

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

Tiotropium Bromide Rotacaps 18 mcg

Tiova - T

Rotacaps

For use with Revolizer

Composition

Each capsule contains :

Tiotropium..... 18 mcg
(as Tiotropium Bromide Monohydrate BP)
Approved colour used in empty capsule.

Description

Tiotropium bromide is a long-acting, specific, muscarinic receptor antagonist, in clinical medicine often called an anticholinergic. By binding to the muscarinic receptors in the bronchial smooth musculature, tiotropium bromide inhibits the cholinergic (bronchoconstrictive) effects of acetylcholine, released from parasympathetic nerve endings. The long duration is probably due to the very slow dissociation from the M3 receptor, exhibiting a significantly longer dissociation half-life than ipratropium.

Indications

Tiotropium bromide is indicated in the maintenance treatment of chronic obstructive pulmonary disease (COPD).

Dosage and Administration

The recommended dosage of tiotropium is the inhalation of one rotacap once daily. Tiotropium bromide should only be inhaled with the Revolizer device. The recommended dose should not be exceeded. Tiotropium bromide rotacaps must not be swallowed.

Contraindications

Tiotropium bromide inhalation powder is contraindicated in patients with hypersensitivity to tiotropium, atropine or its derivatives, e.g. ipratropium or oxitropium or to the excipient lactose monohydrate.

Warnings and precautions

Tiotropium bromide, should not be used for the initial treatment of acute episodes of bronchospasm, i.e. rescue therapy. Immediate hypersensitivity reactions may occur after administration of tiotropium bromide inhalation powder. As with other anticholinergic drugs, tiotropium bromide should be used with caution in patients with narrow-angle glaucoma, prostatic hyperplasia or bladder-neck obstruction. Inhaled medicines may cause inhalation-induced bronchospasm.

Patients should be cautioned to avoid getting the drug powder into their eyes. They should be advised that this may result in precipitation or worsening of narrow-angle glaucoma, eye pain or discomfort, temporary blurring of vision, visual halos or coloured images in association with red eyes from conjunctival and corneal congestion. Patients should stop using

tiotropium bromide and consult a physician immediately 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. Tiotropium bromide should not be used more frequently than once daily.

Drug Interactions

The co-administration of tiotropium bromide with other anticholinergic-containing drugs has not been studied and is therefore not recommended.

Pregnancy and lactation

Tiotropium bromide should not be used in pregnant or nursing women unless the expected benefit outweighs any possible risk to the unborn child or the infant.

Adverse events

Several organ systems and functions are under control of the parasympathetic nervous system and thus can be affected by anticholinergic agents. Possible adverse events attributable to systemic anticholinergic effects include dry mouth, dry throat, increased heart rate, blurred vision, glaucoma, urinary difficulty, urinary retention, and constipation. In addition, local upper airway irritant phenomena were observed in patients receiving tiotropium bromide. An increased incidence of dry mouth and constipation may occur with increasing age.

The most common anticholinergic adverse

reaction reported by COPD patients was dry mouth which was mild in the majority of cases. In general, dry mouth had an onset between 3 and 5 weeks which resolved while patients continued to receive tiotropium bromide. Discontinuation rates due to dry mouth were 0.3% (3 of 906 patients) of the treated patients from the one-year studies

Storage

Store below 30°C

Presentation

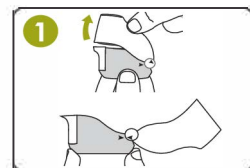
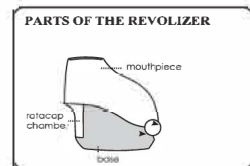
Pack of 15 Rotacaps

Cipla

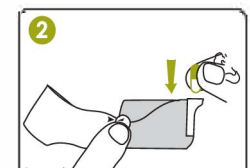
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HOW TO USE ROTACAPS WITH THE REVOLIZER

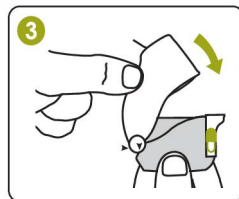
REFER TO THE DIAGRAMS



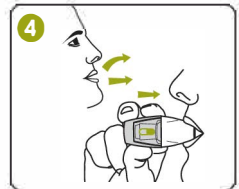
1 : To open, hold the Revolizer at the base with one hand, and pull back the mouthpiece as shown till both arrows meet.



2 : Take a Rotacap from its bottle. Insert the Rotacap into the Rotacap chamber with the transparent end facing down as shown.



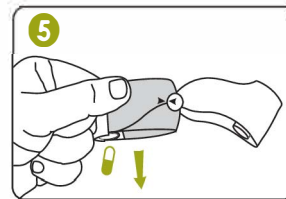
3 : Close the mouthpiece firmly. A 'click' sound will indicate proper closing of the Revolizer.



4 : Breathe out fully through your mouth. Position the mouthpiece between your teeth and close your lips tightly around it.

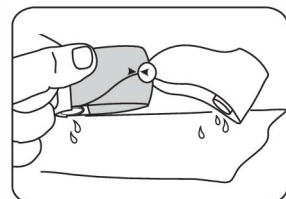
Sit or stand upright, keep your head straight, and breathe in through your mouth as rapidly and deeply as you can. When done correctly, you will hear the Rotacap vibrating inside the Revolizer.

Remove the Revolizer from your mouth and hold your breath for about 10 seconds or for as long as it is comfortable. It is important to inhale all the powder which can be seen through the Rotacap chamber. You may need to repeat step 4 to ensure this.



5 : After every use, open the mouthpiece (till both arrows meet) and discard the empty Rotacap. Close the mouthpiece and store the Revolizer in the convenient carry pouch provided.

For your next use, take a new Rotacap and follow steps 1 to 5.



CLEANING THE REVOLIZER

You must remember to clean the Revolizer at least once a week to ensure smooth functioning.

- Open the mouthpiece (till both arrows meet) of the Revolizer.
- Remove the empty Rotacap (if any) from the Rotacap chamber
- Rinse the mouthpiece and Rotacap chamber in clean running water.

- Shake well to remove excess water and leave to air dry. This can take upto 6 hours, so preferably clean the Revolizer and leave to dry overnight. Do not expose the Revolizer to heat.

CAUTION:
DO NOT PUSH ANY CLOTH OR INSTRUMENT INTO THE MOUTHPIECE OF THE REVOLIZER AS THIS MAY CAUSE DAMAGE

REMEMBER:

- Keep the Revolizer clean and dry at all times.
- Never use the Revolizer when it is wet.
- It is recommended to use a new Revolizer every 6 months.
- Use only as directed by your doctor. If the recommended dose does not provide relief from symptoms or if symptoms become worse, consult your doctor
- Keep the Rotacap bottle tightly closed to avoid exposure to moisture. Open the Rotacap bottle just prior to use.
- At times a fine layer of powder may remain in the empty Rotacap after use This is normal and does not alter the effect of the medicine.
- Store the Revolizer along with the Rotacap bottle in the convenient carry pouch provided.

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