

ALZAIR- cream, nasal, topical, mechanical allergen particle barrier
Hudson Scientific LLC

Home Use Medical Device

Description

Alzair™ is a clinically proven, unique, natural product that works with the body's own nasal defense mechanism to strengthen its resistance to airborne allergens, such as pollen, dust mites, pet dander, and mold, which are inhaled through the nose. **Alzair™** is a natural plant-based extract that meets the highest purity and safety standards.

Studies have shown that by naturally enhancing nasal mucus, it is possible to filter out airborne allergens. **Alzair™** works by forming colorless, mucus-like gel lining in the nasal tract that acts as a barrier against pollen, dust, animal dander and mold.

Rx Only

Indications and Usage

Alzair™ Allergy Blocker is intended to treat hay fever and allergy sufferers by promoting alleviation of mild allergic symptoms (i.e. mild nasal irritation including itchy, runny, or congested nasal passages) triggered by the inhalation of various airborne allergens including indoor and outdoor environmental pollens, house dust, animal hairs and dust mites.

Application of **Alzair™** produces a mucus-like gel barrier that evenly coats the nasal membranes and acts to block inhaled allergens within the nasal cavity.

Who can use Alzair™:

Alzair™ is suitable for adults, including pregnant or breastfeeding women, and for pediatrics*.

Ingredients:

Hydroxypropyl methylcellulose, mint scent

Warnings and Precautions:

Discontinue use if irritation develops.

Dosage & Administration:

Before first use, test the pressure needed to administer an ideal dose. To do this, shake the bottle and remove the cap. Aim the bottle away from yourself and squeeze the bottle into the air.

- For pediatric patients, squeeze gently for a 2-inch plume
- For patients 12 years and up, squeeze firmly for a 6-inch plume.

Shake bottle before each use.

Squeeze the bottle away from yourself. Test the pressure needed to administer an ideal dose, which is approximately a two-inch to six inch plume of powder (see above)

Gently blow your nose. Breath out.

Place a finger over one nostril to close it.

Place the **Alzair™** bottle nozzle in the other nostril

Quickly and firmly push the sides of the bottle together to deliver one "puff" of **Alzair™** powder while

gently inhaling.

Wait two seconds and then gently inhale to enable the **Alzair™** powder to penetrate into the nasal passages. Repeat steps 3-6 on the other nostril.

Alzair™ may be used as often as required but is recommended three times a day (minimum). The key to getting the best out of **Alzair™** is to make sure you maintain a constant layer of powder across the inner lining of your nose. Doing this creates the barrier between the aggravating allergens and sensitive membrane within the nasal tract.

Take **Alzair™** before entering an environment containing airborne allergens- e.g. going out to the garden or dusting.

Remember to reapply each time you blow your nose.

* Based on the results of a clinical trial reported in Pediatric Allergy and Immunology [22 (2011); 594-599] of patients 8-18 years old with seasonal allergic rhinitis who were successfully treated with **Alzair™**.

How **Alzair™** is Supplied

800 mg of **Alzair™** powder is supplied in a proprietary squeeze bottle. It is packaged with an insert (shown below) in a box.

Manufacturer:

Alzair™ is manufactured for

Hudson Scientific LLC

103 W. Main St.

Hudson, MI 49247

Rx Only

Alzair™ Bottle Label:

The **Alzair™** bottle label is pictured below:

Alzair™ Insert

The insert below is included in each box of **Alzair™**:

Alzair™

ALLERGY BLOCKER

RX ONLY

This product is intended only for use as described.

What is Alzair™?

Alzair is a clinically proven, unique, natural product that works with your body's own nasal defense mechanism to strengthen your resistance to airborne allergens, such as pollen, dust mites, pet dander, and mold, which are inhaled through your nose. Alzair is a natural plant-based extract that meets the highest purity and safety standards.

How does Alzair™ work?

Studies have shown that by naturally enhancing nasal mucus, it is possible to filter out airborne allergens. Alzair works by forming a colorless, mucus-like gel lining in the nasal tract that acts as a barrier against pollen, dust, animal dander and mold.

Indications for Use

Alzair Allergy Blocker is intended to treat hay fever and allergy sufferers by promoting alleviation of mild allergic symptoms (i.e. mild nasal irritation including itchy, runny, or congested nasal passages) triggered by the inhalation of various airborne allergens including indoor and outdoor environmental pollens, house dust, animal hairs and dust mites.

Application of Alzair produces a mucus-like gel barrier that evenly coats the nasal membranes and acts to block inhaled allergens within the nasal cavity.

Ingredients: Hydroxypropyl methylcellulose, mint scent

Adverse Reactions

Excessive mucoid or gel buildup

Warnings

For nasal use only.

Do not use if tamper evident seal is broken or missing.

Keep out of reach of children.

Cleaning the Bottle

Should the bottle touch the nose or be contaminated by moisture, before replacing the cap, wipe the bottle thoroughly with a clean, dry, unused tissue. Only replace the cap when you are sure that no sign of dampness or contamination remains. Never use a bottle if you suspect it is contaminated.

Storage

Keep the bottle and especially nozzle dry at all times. Do not rinse the bottle with water or any other liquid as this may block it. Store at room temperature, away from moisture.

Once opened, use within 6 months

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Alzair™

RX ONLY

Who can use Alzair™?

Alzair is suitable for adults, including pregnant or breastfeeding women, and for pediatrics*.

How to use Alzair™

Before first use, test the pressure needed to administer an ideal dose. To do this, shake the bottle and remove the cap. Aim the bottle away from yourself and squeeze the bottle into the air.

For pediatric patients, squeeze gently for a 2-inch plume.

For patients 12 years and up, squeeze firmly for a 6-inch plume.

If using a medicated nasal spray, use prior to Alzair

1. Gently blow your nose. Breathe out.
2. Shake the Alzair bottle.
3. Squeeze the bottle away from yourself to test the pressure needed to administer an ideal dose: 6-inches for patients 12 years and up, 2-inches for pediatric patients, .
4. Place a finger over one nostril to close it.
5. Place the Alzair bottle nozzle in the other nostril.
6. Quickly and firmly push the sides of the bottle together to deliver one "puff" of Alzair powder while gently inhaling.
7. Wait two seconds and then gently inhale to enable the Alzair powder to penetrate into the nasal passages. Repeat steps 3-6 on the other nostril.
8. Alzair may be used as often as required, but it is recommended three times a day (minimum). The key to getting the best out of Alzair is to make sure you maintain a constant layer of powder across the inner lining of your nose. Doing this creates the barrier between the aggravating allergens and sensitive membrane within the nasal tract.
9. Take Alzair before entering an environment containing airborne allergens – e.g., going out to the garden or dusting.
10. Remember to reapply each time you blow your nose.

* Based on the results of a clinical trial reported in *Pediatric Allergy and Immunology* (22 (2011): 594-599) of patients 8-18 years old with seasonal allergic rhinitis who were successfully treated with Alzair.

Manufactured For:
Hudson Scientific LLC
Hudson, MI

For questions or information
visit www.alzair.com
or email info@alzair.com
Call toll-free 888-292-8080



Shake before
each use



Alzair™ Box

Each Alzair™ bottle is sold in the box pictured below:



ALZAIR

cream, nasal, topical, mechanical allergen particle barrier

Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:70914-030
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:70914-030-01	1 in 1 BOX		
1		800 mg in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
premarket notification	K170848	01/01/2018	

Labeler - Hudson Scientific LLC (080339637)

Establishment

Name	Address	ID/FEI	Business Operations
Hudson Scientific LLC		080339637	repack

Revised: 4/2018

Hudson Scientific LLC