

MOMETASONE FUROATE - mometasone furoate spray, metered
Aurohealth LLC

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 new symptoms 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 nose bleeds

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 carton is torn or opened**
- keep package and insert. They contain important information.
- store between 20° to 25°C (68° to 77°F)

Inactive ingredients

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

Questions or comments?

Call toll-free 1-855-274-4122 (Monday – Friday 8:30 AM to 5:00 PM EST)

Insert

Mometasone Furoate Nasal Spray

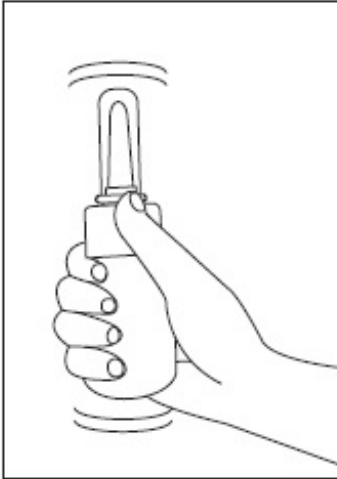
50 mcg per spray

24HR ALLERGY

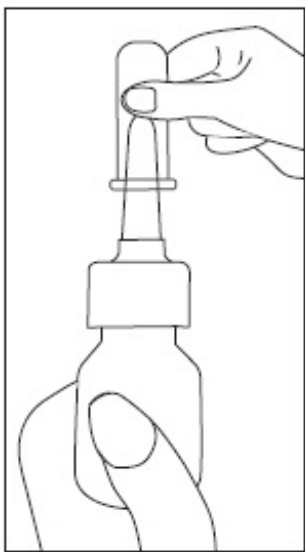
A GETTING STARTED

Mometasone Furoate Nasal Spray 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 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

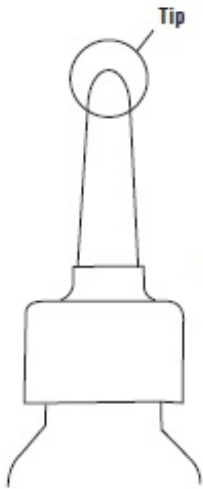


Blow nose gently to clear nostrils.

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 BREATH 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.

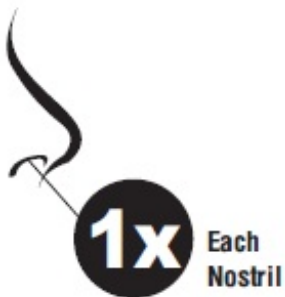
Repeat in other nostril.

Wipe spray nozzle with clean tissue and replace cap.

B DIRECTIONS FOR USE

Mometasone Furoate Nasal Spray works best when you use it daily. Here's how to get started.

Children age 2 to 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 Mometasone Furoate Nasal Spray for longer than two months a year.

Users age 12 or older



Use two sprays in each nostril every day.



WARNING:

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

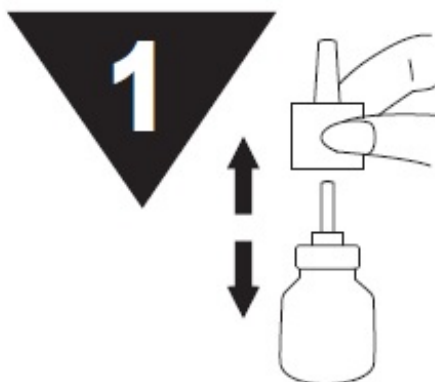
Other important information for use

- **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.

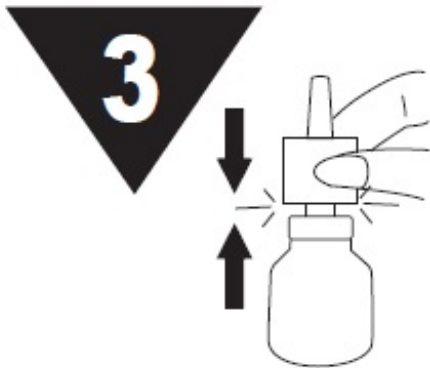


Remove spray nozzle by grasping at base and pulling

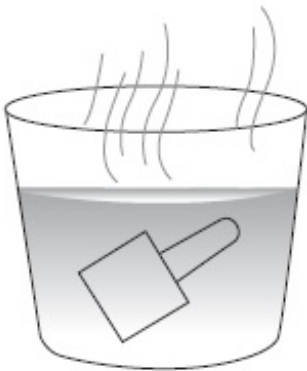
up.



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 **1-855-274-4122** (Monday – Friday 8:30 AM to 5:00 PM EST)

Store between 20° to 25°C (68° to 77°F).

Distributed by:

AUROHEALTH LLC

279 Princeton-Hightstown Road
East Windsor, NJ 08520

Made in India

Code: AP/DRUGS/04/2016

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - Container Label (120 Sprays
0.57 FL.OZ. (17 mL))**

AUROHEALTH

NDC 58602-522-44

**Mometasone Furoate
Nasal Spray**

50 mcg per spray

**ALLERGY SYMPTOM RELIEVER
(GLUCOCORTICOID)**

**120
SPRAYS 0.57 FL. OZ. (17 mL)**



IMPORTANT: Read Drug Facts label and enclosed materials for important information.

Children 2 to 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° to 25°C (68° to 77°F).

Shake well before each use.

Questions or comments?

Call toll-free 1-855-274-4122
(Monday – Friday 8:30 AM to 5:00 PM EST)

Distributed by:

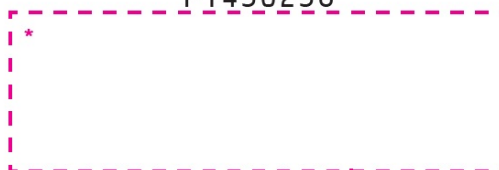
AUROHEALTH LLC

279 Princeton-Hightstown Road
East Windsor, NJ 08520

Made in India

Code: AP/DRUGS/04/2016

P1430236



* Expiry Date and LOT will be printed during packing.

Coding Area
(32 x 10 mm)

Dotted lines not to be printed

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - Container Carton Label (120
Sprays 0.57 FL.OZ. (17 mL))**

AUROHEALTH

NDC 58602-522-44

**#compare to the active ingredient in
NASONEX™ 24HR ALLERGY**

non-drowsy / scent-free mist

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

***Mometasone Furoate is a steroid**
medicine known as a glucocorticoid

120
SPRAYS 0.57 FL. OZ. (17 mL)

Mometasone Furoate Nasal Spray
50 mcg per spray
120 SPRAYS 0.57 FL. OZ. (17 mL)

24HR RELIEF of:
nasal congestion / runny nose
sneezing / itchy nose

***Mometasone Furoate is a steroid medicine known as a glucocorticoid**

120 SPRAYS 0.57 FL. OZ. (17 mL)

Drug Facts
Active ingredient (in each spray) Mometasone furoate monohydrate (glucocorticoid) 50 mcg — Allergy symptom reliever
Purpose 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 15 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 new symptoms such as severe nasal 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.

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

Questions or comments?
 Call toll-free 1-855-274-4352 (Monday - Friday 8:30 AM to 5:00 PM EST)

sealed for your protection

Not to be printed the printed sticker label will be pasted here during packing

MOMETASONE FUROATE
 mometasone furoate / spray, metered

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-522
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 (UNII: K679OBS311)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0KO0R)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-522-44	1 in 1 CARTON	11/22/2024	
1		120 in 1 BOTTLE, SPRAY; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA217498	11/22/2024	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650918514	ANALYSIS(58602-522) , MANUFACTURE(58602-522)