

# **RUGBY MOMETASONE FUROATE NASAL- mometasone furoate spray**

## **Rugby Laboratories**

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### **Rugby Laboratories Mometasone Furoate Nasal Spray, 50 mcg Per 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 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 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

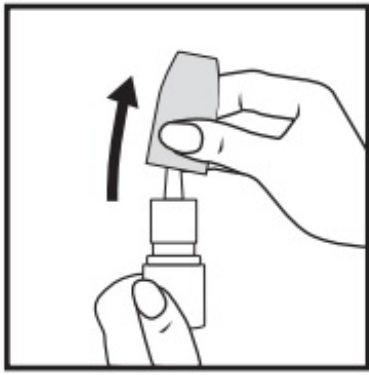
**This product works best at relieving your allergy symptoms when you get a full dose. Here's how to get started, in five easy steps.**

### 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.

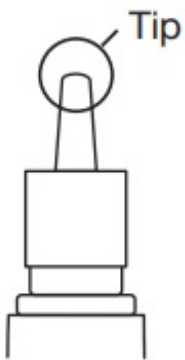


#### **4 AIM**

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.

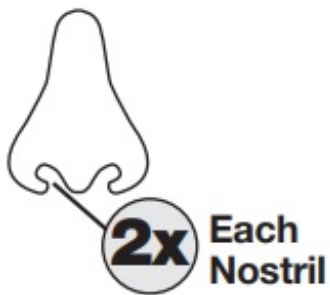
**WARNING:**

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.



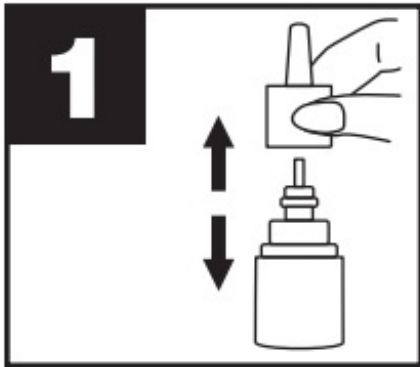
**Other important information for use**

- **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.

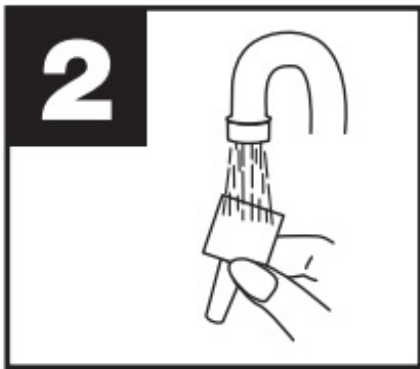
**C KEEP IT CLEAN**

**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.**

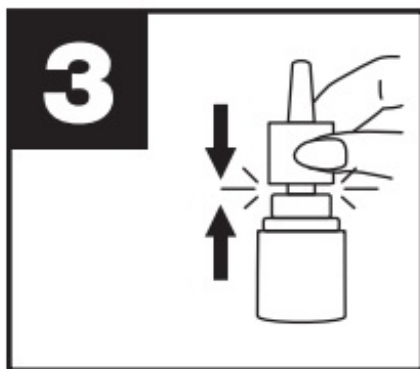
Remove spray nozzle by grasping at base and pulling up.



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

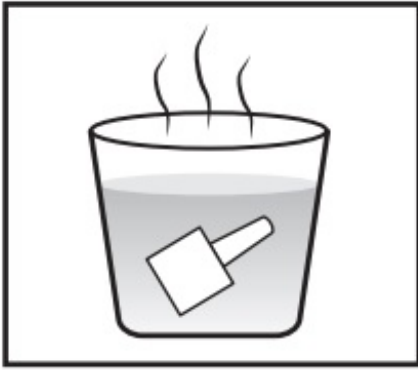


Aim away from your face and gently, but firmly replace spray nozzle.



**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**

Rugby®

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 (17.0 mL)



NDC 0536-1381-30  
Compare to the active ingredient  
in Nasonex® 24HR Allergy\*

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120 SPRAYS 0.57 FL OZ (17.0 mL)

See below for important information about use in children.

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### Uses

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## Drug Facts (continued)

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professional before use.

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## Directions

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■ shake well before each use

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ALLERGY +  
CONGESTION

Distributed by:  
RUGBY LABORATORIES  
Indianapolis, IN 46268  
(800) 616-2471  
www.rugbypharmaceuticals.com



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spradgements

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

\*This mark is a trademark of Organon LLC or its affiliates.

Rev 02/23 R05 Re-order No 371M1

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# RUGBY MOMETASONE FUROATE NASAL

mometasone furoate spray

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1381
Route of Administration	NASAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MOMETASONE FUROATE MONOHYDRATE</b> (UNII: MTW0WEG809) (MOMETASONE - UNII: 8HR4QJ6DW8)	MOMETASONE FUROATE	50 ug

## Inactive Ingredients

Ingredient Name	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM</b> (UNII: K679OBS311)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1381-30	1 in 1 PACKAGE	10/11/2023	
1		120 in 1 BOTTLE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:0536-1381-70	1 in 1 PACKAGE	10/11/2023	
2		60 in 1 BOTTLE; 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
NDA	NDA215712	10/11/2023	

**Labeler -** Rugby Laboratories (079246066)

Revised: 10/2023

Rugby Laboratories