18 micrograms lasts for 24 hours, so you only need to use it once a day. For correct dosing of RESPYVA 18 micrograms, please see section 3. "How to use RESPYVA 18 micrograms", and the instructions on how to use are provided at the end of the leaflet.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE RESPYVA 18 MICROGRAMS ?

Do not use RESPYVA 18 micrograms

- If you are allergic (hypersensitive) to tiotropium, its active substance, 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 RESPYVA 18 micrograms. Talk to your doctor if you suffer from narrow angle glaucoma, prostate problems, or have difficulty passing urine.

If you have kidney problems, please consult your doctor. RESPYVA 18 micrograms is indicated for the 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 RESPYVA 18 micrograms. If this occurs, consult your doctor immediately. Inhaled treatment, such as RESPYVA 18 micrograms, may cause chest tightness, coughing, wheezing or breathlessness immediately after inhalation. If this occurs, consult your doctor immediately. Take care not to let the powder enter your eye as this may result in precipitation or worsening of narrow-angle glaucoma (disease of the eye). Eye pain or discomfort, blurred vision, seeing halos around light 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 RESPYVA 18 micrograms 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 RESPYVA 18 micrograms is the right medicine for you to take. Do not use RESPYVA 18 micrograms more frequently than once daily.

Children and adolescents

RESPYVA 18 micrograms is not recommended for children and adolescents under 18 years old.

Other medicines and RESPYVA 18 micrograms

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including medicines available without a prescription. Tell your doctor or pharmacist if you are using or have used other similar medicines to treat your disease, such as ipratropium or oxitropium. No medicine interactions have been reported when RESPYVA 18 micrograms has been administered with other products used to treat COPD, such as reliever inhalers (eg salbutamol), methylxanthines (eg. theophylline) and/or inhaled or oral steroids (eg.

prednisolone).

Pregnancy and Breastfeeding

If you are pregnant or breastfeeding, 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 your ability to drive or use machines.

RESPYVA 18 micrograms contains lactose monohydrate.

When RESPYVA 18 micrograms is taken as recommended, one capsule once a day, each dose contains 14.97 mg of lactose monohydrate. If your doctor has informed you that you have an intolerance to some sugars, or an allergy to milk proteins (which may be contained in small amounts in the lactose monohydrate), contact him before taking this medicinal product.

3. HOW TO TAKE RESPYVA 18 MICROGRAMS ?

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 one capsule (18 micrograms of tiotropium) once a day. Do not use more than the recommended dose. RESPYVA 18 micrograms is not recommended in children and adolescents under 18 years old. Try to use the capsule at the same time every day. This is important because RESPYVA 18 micrograms is effective over 24 hours. Tiotropium bromide capsules are only for inhalation and not for oral intake. Do not swallow the capsules. The device, which you should put the RESPYVA 18 micrograms capsule into, makes a hole in the capsule and allows you to inhale the powder. Make sure that you have the inhaler and that you can use it properly. Instructions for use of the device are provided at the end of this leaflet. Make sure that you do not blow into the device. If you have any problems using the inhaler, ask your doctor, nurse or pharmacist to show you how it works. You should clean the inhaler once a month. Cleaning instructions for the inhaler are provided at the end of this leaflet. When taking RESPYVA 18 micrograms 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

face or throat (angioedema) - urticaria - itching (pruritus) - infections of the urinary tract

Not known (the frequency of occurrence cannot be estimated from the available clinical 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). Other hypersensitivity reactions (such as sudden reduction in blood pressure or dizziness) may occur individually or as part of a severe allergic reaction (anaphylactic reaction) after administration of RESPYVA 18 micrograms. In addition, in common with all inhaled medicines, some patients may experience unexpected tightness of the chest associated with coughing, wheezing or breathlessness immediately after inhalation (bronchospasm). If any of these effects occur, please consult your doctor immediately.

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 : National Center for Pharmacovigilance (NCPV). By reporting side effects, you can help provide more information about the safety of the medicine.

5. HOW TO STORE RESPYVA 18 MICROGRAMS

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 packaging after "EXP". The expiry date refers to the last day of that month. Once you have taken the first capsule from the blister, you must use capsules from the same blister for the next 9 days (one capsule a day). Discard the inhalation device 12 months after first use. Store at a temperature not exceeding 25°C. Do not freeze. Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everyone gets them. The side effects described below have been seen in patients taking this medicine and they are listed according to frequency as common, uncommon, rare, or not known.

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

Dry mouth: it 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 (gastroesophageal reflux disease)
- constipation
- fungal infections of the oral cavity and throat (oropharyngeal candidiasis)
- skin eruption (rash)

- difficulty passing urine (urinary retention)
- painful urination (dysuria)

Rare (may affect up to 1 in 1000 people):

- difficulty in sleeping (insomnia)
- seeing halos around light or coloured images in association with red eyes (glaucoma)
- increased of the measured eye pressure
- irregular heartbeat (supraventricular tachycardia)
- faster heartbeat (tachycardia)
- feeling your heartbeat (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)
- difficulty swallowing (dysphagia)
- inflammation of the mouth (stomatitis)
- nausea
- hypersensitivity including immediate allergic reactions
- serious allergic reactions which causes swelling of the

face or throat (angioedema) - urticaria - itching (pruritus) - infections of the urinary tract

Not known (the frequency of occurrence cannot be estimated from the available clinical 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

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6. CONTENT OF THE PACKAGING AND OTHER INFORMATION?

What RESPYVA 18 micrograms contains

The active substance is tiotropium. Each capsule contains 18 micrograms of tiotropium (as bromide monohydrate). The other ingredient is lactose monohydrate (which may contain small amounts of milk protein).

Aspect of RESPYVA 18 micrograms and content of the outer packaging

RESPYVA 18 micrograms powder for inhalation in capsule is in a box of 30 capsules with 1 inhaler.

Marketing Authorization Holder and Manufacturer :

Neapolis Pharma
Road of Tunis Km 7 - PB 206 Nabeul 8000 - Tunisia.
Tel : +216.31.338.420
Fax : +216.31.338.421
E-mail : neapolispharma@neapolispharma.com

Marketing Authorization Number :

RESPYVA 18 µg Powder for inhalation in capsule box of 30: 939 325 1

Supply and prescription conditions:

LIST I

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LIST I

This leaflet was last reviewed : 08/2024

Instructions for use of the inhalation device

Dear patient,

The inhaler allows you to inhale the product from one RESPYVA 18 microgram capsule, which your doctor has prescribed for you to treat your breathing problems

- 1 Remove the protective cap.
- 2 Open the capsule chamber: firmly hold the base and rotate the mouthpiece in the direction of the arrow.
- 3 Make sure that your fingers are dry and place the capsule in the space provided for this purpose (caution: do not put the capsule in the mouthpiece!). **Important:** remove the capsule from its packaging at the last moment.
- 4 Close the inhaler by returning the mouthpiece to its original position until it clicks
- 5 To release the powder from the capsule, press the 2 push buttons at the same time while keeping the inhaler in an upright position, then release. Do this once.

- 6 Exhale fully
- 7 Place the mouthpiece in your mouth and tighten your lips, tilt your head back, inhale quickly and very deeply through your mouth,

Note : a slight continuous humming should be heard when the capsule swirls in its chamber. If it is not the case, check that the capsule is well in place.

- 8 Remove the inhaler from your mouth, holding your breath for as long as possible. Then breathe normally. Open the inhaler to check that there is no powder left. If powder remains, repeat inhalation.

- 9 After use, take out the empty capsule, refit the mouthpiece and the protective cap.

Maintenance: clean the mouthpiece and the capsule chamber with a dry cloth to remove any powder residue.

Warning: never wash the inhaler with water.

This is a medicine

- A medicine is a product but not like any other product.
- A medicine is a product that affects your health and health its consumption without compliance to the prescription exposes to danger
- Strictly follow your doctor's prescription and directions for use, follow the advice of your pharmacist
- Your doctor and your pharmacist are familiar with the medicine, its indications and contraindications.
- Don't stop treatment on your own initiative during the prescribed period.
- Do not take it again, do not increase the doses without consulting your doctor.

Keep the medicines out of the reach of children

إن هذا الدواء

- الدواء مستحضر ولكن ليس كغيره من المستحضرات.
- الدواء مستحضر يؤثر على صحتك واستعماله بلائلا للتعليمات يعرضك للخطر.
- اتبع بدقة وصفة الطبيب وطريقة الاستعمال الممنوص عليها
- تقيّد بتعليمات الصيدلاني الذي مرصها لك والطبيب والصيدلاني هما الخياران بالدواء وبتفقه وضرره.
- لا تلتقط مدة العلاج الممعدة لك من تلقاء نفسك.
- لاتعد ولاترّد عليها بدون استشارة الطبيب.

لا تتسكك الأدوية في متناول ايدي الأطفال



Formulaire

Bon à Tirer pour notice pharmaceutique (BAT)

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Version : 00
Date : 09/09/2022
Page: 1/1

Informations Générales

Références (Code/Version)	
Désignation de l'Article	notices RESPYVA
Client	medis
Date : 09/09/2024	Création <input checked="" type="checkbox"/> Motif de Modification <input type="checkbox"/>

Caractéristiques Infographiques

Infographiste: Marwa kara	Vérificateur: Mr. Walid KHALFALLAH		
Logiciel : Indesgin	Police :	Corps :	Interlinges :

Caractéristiques Techniques (Impression et Finition)

Support: 50 gr (±5%)	Couleurs d'impression :
Impression: quadrie + pantone 293U	Recto:
Dimensions à plat : 40,8 x 39,2 cm (± 1 mm)	Verso:
Pliage: Oui <input checked="" type="checkbox"/> Non <input type="checkbox"/> Si pliée: voir Fiche de Pliage jointe	Date de BAT :
Dimensions pliées : 6,8 X 9,8 CM	Nom et Signature des Approbateurs:
Conditions / Spécifications : avec bande	
 <small>29, Av. de l'Indépendance - Rés. Meriem - Bloc A App. AR1 - Borj Baccouche 2080 Ariana Tél: 71.723.200 - Fax: 71.723.173 - infographie.tunis@sogim.com.tn - imprimerie.sogim@sogim.com.tn Cité El Médina Zrig 6072- BP 91 Hached Gabès 6001- Tunisie - Tél.: 75.392.270 - Fax: 75.392.944 TVA: 009588G/A/M/000 - RNE: B1442319 98 - CD: 520071/R</small>	



Société Générale d'Impression

FICHE DE PLIAGE
MEDIS PHARMA
Notice RESPYVA 40,8x39,2

- 1- Dimension à Plat = 40,8*39,2 cm
- 2- Dimension Plié = 6,8*9,8 cm
- 3- Schéma de pliage :

