

LEADER NASAL- mometasone furoate spray
Cardinal Health 110, LLC. dba Leader

Cardinal Health Allergy Nasal Spray Drug Facts

Active ingredient (in each spray)

Mometasone furoate monohydrate (glucocorticoid) 50 mcg

Purpose

Allergy symptom reliever

Uses

temporarily relieves these symptoms of hay fever or other upper respiratory allergies:

- nasal congestion
- runny nose
- sneezing
- itchy nose

Warnings

Only for use in the nose. Do not spray into your eyes or mouth.

Do not use

- in children under 2 years of age
- to treat asthma
- if you have an injury or surgery to your nose that is not fully healed
- if you have ever had an allergic reaction to this product or any of the ingredients

Ask a doctor before use if you

- have an eye infection
- have or had glaucoma or cataracts

Ask a doctor or pharmacist before use if you are taking

- medicine for HIV infection (such as ritonavir)
- a steroid medicine for asthma, allergies or skin rash
- ketoconazole pills (medicine for fungal infection)

When using this product

- the growth rate of some children may be slower
- stinging may occur for a few seconds right after use

- you may start to feel relief within 12 hours and full effect after several days of regular, once-a-day use
- do not share this bottle with anyone else as this may spread germs
- remember to tell your doctor about all the medicines you take, including this one

Stop use and ask a doctor if

- you have, or come into contact with someone who has chickenpox, measles or tuberculosis
- your symptoms do not get better within 7 days of starting use or you get a new symptom such as severe facial pain or thick nasal discharge. You may have something more than allergies, such as an infection.
- you get a constant whistling sound from your nose. This may be a sign of damage inside your nose.
- you get an allergic reaction to this product. Seek medical help right away.
- you get new changes to your vision that develop after starting this product
- you have severe or frequent nosebleeds

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

Read insert (inside package) for how to:

- prime the bottle
- use the spray
- clean the nozzle
- shake well before each use
- use this product only once a day
- do not use more than directed

Adults & children 12 years of age and older

- 2 sprays in each nostril once daily while sniffing gently

Children 2 to 11 years of age

- the growth rate of some children may be slower while using this product. **Children should use for the shortest amount of time necessary to achieve symptom relief. Talk to your child's doctor if your child needs to use the spray for longer than two months a year.**
- an adult should supervise use
- 1 spray in each nostril once daily while sniffing gently

Children under 2 years of age

- **do not use**

Other information

- **do not use if sealed package is torn or opened**
- **keep package and insert. They contain important information.**
- **store between 20-25° C (68-77° F)**

Inactive ingredients

benzalkonium chloride, citric acid, glycerin, microcrystalline cellulose and carboxymethylcellulose sodium, polysorbate 80, purified water, sodium citrate

Questions or comments?

Call toll-free **1-800-719-9260**

Consumer information

Mometasone Furoate Nasal Spray, 50 mcg/Spray

1Y800 00 J2

A GETTING STARTED

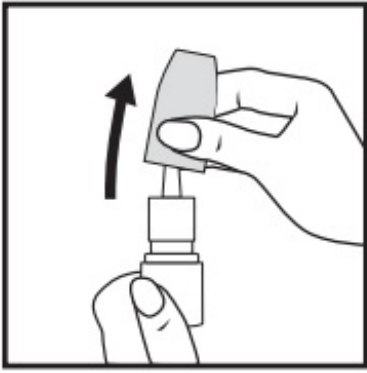
This product works best at relieving your allergy symptoms when you get a full dose. Here's how to get started, in five easy steps.

1 SHAKE

Shake spray bottle well.



Remove cap.



2 PRIME

Do this when:

- Starting a new bottle
- Bottle has not been used in one week
- Just cleaned nozzle

Otherwise go to step 3



Aim away from the face. Grasp spray bottle as shown. Pump until fine mist appears.

Pumped ten times and still no mist? Spray nozzle may be clogged. See **KEEP IT CLEAN,** other side.

NOTE: There is enough medicine in the bottle to allow for priming sprays plus the number of sprays

labeled on the bottle.

3 BLOW

Blow nose gently to clear nostrils.

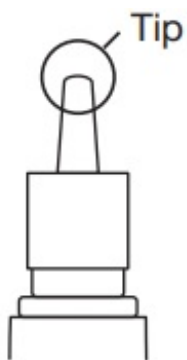


4 AIM

Close one nostril and put tip of spray nozzle in other nostril.



Put just the tip into your nose.



Aim slightly away from center of nose.



5 BREATHE AND SPRAY



While sniffing gently, press down on spray nozzle once or twice (according to dosing instructions).

You'll feel a light mist in your nose. Breathe out through your mouth.

Repeat in other nostril.

Wipe spray nozzle with clean tissue and replace cap.

Dosing and Cleaning instructions

See other side

SIDE 1

B DIRECTIONS FOR USE

This product works best when you use it daily.

Here's how to get started.

Children age 2-11

An adult should supervise use

Use one spray in each nostril once daily.



Check with your child's doctor if child needs to use this product for longer than two months a year.

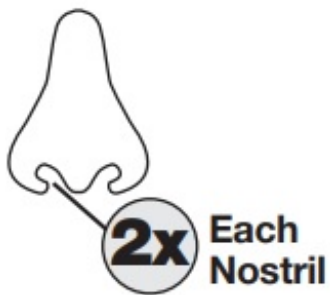
WARNING:

Do not spray in your eyes. Only for use in your nose.



Users age 12 or older

Use two sprays in each nostril every day.



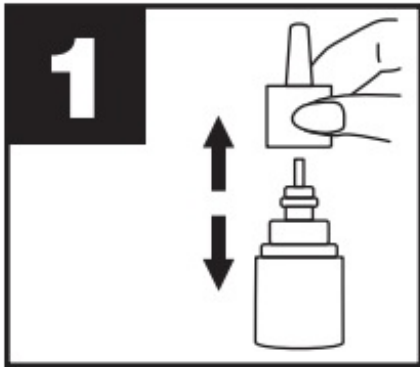
Other important information for use

- **Do not use more than directed.**
- If you forget a dose, do **not** double the next dose.
- Do not spray into eyes or mouth.
- If you get the spray in your eyes, rinse well with water.
- If allergy symptoms do not improve after one week, stop using and talk to a doctor.
- Do not share this bottle with anyone else as this may spread germs.

C KEEP IT CLEAN

A clean spray nozzle helps ensure a full dose. Clean it weekly, or if it's clogged. Don't try to unblock nozzle with pin or sharp object - that can damage it.

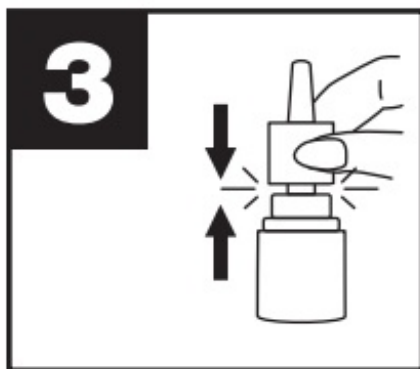
Remove spray nozzle by grasping at base and pulling up.



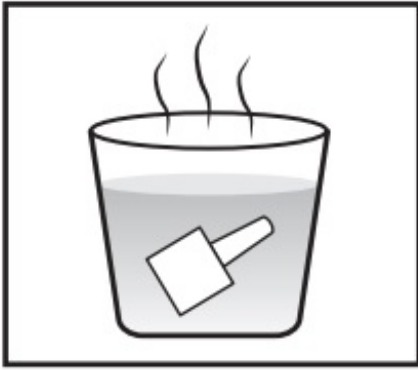
Rinse under running tap water, and dry at room temperature.



Aim away from your face and gently, but firmly replace spray nozzle.



If spray nozzle is clogged, soak in warm water. Then repeat steps **2** and **3**.



Questions or comments? Call toll-free **1-800-719-9260**

Store between 20°-25°C (68°-77°F)

Distributed By

Perrigo®

Allegan, MI 49010

SIDE 2

Package/Label Principal Display Panel

LEADER™

Non-Drowsy | Scent-Free Mist

Allergy Nasal Spray

Mometasone Furoate Nasal Spray, 50 mcg Per Spray

Allergy Symptom Reliever (Glucocorticoid)*

Allergy + Congestion

Full Prescription Strength

24HR Relief Of:

Nasal Congestion

Runny Nose

Sneezing

Itchy Nose

COMPARE TO NASONEX® 24HR ALLERGY active ingredient

100% Money Back Guarantee

*Mometasone furoate is a steroid medicine known as a glucocorticoid

60 SPRAYS 0.34 FL OZ (10.0 mL)

LEADER²TM

NDC 70000-0635-1

Non-Drowsy | Scent-Free Mist

Allergy Nasal Spray

Mometasone Furoate
Nasal Spray, 50 mcg Per Spray
Allergy Symptom Reliever
(Glucocorticoid)*

Allergy + Congestion
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24HR Relief Of:

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COMPARE TO
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active ingredient†

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*Mometasone furoate is a steroid medicine
known as a glucocorticoid

60 SPRAYS 0.34 FL OZ (10.0 mL)





ALLERGY + CONGESTION



Return to place of purchase.

DISTRIBUTED BY
CARDINAL HEALTH
DUBLIN, OHIO 43017
www.myLeader.com
1-800-200-6313



1Y811 E9 S1



REV. 3/23
CIN 5827373

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See below for important information about use in children.

Drug Facts

Active ingredient (in each spray)
Mometasone furoate monohydrate (glucocorticoid) 50 mcg..... Allergy symptom reliever

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temporarily relieves these symptoms of hay fever or other upper respiratory allergies:
■ nasal congestion ■ runny nose
■ sneezing ■ itchy nose

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■ you get an allergic reaction to this product. Seek medical help right away. ▶

Drug Facts (continued)

■ you get new changes to your vision that develop after starting this product
■ you have severe or frequent nosebleeds

If pregnant or breast-feeding, ask a health professional before use.
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Directions
Read insert (inside package) for how to:
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■ shake well before each use
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Adults & children 12 years of age and older
■ 2 sprays in each nostril once daily while sniffing gently

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Other information
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Inactive ingredients benzalkonium chloride, citric acid, glycerin, microcrystalline cellulose and carbonylmethylcellulose sodium polysorbate 80, purified water, sodium citrate

Questions or comments?
Call toll-free 1-800-719-9260

[†]Nasonex® is a trademark of Organon LLC or its affiliates.

IMPORTANT: Read Drug Facts label and enclosed materials for important information. Children 2-11: 1 spray per nostril per day. **Talk to a doctor if your child needs to use for longer than two months a year. Keep out of reach of children.** Only for use in the nose, do not spray into eyes. Store between 20°-25°C (68°-77°F). Shake well before each use.

LEADER?

NDC 70000-0635-1

Allergy Nasal Spray
Mometasone Furoate Nasal Spray, 50 mcg Per Spray
Allergy Symptom Reliever (Glucocorticoid)

60 SPRAYS 0.34 FL OZ (10.0 mL)

Questions or comments?
Call toll-free
1-800-719-9260

100% Money Back Guarantee
Return to place of purchase if not satisfied.

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DUBLIN, OH 43017
1-800-200-6313
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CIN 5827373
REV. 3/23

1Y811 E9 S1



EXP LOT

LEADER NASAL
mometasone furoate spray

| Product Information | | | | |
|--|--|---|----------------------|--------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70000-0635 | |
| Route of Administration | NASAL | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| MOMETASONE FUROATE MONOHYDRATE (UNII: MTW0WEG809) (MOMETASONE - UNII:8HR4QJ6DW8) | | MOMETASONE FUROATE | 50 ug | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) | | | | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | | | | |
| CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311) | | | | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | | | | |
| WATER (UNII: 059QF0KOOR) | | | | |
| SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR) | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:70000-0635-1 | 1 in 1 PACKAGE | 09/22/2023 | |
| 1 | | 60 in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | | |
| 2 | NDC:70000-0635-2 | 1 in 1 PACKAGE | 09/22/2023 | |
| 2 | | 120 in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| NDA | NDA215712 | 09/22/2023 | | |

Labeler - Cardinal Health 110, LLC. dba Leader (063997360)

Revised: 9/2023

Cardinal Health 110, LLC. dba Leader