aridol®

(mannitol inhalation powder)
Bronchial Challenge Test Kit

Aridol®
Inhalation Guide

Please see important safety information on reverse.

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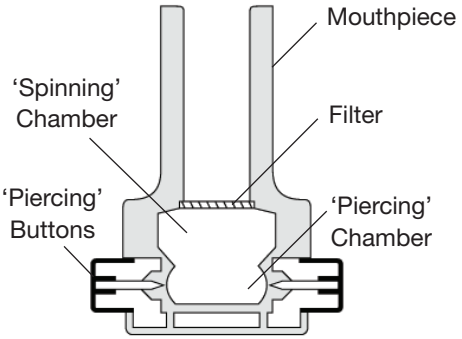
Aridol® Inhalation Guide

aridolchallenge.com

Aridol® inhaler device



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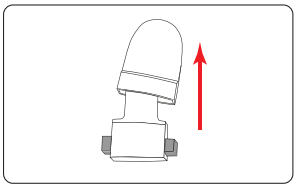
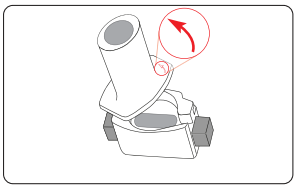
1 **Remove Cap**

Using both hands, hold the inhaler upright and remove the cap.



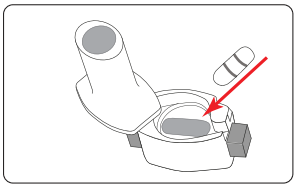
2 **Open**

Hold the base of the inhaler firmly with one hand and open the device by rotating the mouthpiece in the direction of the arrow on the device as shown.



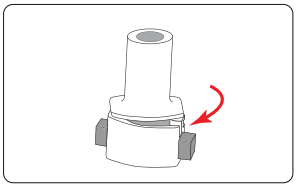
3 **Load**

Using dry hands, remove a capsule from the Aridol® pack and place into the inhaler as illustrated. It does not matter which way the capsule is placed in the chamber.



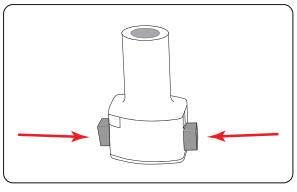
4 **Close**

Keeping the device in an upright position, twist the mouthpiece into the closed position until you hear it 'click' shut.



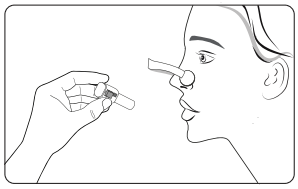
5 **Pierce Capsule**

Hold the inhaler upright and fully depress both piercing buttons on the sides of the device at the same time.



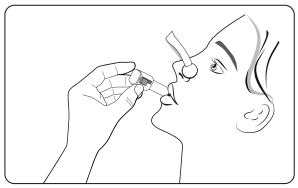
6 Prepare for Inhalation

Tilt the inhaler so that the mouthpiece faces slightly downward at a 45-degree angle as shown. This allows the capsule to drop forward into the spinning chamber. Keep the device tilted in this way and instruct the subject to breathe out completely (away from the inhaler).



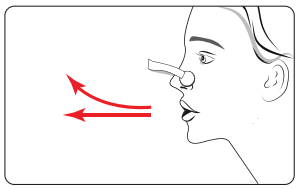
7 Inhale

The subject should tilt their head back slightly, and keeping the inhaler mouthpiece facing down at a 45-degree angle, raise the device to their mouth and ensure they close their lips tightly around the mouthpiece. Encourage the subject to take a controlled deep inhalation until their lungs are full. The subject should then hold their breath for five seconds. ***Note: During a successful inhalation you should hear a rattling sound as the capsule spins in the inhaler.***



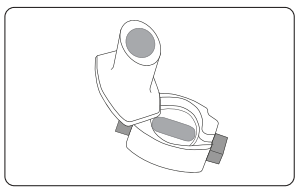
8 Exhale

Remove the inhaler from the subject's mouth, allow them to exhale and resume normal breathing.



9 Check

The Aridol® capsule must spin inside the inhaler in order to empty. A second inhalation (using the same capsule) may be required immediately if the capsule has not been emptied sufficiently following inhalation. Check the capsule following each inhalation.



Important Notes

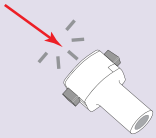
Inhaler Tips

When subjects are exhaling during the Aridol® challenge, ensure they do so AWAY from the inhaler to minimize humidity within the device.

When piercing the capsule, do so once only (by depressing both buttons simultaneously and fully) as re-piercing may cause the capsule to split/fragment.

The inhaler device is designed as SINGLE USE ONLY (one device per challenge) and should not be cleaned during the challenge. Discard following each Aridol® challenge. Do not sterilize and re-use as this may compromise the integrity of subsequent test results.

Using latex gloves when administering the test and handling Aridol® capsules may increase static and inhibit capsule movement within the inhalation device.



If you suspect that static is an issue or notice that the sound of the capsule 'rattling' cannot be heard during inhalation of Aridol®, firmly tap the base of the inhaler with one hand whilst holding it with the other (mouthpiece facing downwards at a 45° angle). This should ensure that the capsule has been 'dislodged' from the piercing chamber into the spinning chamber.

For technical support, please contact us Toll-Free at 1-833-887-7686

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Important Safety Information

WARNING: RISK OF SEVERE BRONCHOSPASM

Mannitol, the active ingredient in ARIDOL, acts as a bronchoconstrictor and may cause severe bronchospasm. Bronchial challenge testing with ARIDOL is for diagnostic purposes only. Bronchial challenge testing with ARIDOL should only be conducted by trained professionals under the supervision of a physician familiar with all aspects of the bronchial challenge test and the management of acute bronchospasm. Medications (such as short-acting inhaled beta-agonist) and equipment to treat severe bronchospasm must be present in the testing area. If severe bronchospasm occurs it should be treated immediately by administration of a short-acting inhaled beta-agonist. Because of the potential for severe bronchoconstriction, bronchial challenge testing with ARIDOL should not be performed in any patient with clinically apparent asthma or very low baseline pulmonary function tests (e.g., FEV_1 <1-1.5 liters or <70% of the predicted values). See full prescribing information for complete boxed warning.

Mannitol, the active ingredient in ARIDOL, is a sugar alcohol indicated for the assessment of bronchial hyperresponsiveness in patients 6 years of age or older who do not have clinically apparent asthma. ARIDOL is not a standalone test or a screening test for asthma. Bronchial challenge testing with ARIDOL should be used only as part of a physician's overall assessment of asthma.

ARIDOL is contraindicated in patients with known hypersensitivity to mannitol, the active ingredient in ARIDOL, or to the gelatin used to make the capsules. The product is also contraindicated for patients with medical conditions that may be compromised by induced bronchospasm or repeated spirometry maneuvers. Bronchial challenge testing with ARIDOL should not be performed in children less than 6 years of age due to their inability to provide reliable spirometric measurements. Use with caution in patients with conditions that may increase sensitivity to the bronchoconstricting or other potential effects of ARIDOL such as: severe cough, ventilatory impairment, unstable angina, or active upper or lower respiratory tract infection that may worsen with use of a bronchial irritant. The most common adverse reactions (rate ≥1%) were headache, pharyngolaryngeal pain, throat irritation, nausea, cough, rhinorrhea, dyspnea, chest discomfort, wheezing, retching and dizziness. No formal drug-drug interaction studies have been conducted with ARIDOL.

Please see complete prescribing information accompanying this piece or consult the Package Insert which is available for download at www.aridolchallenge.com or on request by calling Methapharm Medical Information at 1-800-287-7686 | 519-751-3602 ext. 7804 or faxing us at 519-751-9149. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch or call 1-800-FDA(332)-1088. This information is provided as a professional courtesy, and it is intended to provide data available to us that may assist you in deriving your own conclusions and opinions. This information is not intended to advocate any indications, dosage, or other claim that is not described in the package insert.

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