

**NASACORT ALLERGY 24HR- triamcinolone acetonide spray, metered
Chattem, Inc.**

Nasacort Allergy 24HR

Nasacort Allergy 24HR

Drug Facts

Active ingredient

(in each spray)

Triamcinolone acetonide (glucocorticoid) 55 mcg

Purpose

Nasal allergy symptom reliever

Uses

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

- nasal congestion
- runny nose
- sneezing
- itchy nose

Warnings

Do not use

- in children under 2 years of age
- if you have ever had an allergic reaction to any of the ingredients

Ask a doctor before use if you

- have had recent nose ulcers or nose surgery
- have had a nose injury that has not healed
- are using a steroid medicine for asthma, allergies or skin rash
- have an eye infection
- have or had glaucoma or cataracts

When using this product

- the growth rate of some children may be slower
- some symptoms may get better on the first day of treatment. It may take up to one week of daily use to feel the most symptom relief.
- 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
- you have or develop symptoms of an infection such as a persistent fever

- you have any change in vision
- 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.

Directions

Read insert (inside package) on how to:

- **get a new bottle ready (primed) before first use**
- **prime bottle again if not used for more than 2 weeks**
- **use the spray**
- **clean the spray nozzle**

ADULTS AND CHILDREN 12 YEARS OF AGE AND OLDER	
adults and children 12 years of age and older	<ul style="list-style-type: none"> ▪ once daily, spray 2 times into each nostril while sniffing gently ▪ once your allergy symptoms improve, reduce to 1 spray in each nostril per day
CHILDREN 2 TO UNDER 12 YEARS OF AGE	
<ul style="list-style-type: none"> ▪ the growth rate of some children may be slower while using this product. Talk to your child's doctor if your child needs to use the spray for longer than two months a year. 	
children 6 to under 12 years of age	<ul style="list-style-type: none"> ▪ an adult should supervise use ▪ once daily, spray 1 time into each nostril while sniffing gently ▪ if allergy symptoms do not improve, increase to 2 sprays in each nostril per day. Once allergy symptoms improve, reduce to 1 spray in each nostril per day.
children 2 to under 6 years of age	<ul style="list-style-type: none"> ▪ an adult should supervise use ▪ once daily, spray 1 time into each nostril while sniffing gently
children under 2 years of age	<ul style="list-style-type: none"> ▪ do not 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 allergy symptoms do not improve after one week, stop using and talk to a doctor

- do not use for the common cold
- shake well before each 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, carboxymethylcellulose sodium, dextrose, edetate disodium, hydrochloric acid or sodium hydroxide (for pH adjustment), microcrystalline cellulose, polysorbate 80, purified water

Questions or comments?

call toll-free **1-800-633-1610**

Principal Display Panel

NDC 41167-5800-3

Nasacort Allergy 24HR

triamcinolone acetonide (glucocorticoid)

55 mcg per spray

0.37 fl. oz. (10.8 ml) 60 Sprays

Drug Facts

Active ingredient (in each spray)
Triamcinolone acetonide
(glucocorticoid) 55 mcg

Purpose
Nasal allergy symptom reliever

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

Warnings
Do not use
• in children under 2 years of age
• if you have ever had an allergic reaction to any of the ingredients

Ask a doctor before use if you:
• have had recent nose ulcers or nose surgery
• have had a nose injury that has not healed
• are using a steroid medicine for asthma, allergies or skin rash
• have an eye infection
• have or had glaucoma or cataracts

When using this product:
• the growth rate of some children may be slower
• some symptoms may get better on the first day of treatment. It may take up to one week of daily use to feel the most symptom relief.
• do not share this bottle with anyone else as this may spread germs
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Stop use and ask a doctor if:
• you have, or come into contact with someone who has, chickenpox, measles or tuberculosis
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• you have any change in vision
• 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.

Drug Facts (continued)

Directions
Read insert (inside package) on how to:
• get a new bottle ready (primed) before first use
• prime bottle again if not used for more than 2 weeks
• use the spray
• clean the spray nozzle

ADULTS AND CHILDREN 12 YEARS OF AGE AND OLDER
• once daily, spray 2 times into each nostril while sniffing gently
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CHILDREN 2 TO UNDER 12 YEARS OF AGE
• the growth rate of some children may be slower while using this product. 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
• once daily, spray 1 time into each nostril while sniffing gently
• if allergy symptoms do not improve, increase to 2 sprays in each nostril per day. Once allergy symptoms improve, reduce to 1 spray in each nostril per day.

children 6 to under 12 years of age
• an adult should supervise use
• once daily, spray 1 time into each nostril while sniffing gently

children 2 to under 6 years of age
• do not use

children under 2 years of age
• 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 allergy symptoms do not improve after one week, stop using and talk to a doctor
• do not use for the common cold
• shake well before each use

Other information
• do not use if sealed package is torn or opened
• keep package and insert. They contain important information.
• store between 30°- 25° (58°- 77°)

Nasacort[®] Allergy 24HR

Drug Facts (continued)
Inactive ingredients
benzalkonium chloride, carbomer, methylcellulose sodium, dextrose, edetate disodium, hydrochloric acid or sodium hydroxide (for pH adjustment), microcrystalline cellulose, polyvinylpyrrolidone 90, purified water

Questions or comments?
call toll-free 1-800-633-1610

Original Prescription Strength

NDC 41167-5800-3

Multi-Symptom Nasal Allergy Spray

Nasacort[®] Allergy 24HR

triamcinolone acetonide (glucocorticoid)
55 mcg per spray/Nasal Allergy Symptom Reliever


24 HR
Relief of:

- Nasal Congestion
- Sneezing
- Runny Nose
- Itchy Nose

60
SPRAYS

0.37 fl. oz.
(10.8 ml)

Dist. by: Chatham, Inc.,
a Sunovion Company
Chattanooga, TN 37409-0218
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0 41167 58003 5

Prescription strength allergy relief.
Without a prescription.

Nasacort[®] Allergy 24HR

24 hour symptom relief
from indoor & outdoor allergies

SHAKE WELL
BEFORE EACH USE

Read insert (inside package) for complete instructions on how to:

- Get a new bottle ready (primed) before first use
- Prime bottle again if not used for more than 2 weeks
- Use the spray
- Clean the spray nozzle

BEFORE FIRST USE, A NEW BOTTLE MUST BE PRIMED

Principal Display Panel

Original Prescription Strength
NDC 41167-5800-5
Multi-Symptom
Nasal Allergy Spray
Nasacort
Allergy 24HR
triamcinolone acetonide (glucocorticoid)
55 mcg per spray/Nasal Allergy Symptom Reliever

0.57 fl. oz. (16.9 ml)
120 Sprays

Drug Facts
Active ingredient (in each spray)
Triamcinolone acetonide
(glucocorticoid) 55 mcg Nasal allergy symptom reliever

Uses
Temporarily relieves these symptoms of hay fever or other upper respiratory allergies:
• nasal congestion • runny nose • sneezing • itchy nose

Warnings
Do not use
• in children under 2 years of age
• if you have ever had an allergic reaction to any of the ingredients

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• 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.

Drug Facts (continued)
Directions
Read insert (inside package) on how to:
• get a new bottle ready (primed) before first use
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ADULTS AND CHILDREN 12 YEARS OF AGE AND OLDER
• once daily, spray 2 times into each nostril while sniffing gently
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CHILDREN 2 TO UNDER 12 YEARS OF AGE
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• an adult should supervise use
• once daily, spray 1 time into each nostril while sniffing gently
• if allergy symptoms do not improve, increase to 2 sprays in each nostril per day. Once allergy symptoms improve, reduce to 1 spray in each nostril per day.
do not 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 allergy symptoms do not improve after one week, stop using and talk to a doctor
• do not use for the common cold
• shake well before each 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)

Original Prescription Strength
NDC 41167-5800-5

Nasacort® Allergy 24HR

Multi-Symptom Nasal Allergy Spray
Nasacort® Allergy 24HR
triamcinolone acetonide (glucocorticoid)
55 mcg per spray/Nasal Allergy Symptom Reliever

24 HR
Relief of:
• Nasal Congestion
• Sneezing
• Runny Nose
• Itchy Nose

0.57 fl. oz. (16.9 ml)

120 SPRAYS

Drug Facts (continued)
Inactive ingredients
benzalkonium chloride, carbocymethylnalutol sodium, dextrose, edetate disodium, hydrochloric acid or sodium hydroxide (for pH adjustment), microcrystalline cellulose, polycarbonylate 80, purified water

Questions or comments?
call toll-free 1-800-433-1610

LOT EXP

Prescription strength allergy relief.
Without a prescription.
Nasacort® Allergy 24HR
24 hour symptom relief
from indoor & outdoor allergies

Read insert (inside package) for complete instructions on how to:
• Get a new bottle ready (primed) before first use
• Prime bottle again if not used for more than 2 weeks
• Use the spray
• Clean the spray nozzle

BEFORE FIRST USE, A NEW BOTTLE MUST BE PRIMED

SHAKE WELL BEFORE EACH USE

Principal Display Panel

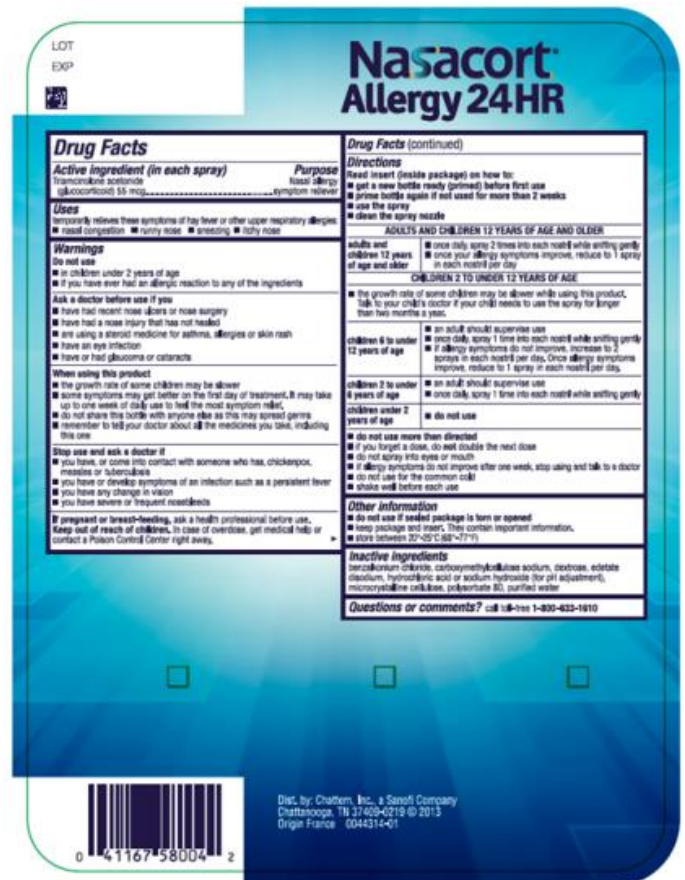
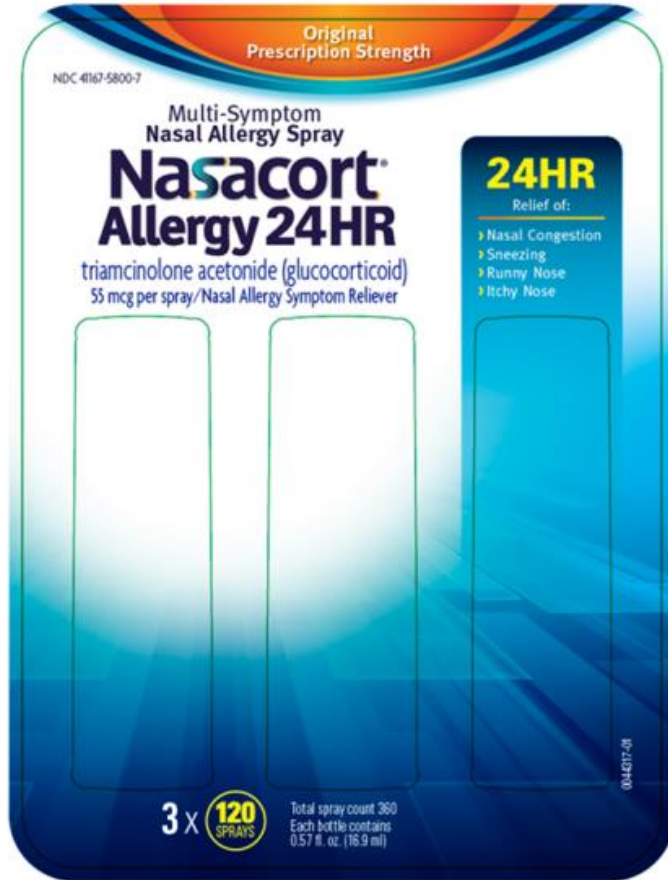
NDC 41167-5800-2
Nasacort Allergy 24HR
triamcinolone acetonide (glucocorticoid)
55 mcg per spray
0.57 fl. oz. (16.9 ml) 2x120 Sprays



Principal Display Panel

Original Prescription Strength
 NDC 41167-5800-7
 Multi-Symptom
 Nasal Allergy Spray
 Nasacort
 Allergy 24HR

triamcinolone acetonide (glucocorticoid)
 55 mcg per spray/Nasal Allergy Symptom Reliever
 0.57 fl. oz. (16.9 ml)
 3 X 120 Sprays



Principal Display Panel

Nasacort Allergy 24HR
 Multi-Symptom
 Nasal Allergy Spray
 Insert

Nasacort[®] Allergy 24HR

Multi-Symptom
Nasal Allergy Spray
triamcinolone acetonide (glucocorticoid)
50 mcg per spray / Nasal Allergy Symptom Reliever

IMPORTANT INFORMATION

- Read both sides of this insert for complete instructions on how to get a bottle ready (primed), how to use the spray bottle and how to clean the spray nozzle.
- Keep this insert as it contains important information.

STEPS TO GET A NEW BOTTLE READY FOR USE (PRIMED)

1. Before first use, a new bottle must be primed.

- Remove cap (Figure A).
- Shake bottle.
- Press and release spray nozzle until a fine mist is produced (as shown in Figure B). This may take several times. Take care not to spray in face.



PRIME BOTTLE AGAIN IF NOT USED FOR MORE THAN 2 WEEKS

- Repeat steps for priming a bottle (see above).

USE INSTRUCTIONS

- Blow nose gently to clear nostrils.
- Remove cap, then shake bottle.
- Hold bottle with thumb under bottle and spray nozzle between fingers (as shown in Figure B).
- Press against the outside of your nose with your finger to close off one nostril (as shown in Figure C).
- Place the tip of the spray nozzle into the other nostril. The spray nozzle should not reach far into the nose. Aim nozzle toward back of nose (as shown in Figure C).



DO NOT spray toward nasal septum (the wall between the 2 nostrils) (as shown in Figure D).



- While sniffing gently, spray into nostril

IMPORTANT: For complete dosing instructions, See "Directions for use" on next side.

- Repeat steps "4" through "6" for the other nostril.
- After using the nasal spray, wipe nozzle with a tissue and replace cap by pressing it down over the spray nozzle.

NOTE: Avoid blowing nose for 15 minutes after use.

If nozzle does not spray properly, see cleaning instructions on next side.

(continued on side 2)

SIDE 1

DIRECTIONS FOR USE

- BEFORE first use, you must get a new bottle ready (primed).**
- If bottle is not used for more than 2 weeks, prime bottle again.**

Dosing

ADULTS AND CHILDREN 12 YEARS OF AGE AND OLDER

- | | |
|---|--|
| adults and children 12 years of age and older | <ul style="list-style-type: none"> once daily, spray 2 times into each nostril while sniffing gently once your allergy symptoms improve, reduce to 1 spray in each nostril per day |
|---|--|

CHILDREN 2 TO UNDER 12 YEARS OF AGE

- | | |
|--|--|
| <ul style="list-style-type: none"> the growth rate of some children may be slower while using this product. Talk to your child's doctor if your child needs to use the spray for longer than two months a year. | |
| children 6 to under 12 years of age | <ul style="list-style-type: none"> an adult should supervise use once daily, spray 1 time into each nostril while sniffing gently if allergy symptoms do not improve, increase to 2 sprays in each nostril per day. Once allergy symptoms improve, reduce to 1 spray in each nostril per day. |
| children 2 to under 6 years of age | <ul style="list-style-type: none"> an adult should supervise use once daily, spray 1 time into each nostril while sniffing gently |
| children under 2 years of age | <ul style="list-style-type: none"> do not use |

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.

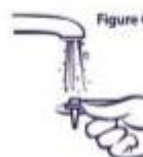
IF PUMP DOES NOT SPRAY PROPERLY, THE NOZZLE MAY BE BLOCKED

- Never try to unblock nozzle with a pin or any other object (as shown in Figure E).
- Clean the nozzle as shown below.



CLEANING INSTRUCTIONS

- Gently pull spray nozzle away from bottle (as shown in Figure F).
- Rinse **SPRAY NOZZLE ONLY** under warm water (as shown in Figure G).
- Shake or tap to remove excess water.
- Re-attach spray nozzle to bottle.
- Press and release spray nozzle until a fine spray is produced, taking care not to spray in face.



Nasacort Allergy 24HR pump is now ready to use.

Where can I get more information?
1-800-633-1610

Store between 20°-25°C (68°-77°F)

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SIDE 2

NASACORT ALLERGY 24HR

triamcinolone acetonide spray, metered

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:41167-5800

Route of Administration		NASAL		
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
TRIAMCINOLONE ACETONIDE (UNII: F446C597KA) (TRIAMCINOLONE ACETONIDE - UNII:F446C597KA)		TRIAMCINOLONE ACETONIDE	55 ug	
Inactive Ingredients				
Ingredient Name			Strength	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
DEXTROSE (UNII: IY9XDZ35W2)				
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
HYDROCHLORIC ACID (UNII: QTT17582CB)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167-5800-7	3 in 1 CARTON	02/03/2014	
1		120 in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		
2	NDC:41167-5800-3	1 in 1 CARTON	02/03/2014	
2		60 in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		
3	NDC:41167-5800-5	1 in 1 CARTON	02/03/2014	
3		120 in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		
4	NDC:41167-5800-2	2 in 1 CARTON	02/03/2014	
4		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		NDA020468	02/03/2014	

Labeler - Chattem, Inc. (003336013)

