

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

215712Orig1s000

LABELING

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.

NDC 0113-1720-02

NASONEX[®]

24HR ALLERGY

Mometasone Furoate Nasal Spray 50 mcg per spray
Allergy Symptom Reliever (glucocorticoid)

120 SPRAYS 0.57 FL. OZ. (17.0 mL)

Questions or comments?
Call to 1-free
1-800-964-9649

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Parigo
Asteris, MI 48010
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72A1E5Y F1



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NDC 0113-1720-11

NASONEX

24HR ALLERGY

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
1-800-864-9649

72A11 ST F1



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72A1D SY S1



Use dundred he are.
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Allergan, M149010
Distributed by Perrigo
nasal congestion / runny nose
sneezing / itchy nose
24HR RELIEF of
24HR ALLERGY



Drug Facts (continued)

Active ingredient (in each spray): Purpose
Mometasone furoate (50 mcg) is a steroid medicine known as a glucocorticoid. Mometasone furoate relieves the symptoms of allergic rhinitis and congestion.

Uses
Temporarily relieves the symptoms of hay fever or other upper respiratory allergies: sneezing, runny nose, itchy nose, itchy throat, and watery eyes.

Warnings
Do not use if you have had a recent eye infection or if you have had a recent eye surgery. Do not use if you have had a recent eye injury or if you have had a recent eye operation. Do not use if you have had a recent eye infection or if you have had a recent eye surgery. Do not use if you have had a recent eye injury or if you have had a recent eye operation.

Directions
Use as directed. Do not use if you have had a recent eye infection or if you have had a recent eye surgery. Do not use if you have had a recent eye injury or if you have had a recent eye operation.

Other information
Keep out of reach of children. Do not use if you have had a recent eye infection or if you have had a recent eye surgery. Do not use if you have had a recent eye injury or if you have had a recent eye operation.

Questions or comments?
Call 1-800-441-4640

ALLERGY X CONGESTION

NEW! non-drowsy, scent-free mist

NASONEX
24HR ALLERGY MOMETASONE FUROATE NASAL SPRAY,
50 MCG/SPRAY ALLERGY SYMPTOM
RELIEVER (GLUCOCORTICOID)*

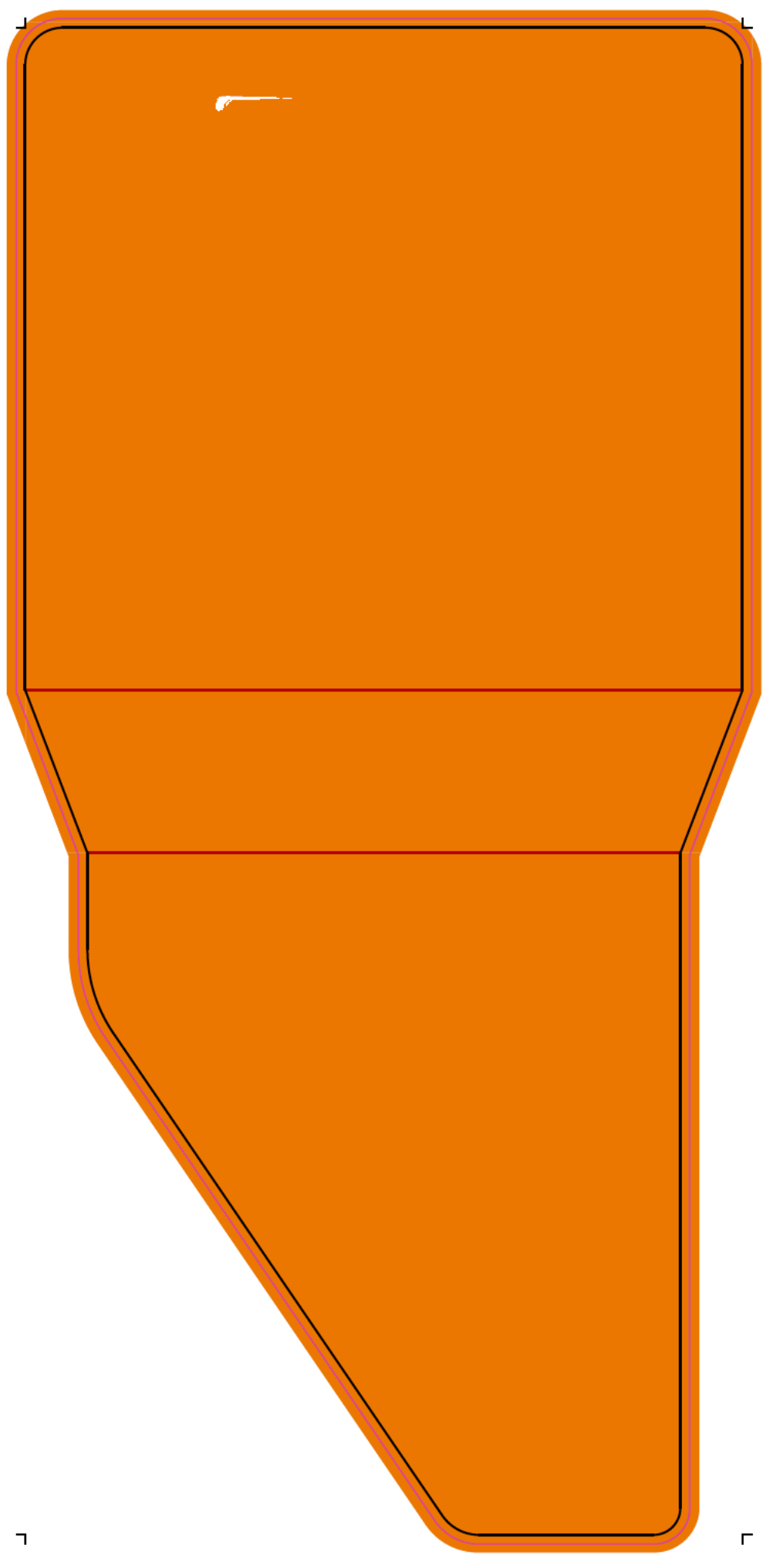
ALLERGY + CONGESTION

FULL PRESCRIPTION STRENGTH

24HR RELIEF of:

nasal congestion / runny nose
sneezing / itchy nose

30 *Mometasone Furoate is a steroid medicine known as a glucocorticoid
SPRAYS 0.25 FL. OZ. (7.5 mL)





72A1D SY F1

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NASONEX
24HR ALLERGY
Mometasone Furoate
Nasal Spray 50 mcg per spray
Allergy Symptom Reliever
(glucocorticoid)

Manufactured by Perrigo
Allerga, NJ 08010
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30 SPRAYS
0.25 FL. OZ. (7.5 mL)

Questions? 1-800-864-9649



NASONEX™

24HR ALLERGY

72A00 SY J1

A GETTING STARTED



NASONEX™ 24HR Allergy 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

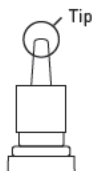


Blow nose gently to clear nostrils.

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 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

NASONEX™ 24HR Allergy 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 NASONEX 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.
- Discard 75 days after first use of the product.

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 1-800-864-9649

Store between 20°-25°C (68°-77°F)

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Allegan, MI 49010

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SIDE 2

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

NUSHIN F TODD
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