ALLERGY RELIEF NASAL- fluticasone propionate spray, metered
Publix Super Markets Inc

Publix Super Markets, Inc. Allergy Relief Nasal Spray Drug Facts

Active ingredient (in each spray)

Fluticasone propionate (glucocorticoid)* 50 mcg

* read the Question & Answer leaflet

Purpose

Allergy symptom reliever

Uses

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

- nasal congestion
- itchy nose
- runny nose
- itchy, watery eyes
- sneezing

Warnings

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

Do not use

- in children under 4 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 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 or sneezing may occur for a few seconds right after 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, chicken pox, 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.

Directions

- read the Quick Start Guide for how to:
    - prime the bottle
    - use the spray
    - clean the spray nozzle
- shake gently before each use
- use this product only once a day
- do not use more than directed

ADULTS AND CHILDREN 12 YEARS OF AGE AND OLDER
• Week 1 – use 2 sprays in each nostril once daily • Week 2 through 6 months – use 1 or 2 sprays in each nostril once daily, as needed to treat your symptoms • After 6 months of daily use – ask your doctor if you can keep using
CHILDREN 4 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

- use 1 spray in each nostril once daily

CHILDREN UNDER 4 YEARS OF AGE

- **do not use**

Other information

- you may start to feel relief the first day and full effect after several days of regular, once-a-day use
- store between 39º and 86ºF (4º and 30ºC)
- keep this package and enclosed materials. They contain important additional information.

Inactive ingredients

benzalkonium chloride, dextrose, microcrystalline cellulose, phenylethyl alcohol, polysorbate 80, purified water, sodium carboxymethylcellulose

Consumer Information

FLUTICASONE PROPIONATE NASAL SPRAY QUESTIONS & ANSWERS

WHAT FLUTICASONE PROPIONATE NASAL SPRAY IS, HOW TO USE IT, AND WHAT TO EXPECT

UNDERSTANDING FLUTICASONE PROPIONATE NASAL SPRAY

What Fluticasone Propionate Nasal Spray is, and how it works.

What is Fluticasone Propionate Nasal Spray?

Fluticasone Propionate Nasal Spray is an effective allergy medicine that you can buy without a prescription. It works directly in the nose to help block your allergic reactions. Fluticasone Propionate Nasal Spray relieves allergy symptoms caused by pollen, mold, dust and pets.

What is the active ingredient in Fluticasone Propionate Nasal Spray?

The active ingredient in Fluticasone Propionate Nasal Spray is called fluticasone propionate. Fluticasone propionate is a glucocorticoid – a substance produced naturally by your body to help fight inflammation. It works in your nose to relieve your allergy symptoms. Barely any of it travels through your body. It's been prescribed by doctors for over 20 years, and used effectively by millions.

A glucocorticoid is a kind of steroid that is different from the anabolic (muscle-building) steroids sometimes misused by athletes. In fact, world class athletes are allowed to use glucocorticoids during competition to treat their allergies.

Who should not use Fluticasone Propionate Nasal Spray?

For complete guidance, check the *Drug Facts* label on the back of the Fluticasone

Propionate Nasal Spray package.

Can I use Fluticasone Propionate Nasal Spray for asthma?

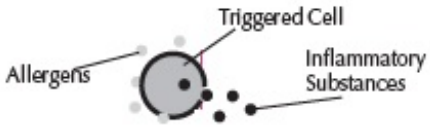
No, Fluticasone Propionate Nasal Spray is not a treatment for asthma. Ask your doctor what medicine to take for your asthma.

Can I use Fluticasone Propionate Nasal Spray for colds?

No, use Fluticasone Propionate Nasal Spray to treat only your allergies – not your cold symptoms. If you're not sure whether your symptoms come from allergies or a cold, ask your doctor.

What happens when you have allergies?

Allergies start when allergens like pollen or pet dander enter your body and trigger your immune system to respond. **Your body's natural response** is to release multiple inflammatory substances, (also referred to as mediators) that cause your allergy symptoms.



How does Fluticasone Propionate Nasal Spray work?

Fluticasone Propionate Nasal Spray works right in your nose to help block your allergic reaction at the source to relieve the symptoms that make you uncomfortable. **Fluticasone Propionate Nasal Spray** acts on multiple inflammatory substances, including histamine, prostaglandins, cytokines, tryptases, chemokines and leukotrienes. Most common OTC allergy pills act on histamine alone.

Because of the way it works, it may take several days for Fluticasone Propionate Nasal Spray to reach maximum effect. That's why it's best to use Fluticasone Propionate Nasal Spray regularly, once a day. Fluticasone Propionate Nasal Spray not only relieves sneezing, itchy nose, runny nose and itchy, watery eyes, but also relieves nasal congestion.

What problems can Fluticasone Propionate Nasal Spray help with?

Allergies can cause uncomfortable symptoms like congestion and itchy eyes. These symptoms can be triggered by allergens like pollen, mold, dust or pet dander. **Fluticasone Propionate Nasal Spray helps relieve a broad range of symptoms**

from many allergens. For example, Fluticasone Propionate Nasal Spray helps with:

Nasal symptoms	Eye symptoms	Outdoor allergens	Animal allergens	Indoor allergens
• Congestion	• Itchy eyes	• Weed pollen	• Cats	• Dust
• Runny nose	• Watery eyes	• Grass pollen	• Dogs	• Dust mites
• Sneezing		• Tree pollen		• Mold
• Itchy nose		• Mold spores		

Who should not use Fluticasone Propionate Nasal Spray or check with a doctor first?

Some people should not use Fluticasone Propionate Nasal Spray, or need to check with a health professional first. This table offers a quick summary of these situations.

If you…	**Here's what to do…**
Are younger than 4	Do not use Fluticasone Propionate Nasal Spray
Are pregnant or breast-feeding	Talk to a health professional before using Fluticasone Propionate Nasal Spray
Have or had glaucoma or cataracts	Talk to your doctor before using Fluticasone Propionate Nasal Spray
Have an injury or surgery to your nose that is not fully healed	Do not use Fluticasone Propionate Nasal Spray
Have ever had an allergic reaction to Fluticasone Propionate Nasal Spray or any of its ingredients	Do not use Fluticasone Propionate Nasal Spray
Are taking a medicine for HIV infection (such as ritonavir)	Talk to your doctor or pharmacist before using Fluticasone Propionate Nasal Spray
Are taking ketoconazole pills (medicine for fungal infection)	Talk to your doctor or pharmacist before using Fluticasone Propionate Nasal Spray
Are using a steroid medicine for	Talk to your doctor or pharmacist before

asthma, allergies, skin rash, allergic reactions, inflammation or eye conditions	using Fluticasone Propionate Nasal Spray

USING FLUTICASONE PROPIONATE NASAL SPRAY

How to get the best results with Fluticasone Propionate Nasal Spray.

Read the *Drug Facts* label on the back of the package or the Quick Start Guide on the other side for simple directions on using Fluticasone Propionate Nasal Spray.

Watch for purple color - it shows where there is different information for children ages 4-11, compared to users age 12 or older.

If you still have questions about using Fluticasone Propionate Nasal Spray after reading the Quick Start Guide, read this section for answers.

I know how to use a nasal spray. Why do I have to follow the directions?

If you don't use the spray bottle correctly, you might not get a full dose. Without a full dose each time, you might not get the relief you deserve. **Follow the simple directions in theQuick Start Guide** on other side.

If my symptoms go away, should I stop using Fluticasone Propionate Nasal Spray?

You may be tempted to stop using Fluticasone Propionate Nasal Spray when you start to feel better. **It's important you keep using Fluticasone Propionate Nasal Spray daily as long as you're exposed to allergens** that bother you, like pollen, mold, dust or pet dander. This way you'll keep feeling relief.

If you suffer allergy symptoms only during certain times, like when pollen levels are high, you may stop using Fluticasone Propionate Nasal Spray when that time ends. If you are age 12 or older and need to use daily for longer than 6 months or age 4-11 and need to use for longer than 2 months a year, check with your doctor.

What if I miss a dose by accident?

If you miss a dose, just use your regular dose the next day. Don't add an extra dose to make up for it.

Can I keep using Fluticasone Propionate Nasal Spray year round?

Some people suffer from allergies all year. If you are age 12 or older and have used Fluticasone Propionate Nasal Spray for six months or age 4-11 and have used for two months a year, check with your doctor to make sure it's OK to keep using Fluticasone Propionate Nasal Spray daily. In fact, it's a good idea for anyone with persistent allergies to talk with a doctor every so often about symptoms and medicines.

Can I share my Fluticasone Propionate Nasal Spray?

Do not share a bottle of Fluticasone Propionate Nasal Spray. Sharing the bottle can spread germs, because you insert the nozzle in your nose.

Can I spray Fluticasone Propionate Nasal Spray in my eyes or mouth?

No, Fluticasone Propionate Nasal Spray is meant to work only in your nose to

relieve your allergy symptoms, including itchy, watery eyes.

Never spray Fluticasone Propionate Nasal Spray in your eyes or your mouth.

Some decongestants may increase blood pressure. Does Fluticasone Propionate Nasal Spray increase blood pressure?

When used as directed, Fluticasone Propionate Nasal Spray does not increase blood pressure.

Won't I waste product by priming?

It's not a waste to prime the pump, because it helps you get a full dose. Getting a full dose is important for getting the relief you deserve. See the Quick Start Guide for when and how to prime the pump.

Don't worry about running out due to priming. There is enough medicine in the spray bottle to allow for priming sprays plus the number of sprays labeled on the bottle. **Always point the spray bottle away from your face** when priming.

How long should a bottle of Fluticasone Propionate Nasal Spray last?

This table shows roughly how long your bottle will last. It assumes you follow the instructions for priming the pump, and that those age 12 or older use two sprays in each nostril every day while children age 4-11 use one spray in each nostril every day.

After you've used the number of sprays shown on the label, each spray may not deliver a full dose — even if there is liquid left in the bottle.

If the label says…	**The bottle should last age 12+…**	**The bottle should last age 4-11…**
60 sprays	2 weeks	4 weeks
72 sprays	2.5 weeks	5 weeks
90 sprays	3 weeks	6 weeks
120 sprays	4 weeks	8 weeks
144 sprays	5 weeks	10 weeks*
*Check with a doctor if a child 4-11 needs to use longer than 2 months a year		

Is Fluticasone Propionate Nasal Spray OK to use with other medicines?

You should tell your doctor about all the medicines you take, including Fluticasone Propionate Nasal Spray. Fluticasone Propionate Nasal Spray can be used with most non-prescription and prescription medicines. However, there are a few medicines to look out for because they may cause the level of

Fluticasone Propionate Nasal Spray in your body to become too high. **Just to be safe, check this table** to see if you're taking any of these medicines.

If you're taking…	**Here's what to do…**
Medicines for HIV infection (such as ritonavir)	Talk to your doctor or pharmacist before using Fluticasone Propionate Nasal Spray
Medicines with glucocorticoids Including some medicines for skin rash such as eczema, asthma, inflammation, allergic reactions, or eye conditions	Talk to your doctor or pharmacist before using Fluticasone Propionate Nasal Spray
Ketoconazole Pills for fungal infection	Talk to your doctor or pharmacist before using Fluticasone Propionate Nasal Spray

What are the differences in the way children age 4-11 should use Fluticasone Propionate Nasal Spray?

Children age 4-11 should use a **lower dose** of Fluticasone Propionate Nasal Spray for a **shorter period of time.**

Ages	**Children 4-11 years of age**	**Users 12 years of age and older**
Dosage	1 spray in each nostril once daily	Up to 2 sprays in each nostril once daily
Duration before checking with a doctor	Up to 2 months of use a year	Up to 6 months of daily use

Why is the use of Fluticasone Propionate Nasal Spray for children age 4-11 limited to 2 months a year before checking with a doctor?

When used long-term, intranasal glucocorticoids like Fluticasone Propionate Nasal Spray may cause the growth rate of some children to be slower. Whether this will affect a child's ultimate height is not known. As a precaution, 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 2 months a year.

WHAT TO EXPECT

What it's like to use Fluticasone Propionate Nasal Spray.

How soon will I get relief?

You may start to feel relief the first day you use Fluticasone Propionate Nasal Spray. Keep using it every day, though. It takes several days before Fluticasone Propionate Nasal Spray builds up to full effectiveness.

How long will the relief last?

Fluticasone Propionate Nasal Spray is meant to control your symptoms every day, all day and all night. To help you get this lasting relief, it's important to use Fluticasone Propionate Nasal Spray regularly, once a day.

Does Fluticasone Propionate Nasal Spray cause a "rebound" effect?

No, Fluticasone Propionate Nasal Spray does not cause a rebound effect.

Some nasal decongestant sprays may cause your nasal passages to swell up even more when you use them too often or for longer than their label says you should (three days). This is sometimes called a “rebound effect.” Fluticasone Propionate Nasal Spray is a different kind of medicine and does not cause any rebound effect. You can use Fluticasone Propionate Nasal Spray for up to six months if you are age 12 or older or up to two months a year if you are age 4-11 before checking with a doctor.

Will Fluticasone Propionate Nasal Spray make me drowsy?

No, Fluticasone Propionate Nasal Spray does not cause drowsiness. Some allergy medications can cause drowsiness, but Fluticasone Propionate Nasal Spray does not.

Why does Fluticasone Propionate Nasal Spray have a smell?

The light floral scent you may notice comes from one of the important ingredients in the Fluticasone Propionate Nasal Spray formula. No fragrance is added to Fluticasone Propionate Nasal Spray.

What if little or nothing is spraying out?

Try priming the spray bottle. It may take a few pumps to get the dispenser spraying again.

If that doesn’t work, the spray nozzle may be clogged.

You can clean it following the directions in the Quick Start Guide on the other side.

What if I feel stinging in my nose, or I sneeze?

Some people may feel a slight stinging, or may sneeze, after spraying Fluticasone Propionate Nasal Spray in their nostrils. **This feeling should go away** in a few seconds.

What if I feel or taste the medicine in my throat?

Generally, you can avoid this by taking a shallower breath next time you spray Fluticasone Propionate Nasal Spray into your nostrils. For example, take the kind of breath you would use to smell a flower.

What if I have chicken pox, measles or tuberculosis or come into contact with someone who does?

Stop using Fluticasone Propionate Nasal Spray and ask your doctor.

What if I’m having severe sinus pain?

If you feel severe pain in your face, have thick nasal discharge, or think you may have a sinus infection, **stop using Fluticasone Propionate Nasal Spray and see your doctor.** Your doctor may want to consider if other medicines are needed.

What if my symptoms aren’t better after one week?

If you have used Fluticasone Propionate Nasal Spray for a week and your allergy symptoms are not getting better, **stop use and ask your doctor.** You may have an infection.

Does Fluticasone Propionate Nasal Spray have side effects?

Serious side effects are rare with Fluticasone Propionate Nasal Spray because Fluticasone Propionate Nasal Spray works in your nose, and barely any of it travels through your body.

However, like all medicines, Fluticasone Propionate Nasal Spray can cause side effects in some people.

Here are some side effects that have been reported when using Fluticasone Propionate Nasal Spray. If you have any concerns about side effects, talk with your doctor.

Side effect	What could happen	What to do
Allergic reaction to the product	• Sudden swelling of face or tongue • A rash • Wheezing or feeling faint	If you feel any of these symptoms, stop using Fluticasone Propionate Nasal Spray and see a doctor right away.
Nose injury	• Severe or frequent nosebleeds	Apply pressure to your nose. Stop using Fluticasone Propionate Nasal Spray and see a doctor.
	• Constant whistling sound that does not go away	This could be a sign of damage to your nose. Stop using Fluticasone Propionate Nasal Spray and see a doctor right away.
Eye conditions such as cataracts or glaucoma	• Cloudy vision • Reduced vision	Have a yearly eye exam to check for these conditions. Read the *Drug Facts* on the back of the Fluticasone Propionate Nasal Spray package for more details.
Growth effects	• Slower growth rate in some children while using product	Talk to your doctor if you are concerned or if a child age 4-11 needs to use Fluticasone Propionate Nasal Spray for longer than two months a year.
Other side effects	• Headaches or sneezing • Bad taste or smell • Minor nosebleeds • Dry or irritated nose or throat	Talk to your doctor or pharmacist if you are concerned.

STILL HAVE QUESTIONS?

Call **1-800-719-9260**

Distributed By

Perrigo®

Allegan, MI 49010

FLUTICASONE PROPIONATE NASAL SPRAY

QUICK START GUIDE

HOW TO START GETTING ALLERGY RELIEF RIGHT NOW

USE THE RIGHT DOSE

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

Children age 4-11

An adult should supervise use

Use one spray in each nostril once daily.

Don't use more than one spray in each nostril per day.

If you miss a dose, just use your regular dose the next day. Don't add an extra dose.

Check with a doctor if a child needs to use Fluticasone Propionate Nasal Spray for longer than two months a year.

Users age 12 or older

In your first week

Use two sprays in each nostril every day.

Don’t use more than two sprays in each nostril per day.

After your first week

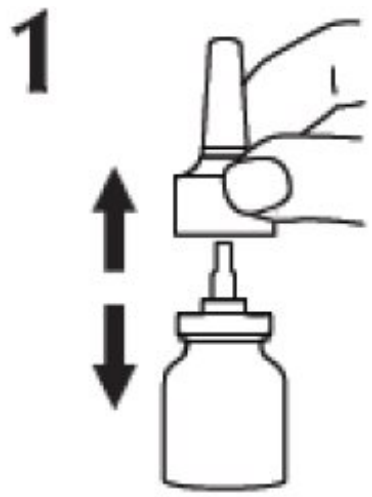
If your symptoms are under control, you may reduce to one spray in each nostril every day. If your symptoms get worse, go back to two sprays in each nostril.

If you miss a dose, just use your regular dose the next day. Don’t add an extra dose.

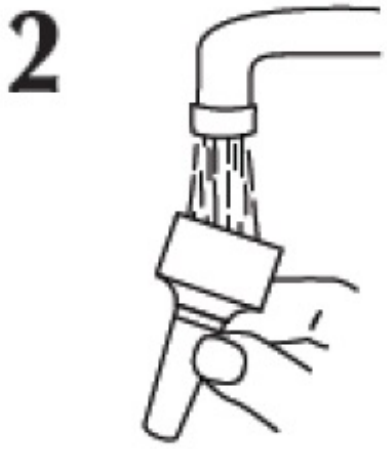
WARNING:Do not spray in your eyes. Only for use in your nose.

KEEP IT CLEAN

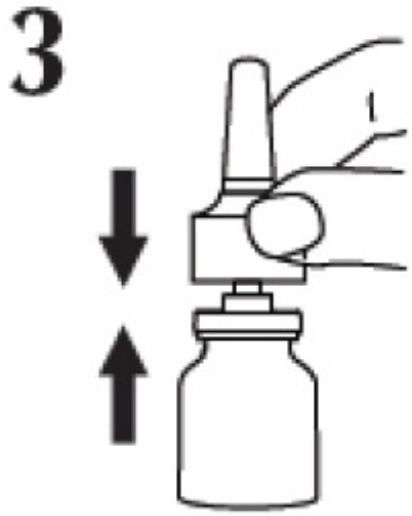
A clean spray nozzle helps ensure a full dose. Clean it weekly, or if it’s clogged. Don’t try to unblock nozzle with pin or sharp object — that can damage it.



Remove spray nozzle by grasping at base and pulling up.



Rinse under running tap, and dry at room temperature.



Aim away from your face and gently replace spray nozzle until you hear a soft click.

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

GET THE RELIEF YOU NEED.

Fluticasone Propionate Nasal Spray can relieve your allergy symptoms. For best results, it's important to get a full dose.

Here's how, in five easy steps.

1 Shake

Gently shake spray bottle.

Remove clear cap.

Do this when:

- Starting new bottle
- Haven’t used it in a week
- Just cleaned nozzle

Otherwise go to Step 3.

2 Prime

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

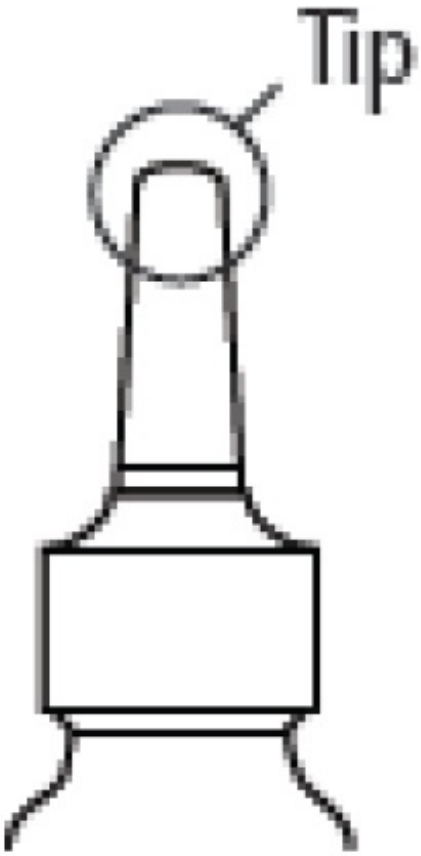
Pumped six times and still no mist? Spray nozzle may be clogged. See **KEEP IT CLEAN**.

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.

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Package/Label Principal Display Panel

p

24-HOUR

allergy relief nasal spray

FLUTICASONE PROPIONATE NASAL SPRAY, 50 mcg PER SPRAY

ALLERGY SYMPTOM RELIEVER (GLUCOCORTICOID)**

Relief of:

- Nasal Congestion
- Itchy, Watery Eyes
- Itchy Nose
- Runny Nose

• Sneezing

FULL PRESCRIPTION STRENGTH

NON-DROWSY

24 HOUR RELIEF

**Fluticasone propionate is a steroid medicine known as a glucocorticoid.

72 METERED SPRAYS

Compare to Flonase® Allergy Relief active ingredient

0.38 FL OZ (11.1 mL)

ALLERGY RELIEF NASAL

fluticasone propionate spray, metered

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:56062-107
Route of Administration	NASAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FLUTICASONE PROPIONATE (UNII: O2GMZ0LF5W) (FLUTICASONE - UNII:CUT2W21N7U)	FLUTICASONE PROPIONATE	50 ug

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0KO0R)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	

Product Characteristics

Color	WHITE (off-white)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56062-107-01	1 in 1 CARTON	09/08/2016	09/08/2016
1		120 in 1 BOTTLE, SPRAY; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:56062-107-02	1 in 1 CARTON	09/08/2016	09/08/2016
2		60 in 1 BOTTLE, SPRAY; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
3	NDC:56062-107-09	1 in 1 CARTON	04/28/2021	
3		144 in 1 BOTTLE, SPRAY; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
4	NDC:56062-107-08	1 in 1 CARTON	06/02/2021	
4		72 in 1 BOTTLE, SPRAY; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
ANDA	ANDA207957	09/08/2016	

Labeler - Publix Super Markets Inc (006922009)

Revised: 1/2026 Publix Super Markets Inc