Intranasal Corticosteroid STEPS
January 9, 2007

Recommendation

Since all intranasal corticosteroids are considered equally efficacious, choice should be based on patient preference and cost. Generally, patients prefer other agents to fluticasone, however, individual patient perceptions are highly variable. Since fluticasone is the least expensive it should be the agent of first choice. A good second option for patients that do not like fluticasone would be budesonide. It has been used the longest, is pregnancy category C, has the fewest sprays per day, and patients sometimes find it to have more favorable sensory characteristics compared to fluticasone.

Brand Name **Generic Name**	**Beconase AQ** **Beclomethasone dipropionate**	**Rhinocort Aqua** **Budesonide**	**Omnaris** **Ciclesonide**	**Nasarel** **Flunisolide**	**Veramyst** **Fluticasone Furoate**	**Flonase** **Fluticasone propionate**	**Nasonex** **Mometasone furoate**	**Nasacort AQ, Tri-Nasal(HFA)** **Triamcinolone acetonide**
Generic	No	No	No	Yes	No	Yes	No	No
Safety	=	+	=	=	=	=	=	=
Drug Interactions	Clinically significant drug interactions unlikely	Metabolized by CYP 3A4. Increased exposure with ketoconazole	Substrate of CYP 3A4 & 2D6. Increased exposure with ketoconazole	Clinically significant drug interactions unlikely	Substrate of CYP 3A4. Caution with potent CYP3A4 inhibitors	Substrate of CYP 3A4. Use caution with potent CYP3A4 inhibitors	Clinically significant drug interactions unlikely	Clinically significant drug interactions unlikely.
Pregnancy/ Lactation	Category C Enters breastmilk	Category B Enters breast milk	Category C Excretion in breast milk unknown	Category C Excretion in breast milk unknown	Category C Excretion in breast milk unknown	Category C Excretion in breast milk unknown	Category C Excretion in breast milk unknown	Category C Excretion in breast milk unknown
Look-alike Sound-alike ~ (confused with)				Flunisolide~ *Flumadine*, fluocinonide *Nasarel~Nizoral*				*Nasacort~ NasalCrom*
Pediatric	Safety and Efficacy not established for age < 6 years	Safety and Efficacy not established for age < 6 years	Safety and Efficacy not established for age < 12years	Safety and Efficacy not established for age < 6 years	Safety and efficacy not established for age < 2years	Safety and Efficacy not established for age < 4years	Safety and efficacy not established for age < 2years	Safety and Efficacy not established for age < 6 years
Elderly	Use caution. Start at low end of the dosing range, reflecting greater frequency of decreased hepatic, renal, or cardiac function and concomitant disease							
Hepatic Impairment	Reduced liver function may affect the elimination of corticosteroids. Those with hepatic impairment may require dosage adjustment. Use caution and monitor							
Contraindications	Hypersensitivity to the drug or any component of the product. Flunisolide – untreated localized infections involving the nasal mucosa							
Precautions	❑ Rare instances of wheezing, nasal septum perforation, cataracts, glaucoma, and increased intraocular pressure ❑ Replacement of systemic corticosteroids with intranasal corticosteroids can be accompanied by signs of adrenal insufficiency ❑ Do not exceed recommended dose – HPA symptoms may occur. If symptoms occur, discontinue slowly ❑ May cause a reduction of growth velocity when administered to pediatric patients ❑ Persistent nasopharyngeal irritation may be an indication to stop therapy ❑ May be more susceptible to infection. Use with caution in patients with untreated localized infection involving the nasal mucosa. ❑ Do not use in patients who have experienced recent nasal septal ulcers, recurrent epistaxis, or nasal surgery or trauma until healing has occurred ❑ In the presence of excessive nasal mucosa secretion or edema of the nasal mucosa, the drug may fail to reach the site of intended action ❑ Examine patient periodically over several months or longer for possible changes in the nasal mucosa ❑ Flunisolide - Temporary or permanent loss of the sense of smell and taste has been reported							

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Tolerability	**= (?)**	**+**	**= (?)**	**= (?)**	**= (?)**	**-**	**=**	**+**
Side effects (%)	Nasopharyngeal irritation (24), HA (5), N (5), lightheadedness (5), stuffiness (3), epistaxis (3), rhinorrhea (3), tearing eyes (3)	Nasopharyngeal irritation (2), epistaxis (8), pharyngitis (4), bronchospasm (2), cough (2)	Nasal irritation (4), HA(6), epistaxis (5), pharyngitis 3.7), ear pain (2.2)	Nasal burning (13), HA (5), N (1), stuffiness (5), epistaxis (3-9), tearing eyes (5), pharyngitis (1), cough (1), transient aftertaste (17), sinusitis (1)	Pharyngolaryngeal pain (15), HA (9), epistaxis (4), back pain (1)	Nasal irritation (2-3), HA (7-16), N (3-5), epistaxis (6-7), pharyngitis (6-8), cough (4), asthma symptoms (3-7), viral infection (8-14), aches and pains (1-3)	Nasal irritation(2-5), HA(17–26), N (2-5), epistaxis (8-11), rhinorrhea(1-3), pharyngitis(10-12), cough (7-13) ear pain (2-5), asthma sx (2-5), resp. inf. (5-7)	AQ: HA (2), epistaxis (3), pharyngitis (5), cough (2), asthma symptoms (2), sinusitis (1) HFA: nasal irritation (6-7.5), HA (6-10)
Patient perceptions	Rhinocort, Flonase, Nasonex, and Nasacort AQ are the steroids that have been evaluated for patient preference. Patients generally prefer the attributes of Rhinocort or Nasacort compared to Flonase or Nasonex. Although one Indian study found an increased preference for Nasonex over Rhinocort and Flonase. It is hypothesized that patients prefer formulations that are fragrance and alcohol-free. Currently, budesonide, triamcinolone, and mometasone are all alcohol-free. At the time the studies were done, mometasone was not alcohol-free (became alcohol free 8/04). It is possible that the new formulation of mometasone may have improved patient acceptance, however no studies have been done to confirm this theory. The presence of benzalkonium may also determine patient acceptance. This is a preservative described as having a bitter taste that is present in all intranasal steroids except Rhinocort and Omaris. This suggests that patients may prefer Rhinocort to Nasacort, although there are no studies that have directly compared Rhinocort to Nasacort.							
Overall comfort	=	+	?	?	?	=	=	+
Less rundown into nose/throat	=	+	?	?	?	=	=	+
Less runout from nostrils	=	+	?	?	?	=	?	?
Less irritation	-	+	?	?	?	-	=	+
Milder odor	=	+	?	?	?	-	=	+
Preferred odor	=	?	?	?	?	-	=	+
Milder taste	=	+	?	?	?	-	-	+
Preferred taste	?	?	?	?	?	-	=	+
Preferred feel of spray in nose/throat	?	+	?	?	?	-	-	+
Preferred force of spray	?	+	?	?	?	-	?	?
Less Aftertaste	-	+	?	?	?	-	=	+
Mean volume of spray per actuation (μL^3)	?	53.4	70	?	50	94.6	100.1	94.9
Alcohol	Yes	No	No	No	Yes	Yes	No	No
Fragrance	No	No	?	?	No	Yes	No	No
Benzalkonium	Yes	No	No	Yes	Yes	Yes	Yes	Yes

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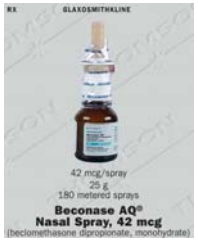
Efficacy	=	=	=	=	=	=	=	=
FDA-approved indications	• Perennial & seasonal allergic rhinitis • Nonallergic rhinitis • Nasal polyps	• Perennial & seasonal allergic rhinitis	• Perennial & seasonal allergic rhinitis	• Perennial & seasonal allergic rhinitis	• Perennial & seasonal allergic rhinitis	• Perennial & seasonal allergic rhinitis • Nonallergic rhinitis	• Perennial allergic rhinitis • Tx & px of seasonal allergic rhinitis • Nasal polyps	Perennial and seasonal allergic rhinitis
Unlabeled uses		• Nasal polyps • Recurrent chronic sinusitis				• Nasal polyps • Recurrent chronic sinusitis	• Recurrent chronic sinusitis	
Pharmacokinetics								
Onset of effect	Within 3days	24hrs to 3days	Within 3days	24 – 48hrs	12hrs to 3 days	12hrs to 3days	11hrs to 2 days	24hrs to 7 days
Max. benefit time	14 days	14 days	14 – 21 days	7 – 14 days	7 days	7 days	7 – 14 days	7 days
Intranasal Bioavailability (%)	17	10 – 34	40 – 50	1	0.5	<2	<0.1	22
Clinical Studies	No study has been identified to show that there is any clinically significant benefit of one agent over another. Consensus guidelines consider all agents equally effective and tolerated when administered in equipotent doses.							
Price	-	-		+	-	+	-	-
Usual Dose	1–2 sprays each nostril BID	1 spray in each nostril daily	2 sprays in each nostril daily	2 sprays in each nostril BID (up to tid)	2 sprays in each nostril daily	2 sprays in each nostril daily	2 sprays in each nostril daily	AQ: 1- 2 sprays in each nostril daily HFA: 2 sprays in each nostril daily
Strength/Dosage Form	Aq. susp. spray 42mcg/spray 25gm bottle (180 sprays) 	Aq. Susp. spray 32mcg/spray 8.6gm bottle (120 sprays) 	Aq. susp. spray 50mcg/spray 12.5gm bottle (120 sprays)	Intranasal solution spray, 29mcg/spray 25ml bottle (200 sprays)	Aq. susp. spray, 27.5mcg/spray, 10g container (120 sprays) 	Aq. susp. spray, 50mcg/spray 16g container (120 sprays) 	Aq. susp. spray, 50mcg/spray 17g bottle (120 sprays) 	AQ: Aq. susp. spray, 55mcg/spray, 16.5g container (120 sprays) HFA: Aerosol for nasal inhalation, 55mcg/inhalation, 9.3g container (100 sprays) 

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Price	-	-		+	-	+	-	-
Hospital ($) Acquisition Cost	$$$$$$$$$$	$$$$$$$$		$$	$$$$$$$$	$	$$$$$$	AQ: $$$$$$$$ HFA: $$$$$$
Cost per day ($)	$$$$$$$$	$$$$		$$	$$$$$$$$	$	$$$$$$	AQ: $$$$$ HFA: $$$$$$
Drugstore.com ($)	119.99	92.99		37.99	84.99	59.99	89.24	AQ: 89.99
Cost per day ($)	2.67	1.54		1.51	2.83	1.99	2.97	1.50
Simplicity	-	+	=	-	+	=	-	=
	Patients should be advised that 1 –2 weeks may pass before full effect is achieved. Benefit requires regular use. Nasal passages should be cleared before use. All require gently shaking before use except flunisolide. Patients should close the other nostril with a finger and tilt head slightly forward while using. Avoid blowing nose for at least 10 – 15 minutes after use. Avoid spraying into eyes or directly into nasal septum. Discard bottle if the labeled number of actuations have been used. When maximum benefit has been achieved and symptoms have been controlled, dosages may be reduced.							
	• BID drug • 4-8 sprays/day • 6 pumps to prime • Prime again if not used for 7 days	• Daily drug • 2 sprays/day • 8 pumps to prime • Prime again with 1 spray if not used for 2 days. >14 days rinse and reprime with 2 sprays	• Daily drug • 4 sprays/day • 8 pumps to prime • Prime again if not used for 4 days	• BID - TID drug • 8-12 sprays/day • 6 pumps to prime • Prime again if not used for 5 days	• Daily drug • 4 sprays/day • 6 sprays to prime • Prime again if not used for 30 days or if the cap has been left off for >5 days • Ergonomic egg-shape. Has a button on the side that when pressed releases the dose • Viewing window shows how much is left in contianer	• Daily drug • 4 sprays/day • 6 pumps to prime	• Daily drug • 4 sprays/day • 10 pumps to prime • Prime again if not used within 1 week • When removed from cardboard container, avoid prolonged exposure to direct light. Brief exposure to light, as with normal use, is acceptable.	• Daily drug • 4sprays/day • 5 pumps to prime • Prime again if not used for 14 days
BCBS	Non-formulary	Tier II	Non-formulary	Non-formulary	Non-formulary	Tier I	Tier II	Tier II
UPHP	Non-formulary	Step Therapy	Non-formulary	Non-formulary	Non-formulary	Preferred	Step Therapy	Non-formulary