

FULL PRESCRIPTION STRENGTH • NON-DROWSY

This label may not be the latest approved by FDA. For complete labeling information, please visit <https://www.fda.gov/drugsatfda>



Fluticasone Propionate Nasal Spray 50 mcg Per Spray
Allergy Symptom Reliever
(Glucocorticoid)*

AGES
4
YEARS
& OLDER

gsk

24 Hour Relief of:

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



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



2 Bottles / 0.34 fl oz (9.9 mL) each
0.68 fl oz (19.8 mL) total


NO COPY
Cutout
Area

Two bottles
60 sprays per bottle

GSK Regulatory Spec Box		Verified Date: 03.06.17
Drug Facts Info		
Drug Facts (Title)	Font Name: N/A	N/A
Drug Facts (continued)	Font Name: N/A	N/A
Headings	Font Name: N/A	N/A
Subheadings	Font Name: N/A	N/A
Body text	Font Name: N/A	N/A
Bullets	Font Name: N/A	N/A
Bullets on same lines: end of statement separated from bulleted statement by two ems		N/A
Spacing of the hair lines from edge of box – i.e. Minimum of 2 spaces either side of Drug Fact Box		N/A
Tracking	N/A	Horizontal Scale: N/A
Leading (Minimum space in body copy of Drug Facts)	N/A	Maximum Characters/Inch: N/A
Barlines	N/A	Hairlines: N/A
Primary Display Panel Info		
Font size of Net Wt/Contents (Smallest character height in inches)		0.1875 in.
PDP dimensions (in square inches)		98.91 sq. in.
Font size of Statement of Identity (If not live text, to be measured in Helvetica capital "M")		V N/A H 9.05 pt.
Font size of Logo/Largest Copy on PDP (If not live text, to be measured in Helvetica capital "M")		V N/A H 50.25 pt.
Ratio of Statement of Identity to Logo/Largest Copy on PDP		
Statement of Identity (pt.) (Divided by) Largest Logo Copy (pt.)		V N/A H 18%

FULL PRESCRIPTION STRENGTH • NON-DROWSY

CHILDREN'S





ALLERGY RELIEF

Fluticasone Propionate Nasal Spray 50 mcg Per Spray
Allergy Symptom Reliever
(Glucocorticoid)*


What problems can CHILDREN'S FLONASE Allergy Relief help with?


CHILDREN'S FLONASE Allergy Relief helps relieve a broad range of uncomfortable symptoms like congestion and itchy eyes.


 **Nasal symptoms**


 **Eye symptoms**

These symptoms can be triggered by allergens like pollen, mold, dust or pet dander.

 **Outdoor allergens**

 **Animal allergens**


 **Indoor allergens**

 **Animal allergens**

AGES 4 YEARS & OLDER

See below for important information about use in children. *Fluticasone propionate is a steroid medicine known as a glucocorticoid

Drug Facts	Drug Facts (continued)
<p>Active ingredient (in each spray) Fluticasone propionate (glucocorticoid) 50 mcg Allergy symptom reliever</p> <p>Uses Temporarily relieves these symptoms of hay fever or other upper respiratory allergies: • nasal congestion • runny nose • sneezing • itchy nose • itchy, watery eyes</p> <p>Warnings Only for use in the nose. Do not spray into your eyes or mouth.</p> <p>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</p> <p>Ask a doctor before use if you have or had glaucoma or cataracts</p> <p>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)</p> <p>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</p> <p>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</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p>	<p>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</p> <p style="text-align: center;">ADULTS AND CHILDREN 12 YEARS OF AGE AND OLDER</p> <p>• 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</p> <p style="text-align: center;">CHILDREN 4 TO 11 YEARS OF AGE</p> <p>• 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</p> <p style="text-align: center;">CHILDREN UNDER 4 YEARS OF AGE</p> <p>• do not use</p> <p>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 4° and 30°C (39° and 86°F) • keep this label and enclosed materials. They contain important additional information.</p> <p>Inactive ingredients benzalkonium chloride, dextrose, microcrystalline cellulose, phenylethyl alcohol, polysorbate 80, purified water, sodium carboxymethylcellulose</p> <p>Questions or comments? call toll-free 1-844-FLONASE (1-844-356-8273)</p>



TAMPER-EVIDENT features for your protection. The product is packaged in a sealed plastic container. Under the cap and nozzle, each bottle has an aluminum seal around bottle neck. Do not use if any of these features are torn or damaged.

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Lot: [REDACTED]

Exp: [REDACTED]

GSK Regulatory Spec Box		Verified Date: 3.16.17
Drug Facts Info		
Drug Facts (Title)	Font Name: Helvetica Neue 77 Bold Condensed Oblique	10.0 point type
Drug Facts (continued)	Font Name: Helvetica Neue 77 Bold Condensed Oblique/Helvetica Neue 57 Condensed	8.00 point type
Headings	Font Name: Helvetica Neue 77 Bold Condensed Oblique	8.00 point type
Subheadings	Font Name: Helvetica Neue 77 Bold Condensed	7.00 point type
Body text	Font Name: Helvetica Neue 57 Condensed/Helvetica Neue 77 Bold Condensed	7.00 point type
Bullets	Font Name: Helvetica Neue 56 Roman	5.00 point type
Bullets on same lines: end of statement separated from bulleted statement by two ems		Yes
Spacing of the hair lines from edge of box – i.e. Minimum of 2 spaces either side of Drug Fact Box		Yes
Tracking	0	Horizontal Scale: 94%-100%
Leading (Minimum space in body copy of Drug Facts)	7.50 pt.	Maximum Characters/Inch: 30
Baselines	1.50 pt.	Hairlines 0.50 pt.
Primary Display Panel Info		
Font size of Net Wt/Contents (Smallest character height in inches)		N/A
PDP dimensions (in square inches)		N/A
Font size of Statement of Identity (if not live text, to be measured in Helvetica capital "M")		V N/A H 10.05 pt.
Font size of Logo/Largest Copy on PDP (if not live text, to be measured in Helvetica capital "M")		V N/A H 55.89 pt.
Ratio of Statement of Identity to Logo/Largest Copy on PDP		
Statement of Identity (pt.) (Divided by) Largest Logo Copy (pt.)		V N/A H 18%

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CHILDREN'S 



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Allergy Symptom Reliever
(Glucocorticoid)*

24 Hour Relief of:

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





**AGES
4
& OLDER**

60 METERED
SPRAYS
0.34 fl oz (9.9 mL)

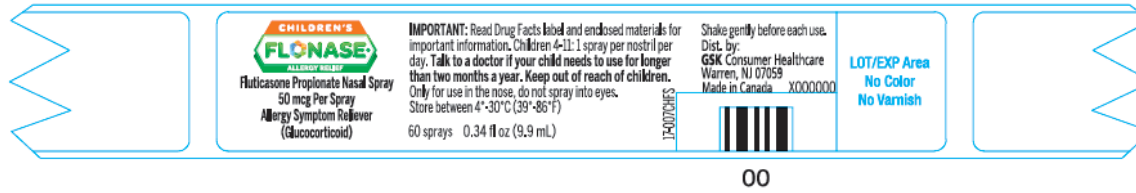


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104854XD

GSK Regulatory Spec Box		Verified Date: 02.21.17
Drug Facts Info		
Drug Facts (Title)	Font Name: N/A	N/A
Drug Facts (continued)	Font Name: N/A	N/A
Headings	Font Name: N/A	N/A
Subheadings	Font Name: N/A	N/A
Body text	Font Name: N/A	N/A
Bullets	Font Name: N/A	N/A
Bullets on same lines: end of statement separated from bulleted statement by two ems		N/A
Spacing of the hair lines from edge of box – i.e. Minimum of 2 spaces either side of Drug Fact Box		N/A
Tracking	N/A	Horizontal Scale: N/A
Leading (Minimum space in body copy of Drug Facts)	N/A	Maximum Characters/Inch: N/A
Barlines	N/A	Hairlines N/A
Primary Display Panel Info		
Font size of Net Wt/Contents (Smallest character height in inches)		0.0687 in.
PDP dimensions (in square inches)		17.5 sq. in.
Font size of Statement of Identity (If not live text, to be measured in Helvetica capital "M")	V N/A	H 7.66 pt.
Font size of Logo/Largest Copy on PDP (If not live text, to be measured in Helvetica capital "M")	V N/A	H 38.65 pt.
Ratio of Statement of Identity to Logo/Largest Copy on PDP		
Statement of Identity (pt.) (Divided by) Largest Logo Copy (pt.)	V N/A	H 20%



GSK Regulatory Spec Box		Verified Date: 8/10/17
Drug Facts Info		
Drug Facts (Title)	Font Name: N/A	N/A
Drug Facts (continued)	Font Name: N/A	N/A
Headings	Font Name: N/A	N/A
Subheadings	Font Name: N/A	N/A
Body text	Font Name: N/A	N/A
Bullets	Font Name: N/A	N/A
Bullets on same lines: end of statement separated from bulleted statement by two ems		N/A
Spacing of the hair lines from edge of box – i.e. Minimum of 2 spaces either side of Drug Fact Box		N/A
Tracking	N/A	Horizontal Scale: N/A
Leading (Minimum space in body copy of Drug Facts)	N/A	Maximum Characters/Inch: N/A
Barlines	N/A	Hairlines N/A
Primary Display Panel Info		
Font size of Net Wt/Contents (Smallest character height in inches)		0.0449 in.
PDP dimensions (in square inches)		0.781 sq. in.
Font size of Statement of Identity (If not live text, to be measured in Helvetica capital "M")		V N/A H 6.0 pt.
Font size of Logo/Largest Copy on PDP (If not live text, to be measured in Helvetica capital "M")		V N/A H 8.18 pt.
Ratio of Statement of Identity to Logo/Largest Copy on PDP		
Statement of Identity (pt.) (Divided by) Largest Logo Copy (pt.)		V N/A H 73%