

- elicited.
- Cautiously used with immunosuppressant drugs lead to susceptibility to infections.
- Use of drug with alcohol or depressants or antihistamines must be avoided.
- When use as a long-term therapy, hematological and adrenal function should be monitored.
- Can be used in pregnancy only if the potential benefits justify the potential risk to the foetus.
- Should be used cautiously in nursing mothers.

DRUG INTERACTIONS

Use of the drug with potent inhibitors of cytochrome 450 3A4 can lead to increase systemic exposure of fluticasone.

SIDE EFFECTS

- Headache
- Somnolence
- Pharyngitis
- Epistaxis
- Nausea, vomiting, taste disturbance
- Nasal burning

STORAGE AND STABILITY:

- Store at temperature not exceeding 30°C
- Do not freeze.
- Keep the nasal spray away from direct heat and sunlight.
- Do not use after the expiry date shown on the package. Do not use longer than 6 months after the bottle was first opened.
- Keep away from children

PRESENTATION

Combinate AQ Nasal Spray
Pack contains 70 metered doses.



German Remedies

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**PLAINTIFFS'
TRIAL EXHIBIT
PTX0026**

exhibitstick.com

MEDA_APTX03502796

CIP2031

Argentum Pharmaceuticals LLC v. Cipla Ltd.

IPR2017-00807

PTX0026-00001



Azelastine Hydrochloride and
Fluticasone Propionate Nasal Spray
COMBINASE[®] AQ Nasal Spray

Each spray delivers -
Azelastine Hydrochloride IP 140 mcg
Fluticasone Propionate IP 50 mcg

COMPOSITION :

Azelastine Hydrochloride IP 0.14% w/v
Fluticasone Propionate IP 0.05% w/v
Preservatives -
Benzalkonium
Chloride Solution IP 0.02% w/v
Phenylethyl Alcohol IP 0.25% w/v
Excipients q.s.

DESCRIPTION:

Combinase AQ nasal spray is an antihistamine-corticosteroid combination available for intra nasal administration. It contains azelastine hydrochloride an H1 receptor antagonist and fluticasone propionate a synthetic corticosteroid with antiinflammatory properties.

INDICATIONS:

Combinase AQ is indicated for the management of allergic rhinitis. It is recommended to treat severe persistent symptoms in adults. For children above 5 years Combinase AQ is recommended for severe symptoms of allergic rhinitis. It can be used for non-allergic rhinitis in adults and children.

CONTRAINDICATIONS:

Combinase AQ contraindicated in patients with or known hypersensitivity to any of the components of the preparation.

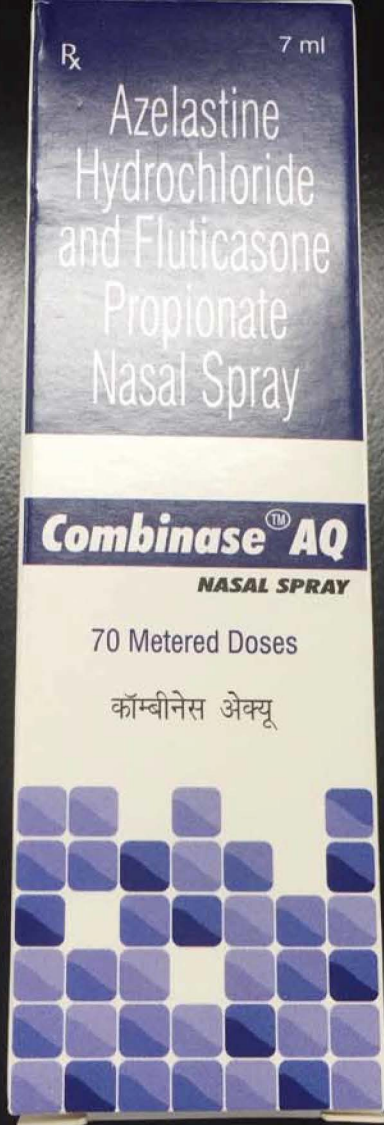
DOSAGE AND ADMINISTRATION:

Adults: 1 spray/nostril twice daily.
Children 1 spray/nostril twice daily.

Not recommended for children (below 5 years). Dosage should not be exceeded.

PRECAUTIONS:

- Use of intranasal corticosteroid with other steroid could increase risk of suppression of HPA axis or increase risk of hypocorticismism therefore cautiously used in patients with other pathological conditions in steroids.
- Reduction in growth velocity when higher dose is administered.
- Adrenal insufficiency signs may be seen due to replacement of systemic corticosteroid with topical corticosteroid. Withdrawal symptoms can be



MEDA_APTX03502798

CombinaseTM AQ

Nasal Spray

Each spray delivers :

Azelastine Hydrochloride IP	140 mcg
Fluticasone Propionate IP	50 mcg

Composition :

Azelastine Hydrochloride IP	0.14% w/v
Fluticasone Propionate IP	0.05% w/v

Preservatives :

Benzalkonium	
Chloride Solution IP	0.02% w/v
Phenylethyl Alcohol IP	0.25% w/v
Excipients	q.s.

**Store at temperature
not exceeding 30°C**

Do not freeze. Protect from light.

**Keep away from children.
Shake well before each use.**

FOR NASAL USE ONLY

Dosage : As directed by the physician.

SCHEDULE H DRUG
Warning : To be sold by
retail on the prescription
of a Registered Medical
Practitioner only.

Each spray delivers:

Azelastine Hydrochloride IP 140 mcg
Fluticasone Propionate IP 50 mcg

Composition:

Azelastine Hydrochloride IP 0.14% w/v
Fluticasone Propionate IP 0.05% w/v

Preservatives:

Benzalkonium Chloride IP 0.01% w/v
Phenylethyl Alcohol IP 0.25% w/v
Excipients q.s.

DESCRIPTION

Nasocom AZ is an antihistamine-corticosteroid combination available as a metered spray formulation for intranasal administration. It contains azelastine hydrochloride a second generation H1 receptor antagonist and fluticasone propionate, a synthetic corticosteroid.

Nasocom AZ Nasal Spray is an aqueous suspension of microfine azelastine hydrochloride and fluticasone propionate for topical administration to the nasal mucosa by means of a metering, atomizing spray pump. It is necessary to prime the pump before first use or after a period of non-use (1 week or more). After initial priming (6 actuations), each actuation delivers 140 mcg of azelastine hydrochloride and 50 mcg of fluticasone propionate through the nasal adapter. Each 15 ml bottle of Nasocom Nasal Spray provides 70 metered sprays. After 70 metered sprays, the amount of azelastine hydrochloride and fluticasone propionate delivered per actuation may not be consistent and the unit should be discarded.

Nasocom® AZ - 005998

Page 9 of 18

INDICATIONS

Nasocom AZ is indicated for the management of symptoms of allergic rhinitis once the need for an antihistamine and corticosteroid has been established. It is recommended to treat moderate to severe symptoms in adults above 12 years. For children above 5 years, Nasocom AZ is recommended for severe symptoms of allergic rhinitis. Nasocom AZ can also be used for treating non-allergic vasomotor rhinitis in adults and children 12 years of age and older.

DOSAGE AND ADMINISTRATION**Adults and children 5 years and older:**

1 spray intranasal twice daily the recommended dosage should not be exceeded. Not recommended for use in children below 5 years.

CONTRAINDICATIONS

Nasocom AZ is contraindicated in patients with or known hypersensitivity to azelastine hydrochloride or fluticasone propionate or any of the components of the preparation.

WARNINGS AND PRECAUTIONS

Concurrent use of this combination with alcohol or other CNS depressants or other antihistamines should be avoided as additional reductions in alertness and additional impairment of CNS performance may occur due to azelastine.

The replacement of a systemic corticosteroid with a topical corticosteroid can be accompanied by signs of adrenal insufficiency. Some patients may experience symptoms of withdrawal e.g. joint and /

Nasocom® AZ - 005998

Page 10 of 18



For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.

Patient Information Leaflet

NASOCOM[®]AZ

Azelastine Hydrochloride and
Fluticasone Propionate Nasal Spray

NASOCOM[®]AZ

Azelastine Hydrochloride and
Fluticasone Propionate Nasal Spray



NASOCOM[®]-AZ

Each spray delivers:

Azelastine Hydrochloride IP 140 mcg

Fluticasone Propionate IP 50 mcg

Composition:

Azelastine Hydrochloride IP 0.14% w/v

Fluticasone Propionate IP 0.05% w/v

Preservatives:

Benzalkonium Chloride IP 0.01%w/v

Phenylethyl Alcohol IP 0.25%w/v

Excipients q.s.

DOSAGE: As directed by the Physician.

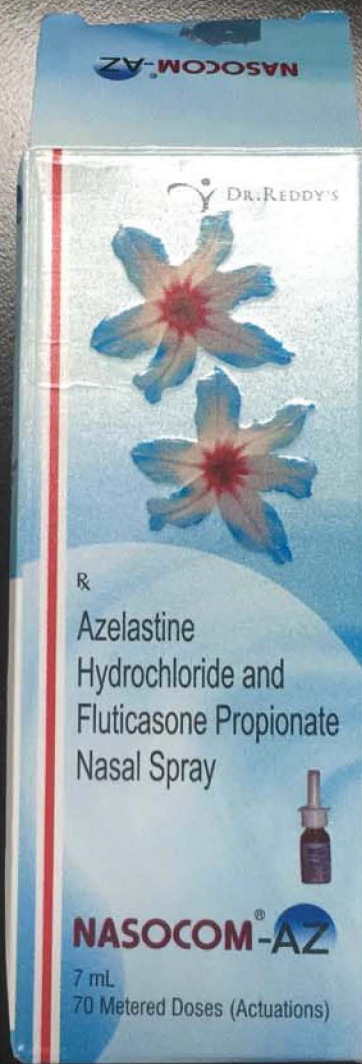
Directions for use:

Please refer the enclosed leaflet
before use.

SHAKE WELL BEFORE EACH USE.

For External Use Only.

Store in a cool place, protected
from light. Do not freeze.



MEDA_APTX03502803



MEDA_APTX03502804

Rx Azelaſtine Hydrochloride & Fluticasone Propionate Naſal Spray

FLORESPTM-AZ

Nasal Spray

EACH SPRAY DELIVERS :

Azelastine Hydrochloride BP 140 mcg
Fluticasone Propionate IP 50 mcg

COMPOSITION :

Azelastine Hydrochloride BP 0.14 % w/v
Fluticasone Propionate IP 0.05 % w/v

PRESERVATIVES :

Benzalkonium Chloride Solution IP 0.02 % w/v
Phenyl Ethyl Alcohol USP 0.25 % w/v
Excipients q.s.

DESCRIPTION :

FLORESP-AZ Nasal Spray is an antihistamine-corticosteroid combination available as a metered spray formulation for intranasal administration. It contains Azelastine Hydrochloride, which is a second generation H1 receptor-antagonist with potent topical activity, and Fluticasone Propionate, a synthetic corticosteroid with anti-inflammatory properties.

PHARMACOLOGY :

Pharmacodynamics

Fluticasone Propionate is a synthetic, trifluorinated corticosteroid with antiinflammatory activity. Fluticasone Propionate was 3-fold to 5-fold more potent than dexamethasone in the *in vitro* assays. In pre-clinical studies, Fluticasone Propionate revealed progesterone-like activity similar to the natural hormone. However, the clinical significance of these findings in relation to the low plasma levels is not known. The precise mechanism through which Fluticasone Propionate affects allergic rhinitis symptoms is not known. Corticosteroids have been shown to have a wide range of effects on multiple cell types (e.g., mast cells, eosinophils, neutrophils, macrophages, and lymphocytes) and mediators (e.g., histamine, eicosanoids, leukotrienes, and cytokines) involved in inflammation.

Azelastine Hydrochloride, a phthalazine derivative, exhibits histamine H1receptor- antagonist activity in isolated tissues, animal models, and humans. The major metabolite, desmethylazelastine, also possesses H1 receptor-antagonist activity.

Pharmacokinetics

Parameters	Fluticasone Propionate	Azelastine Hydrochloride
Systemic bioavailability	< 2 %	40 %
Onset of action	within 12 hours	within 15 minutes
Tmax	0.9 +/- 0.4 hours.*	2 - 3 hours
Vd	4.2 L/kg#	14.5 L/kg*
Plasma protein binding	91 %	88 %
Half-life	7.8 hours*	22 hours*
Excretion	Less than 5 % oral dose excreted in the urine and remainder is excreted in the faeces.	75 % of an oral dose excreted in the faeces, with less than 10 % as unchanged azelastine.

* - oral dose

- IV

@ - Intranasal 800 mcg tds.

INDICATIONS :

- Management of moderate to severe symptoms of allergic rhinitis in adults.
- Management of moderate to severe symptoms of allergic rhinitis in children 5 years and above.
- Management of symptoms of non-allergic rhinitis in adults and children (5 years and above).

DOSAGE AND ADMINISTRATION :

Dosage

Adults : One spray/nosril twice daily.

Children (5 years and above) : One spray/nosril twice daily.

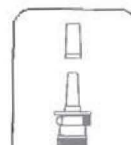
The recommended dosage should not be exceeded.

Administration

Administer nasal spray by the intranasal route only.

Directions for Use

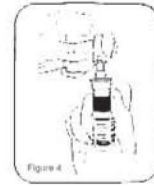
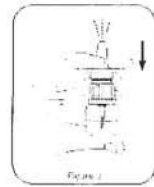
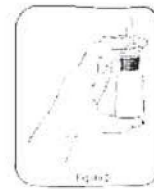
Following are directions for the use of nasal spray:



MEDA_APTX03502805

USING YOUR NASAL SPRAY

- **STEP 1**
Blow your nose gently and then remove the protective cap.
- **STEP 2**
Hold the bottle with your forefinger and middle finger on either side of the nozzle and your thumb underneath the bottle (Figure 2).
- **STEP 3**
If using for the first time or if you have not used it for a week or more, test the spray
Testing the spray : With the nozzle pointing away from you, press down a few times until a fine mist comes out of the nozzle.
- **STEP 4**
Close one nostril and hold the bottle as shown in step 2. Tilt your head forward slightly and keeping the bottle upright, carefully insert the tip of the nozzle in the other nostril.
- **STEP 5**
Start to breathe in through your nose and **while breathing in**, press down with your fingers **once** to release the spray.
- **STEP 6**
Breathe out through your mouth.
- **STEP 7**
Repeat steps 4, 5 and 6 for the other nostril.
- **STEP 8**
Wipe the nozzle with a clean handkerchief/tissue and replace the protective dust cap.



CONTRAINDICATIONS :

This combination is contraindicated in patients with known hypersensitivity to Fluticasone Propionate or Azelastine Hydrochloride or any of the components of the preparation.

WARNINGS AND PRECAUTIONS :

The replacement of a systemic corticosteroid with a topical corticosteroid can be accompanied by signs of adrenal insufficiency. Some patients may experience symptoms of withdrawal, e.g., joint and/or muscular pain, lassitude, and depression. The concomitant use of an intranasal corticosteroid with other inhaled corticosteroids could increase the risk of signs or symptoms of hypercorticism and/or suppression of the HPA-axis. Intranasal corticosteroids may cause a reduction in growth velocity when administered at higher dose. Patients using Fluticasone Propionate nasal spray over several months or longer should be examined periodically for evidence of Candida infection or other signs of adverse effects on the nasal mucosa. Intranasal corticosteroids should be used with caution, if at all, in patients with active or quiescent tuberculous infections of the respiratory tract; untreated local or systemic fungal or bacterial infections; systemic viral or parasitic infections; or ocular herpes simplex. Because of the inhibitory effect of corticosteroids on wound healing, patients who have experienced recent nasal septal ulcers, nasal surgery, or nasal trauma should not use a nasal corticosteroid until healing has occurred.

In clinical trials, the occurrence of somnolence has been reported in some patients taking Azelastine Nasal Spray; due caution should therefore be exercised when driving a car or operating potentially dangerous machinery while using this combination spray.

ADVERSE REACTIONS :

Common adverse reactions seen with Fluticasone Propionate are headache, pharyngitis, epistaxis, and nasal burning /irritation, nausea/vomiting, cough.

Common adverse reactions seen with Azelastine Hydrochloride are bitter taste, taste disturbances, headache, somnolence and epistaxis.

DRUG INTERACTIONS :

Concurrent use of Fluticasone Propionate with potent inhibitors of the cytochrome 450 3A4 system, such as ketoconazole and protease inhibitors such as ritonavir, may be associated with increased systemic exposure of fluticasone.

Concurrent use of Azelastine Hydrochloride with alcohol or other CNS depressants may cause additional reductions in alertness and additional impairment of CNS performance.

USE IN SPECIFIC POPULATION :

● **Pregnancy**

The spray combination should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

● **Nursing mothers**

It is not known whether Fluticasone Propionate or Azelastine Hydrochloride is excreted in human milk. Hence, caution should be exercised while prescribing this combination to nursing mothers.

● **Pediatric**

The combination is not recommended for children below 5 years.

OVERDOSAGE

Chronic overdosage of Fluticasone Propionate may result in signs/symptoms of hypercorticism. Intranasal administration of 2 mg (10 times the recommended dose) of Fluticasone Propionate, twice daily for 7 days, to healthy human volunteers was well tolerated. Single oral doses of up to 10 mg have been studied in human volunteers with no acute toxic effects reported. Repeat oral doses of up to 80 mg daily for 10 days in volunteers and repeat oral doses of up to 10 mg daily for 14 days in patients were also well tolerated.

With Azelastine Hydrochloride nasal administration, there have been no reported overdosage. If overdosage occurs, general supportive measures should be employed as there is no known antidote.

STORAGE :

Store in a cool place, protect from light. Do not freeze or refrigerate.
Keep out of reach of children.

PRESENTATION :

FLORESP-AZ sales pack contains 70 metered doses.

Marketed by



A Joint Venture of Emcure®

5119, Oberoi Garden Estates, D-Wing,
Chandivli, Andheri (E), Mumbai 400 072.
© Trade Mark Owners

Manufactured by :

Biodeal Pharmaceuticals Pvt. Ltd
Village - Saini Majra, Nalagarh Ropar Road,
Nalagarh, Dist. Solan (HP) - 174 101.

BD/01-02/121B

MEDA_APTX03502806

BD/01-02/121B

Each spray delivers .

Azelastine	
Hydrochloride IP	140 mcg
Fluticasone	
Propionate IP	50 mcg

Composition :

Azelastine	
Hydrochloride IP	0.14 % w/v
Fluticasone	
Propionate IP	0.05 % w/v

Preservatives :

Benzalkonium Chloride	
Solution IP	0.02 % w/v
Phenyl Ethyl	
Alcohol IP	0.25 % w/v
Excipients	q.s.

Dosage :

As directed by the Physician.

Direction for use :

Please refer the enclosed leaflet before use.

**SHAKE WELL BEFORE
EACH USE.**

Store in a cool place, protect from light.

Do not freeze or refrigerate.

Keep out of reach of children.

FOR EXTERNAL USE ONLY

MEDA_APTX03502807



MEDA_APTX03502808

Azelastine Hydrochloride & Fluticasone Propionate Nasal Spray

FLORESP-AZ

Nasal Spray

EACH SPRAY DELIVERS:
 Azelastine Hydrochloride IP 140 mcg
 Fluticasone Propionate IP 50 mcg

COMPOSITION:
 Azelastine Hydrochloride IP 0.14 % w/v
 Fluticasone Propionate IP 0.05 % w/v
PRESERVATIVES:
 Benzalkonium Chloride Solution IP 0.02 % w/v
 Phenyl Ethyl Alcohol IP 0.25 % w/v
 Excipients q.s.

DESCRIPTION:
 FLORESP-AZ Nasal Spray is an antihistamine corticosteroid combination available as a metered spray formulation for intranasal administration. It contains Azelastine Hydrochloride, which is a second generation H₁ receptor-antagonist with potent topical activity, and Fluticasone Propionate, a synthetic corticosteroid with anti-inflammatory properties.

PHARMACOLOGY

Pharmacodynamics:
 Fluticasone Propionate is a synthetic, trifluoromethylated corticosteroid with anti-inflammatory activity. Fluticasone Propionate was 3-fold to 5-fold more potent than dexamethasone in the *in vitro* assays. In pre-clinical studies, Fluticasone Propionate revealed progestosterone-like activity similar to the natural hormone. However, the clinical significance of these findings in relation to the low plasma levels is not known. The precise mechanism through which Fluticasone Propionate affects allergic rhinitis symptoms is not known. Corticosteroids have been shown to have a wide range of effects on leukocytes, and (lymphocytes) involved in inflammation.

Azelastine Hydrochloride, a trihalazone derivative, exhibits histamine H₁ receptor-antagonist activity in isolated tissues, animal models, and humans. The major metabolite, desmethylazelastine, also possesses H₁ receptor-antagonist activity.

Pharmacokinetics

Parameters	Fluticasone Propionate	Azelastine Hydrochloride
Systemic bioavailability	< 2 %	40 %
Onset of action	within 12 hours	within 15 minutes
T _{max}	0.9 ± 0.4 hours*	2 - 3 hours
V _d	4.2 L/kg†	14.5 L/kg*
Plasma protein binding	91 %	88 %
Half-life	7.8 hours*	22 hours*
Excretion	Less than 5 % oral dose excreted in the urine and remainder is excreted in the faeces.	75 % of an oral dose excreted in the faeces, with less than 10 % as unchanged azelastine.

* - oral dose

† - IV

@ - Intranasal 800 mcg tds.

INDICATIONS:

- Management of moderate to severe symptoms of allergic rhinitis in adults.
- Management of moderate to severe symptoms of allergic rhinitis in children 5 years and above.
- Management of symptoms of non-allergic rhinitis in adults and children (5 years and above).

DOSAGE AND ADMINISTRATION:

Dosage

Adults - One spray/nostril twice daily.
 Children (5 years and above) - One spray/nostril twice daily.
 The recommended dosage should not be exceeded.

Administration

Administer nasal spray by the intranasal route only.

Directions for Use

Following are directions for the use of nasal spray.

PARTS OF THE NASAL SPRAY

As shown in figure 1, the bottle with Advanced Pump System has nozzle (tip) for delivery of the spray in nostril and a protective dust cap.



Figure 1



MEDA_APTX03502809

Each Actor and Director

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TECHNICAL CULDEGY:

...and the ...

THE D'ARCY PROBLEM

1997, 1998, 1999, 2000, 2001, 2002, 2003, 2004, 2005, 2006, 2007, 2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018, 2019, 2020, 2021, 2022, 2023, 2024, 2025, 2026, 2027, 2028, 2029, 2030, 2031, 2032, 2033, 2034, 2035, 2036, 2037, 2038, 2039, 2040, 2041, 2042, 2043, 2044, 2045, 2046, 2047, 2048, 2049, 2050, 2051, 2052, 2053, 2054, 2055, 2056, 2057, 2058, 2059, 2060, 2061, 2062, 2063, 2064, 2065, 2066, 2067, 2068, 2069, 2070, 2071, 2072, 2073, 2074, 2075, 2076, 2077, 2078, 2079, 2080, 2081, 2082, 2083, 2084, 2085, 2086, 2087, 2088, 2089, 2090, 2091, 2092, 2093, 2094, 2095, 2096, 2097, 2098, 2099, 2100, 2101, 2102, 2103, 2104, 2105, 2106, 2107, 2108, 2109, 2110, 2111, 2112, 2113, 2114, 2115, 2116, 2117, 2118, 2119, 2120, 2121, 2122, 2123, 2124, 2125, 2126, 2127, 2128, 2129, 2130, 2131, 2132, 2133, 2134, 2135, 2136, 2137, 2138, 2139, 2140, 2141, 2142, 2143, 2144, 2145, 2146, 2147, 2148, 2149, 2150, 2151, 2152, 2153, 2154, 2155, 2156, 2157, 2158, 2159, 2160, 2161, 2162, 2163, 2164, 2165, 2166, 2167, 2168, 2169, 2170, 2171, 2172, 2173, 2174, 2175, 2176, 2177, 2178, 2179, 2180, 2181, 2182, 2183, 2184, 2185, 2186, 2187, 2188, 2189, 2190, 2191, 2192, 2193, 2194, 2195, 2196, 2197, 2198, 2199, 2200, 2201, 2202, 2203, 2204, 2205, 2206, 2207, 2208, 2209, 2210, 2211, 2212, 2213, 2214, 2215, 2216, 2217, 2218, 2219, 2220, 2221, 2222, 2223, 2224, 2225, 2226, 2227, 2228, 2229, 2230, 2231, 2232, 2233, 2234, 2235, 2236, 2237, 2238, 2239, 2240, 2241, 2242, 2243, 2244, 2245, 2246, 2247, 2248, 2249, 2250, 2251, 2252, 2253, 2254, 2255, 2256, 2257, 2258, 2259, 2260, 2261, 2262, 2263, 2264, 2265, 2266, 2267, 2268, 2269, 2270, 2271, 2272, 2273, 2274, 2275, 2276, 2277, 2278, 2279, 2280, 2281, 2282, 2283, 2284, 2285, 2286, 2287, 2288, 2289, 2290, 2291, 2292, 2293, 2294, 2295, 2296, 2297, 2298, 2299, 2300, 2301, 2302, 2303, 2304, 2305, 2306, 2307, 2308, 2309, 2310, 2311, 2312, 2313, 2314, 2315, 2316, 2317, 2318, 2319, 2320, 2321, 2322, 2323, 2324, 2325, 2326, 2327, 2328, 2329, 2330, 2331, 2332, 2333, 2334, 2335, 2336, 2337, 2338, 2339, 2340, 2341, 2342, 2343, 2344, 2345, 2346, 2347, 2348, 2349, 2350, 2351, 2352, 2353, 2354, 2355, 2356, 2357, 2358, 2359, 2360, 2361, 2362, 2363, 2364, 2365, 2366, 2367, 2368, 2369, 2370, 2371, 2372, 2373, 2374, 2375, 2376, 2377, 2378, 2379, 2380, 2381, 2382, 2383, 2384, 2385, 2386, 2387, 2388, 2389, 2390, 2391, 2392, 2393, 2394, 2395, 2396, 2397, 2398, 2399, 2400, 2401, 2402, 2403, 2404, 2405, 2406, 2407, 2408, 2409, 2410, 2411, 2412, 2413, 2414, 2415, 2416, 2417, 2418, 2419, 2420, 2421, 2422, 2423, 2424, 2425, 2426, 2427, 2428, 2429, 2430, 2431, 2432, 2433, 2434, 2435, 2436, 2437, 2438, 2439, 2440, 2441, 2442, 2443, 2444, 2445, 2446, 2447, 2448, 2449, 2450, 2451, 2452, 2453, 2454, 2455, 2456, 2457, 2458, 2459, 2460, 2461, 2462, 2463, 2464, 2465, 2466, 2467, 2468, 2469, 2470, 2471, 2472, 2473, 2474, 2475, 2476, 2477, 2478, 2479, 2480, 2481, 2482, 2483, 2484, 2485, 2486, 2487, 2488, 2489, 2490, 2491, 2492, 2493, 2494, 2495, 2496, 2497, 2498, 2499, 2500, 2501, 2502, 2503, 2504, 2505, 2506, 2507, 2508, 2509, 2510, 2511, 2512, 2513, 2514, 2515, 2516, 2517, 2518, 2519, 2520, 2521, 2522, 2523, 2524, 2525, 2526, 2527, 2528, 2529, 2530, 2531, 2532, 2533, 2534, 2535, 2536, 2537, 2538, 2539, 2540, 2541, 2542, 2543, 2544, 2545, 2546, 2547, 2548, 2549, 2550, 2551, 2552, 2553, 2554, 2555, 2556, 2557, 2558, 2559, 2560, 2561, 2562, 2563, 2564, 2565, 2566, 2567, 2568, 2569, 2570, 2571, 2572, 2573, 2574, 2575, 2576, 2577, 2578, 2579, 2580, 2581, 2582, 2583, 2584, 2585, 2586, 2587, 2588, 2589, 2590, 2591, 2592, 2593, 2594, 2595, 2596, 2597, 2598, 2599, 2600, 2601, 2602, 2603, 2604, 2605, 2606, 2607, 2608, 2609, 2610, 2611, 2612, 2613, 2614, 2615, 2616, 2617, 2618, 2619, 2620, 2621, 2622, 2623, 2624, 2625, 2626, 2627, 2628, 2629, 2630, 2631, 2632, 2633, 2634, 2635, 2636, 2637, 2638, 2639, 2640, 2641, 2642, 2643, 2644, 2645, 2646, 2647, 2648, 2649, 2650, 2651, 2652, 2653, 2654, 2655, 2656, 2657, 2658, 2659, 2660, 2661, 2662, 2663, 2664, 2665, 2666, 2667, 2668, 2669, 2670, 2671, 2672, 2673, 2674, 2675, 2676, 2677, 2678, 26

Azelaic acid hydrazide

Dr. du J. Staud. "J. du J. Staud."

• **Check:**

of the original and the oral administration. The difference between the oral and intravenous administration was not statistically significant.

Unit 22: 0-5
 Entry: 0.100

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[illegible]

including children, the wife

Paperback

1. The first step is to identify the problem or question that needs to be answered. This involves understanding the context and the specific requirements of the task.

1979-1980

INDICATIONS:

1. The first step is to identify the problem or question that needs to be answered. This involves understanding the context and the specific requirements of the task.

2. *Styrene* 100.0000

© 2005 by the American Psychological Association
0893-3200/05/\$12.00 DOI: 10.1037/0893-3200.19.4.575

16611 (Agad 5-12 years)

For more information, contact your local distributor.

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INDICATIONS

WARNINGS:

1-800-368-6868

Individual characteristics can be categorized as follows:

Conclusions

THE UNIVERSITY OF CHICAGO

DRUG INTERACTIONS:

Proprietor: David Smith

Pregnancy

Department of
Psychiatry

FORN AND/OR DRUGS AS A PRESENT

It is not kno-

ADVERSE EFFECTS:

the given way.

CONTRIBUTOR: THE KODAK CO.

bitter taste, which may lead to occasional nausea. This bitter taste usually disappears after sometime.

OVERDOSSAGE:

Azelastine Hydrochloride

The results of animal studies show that toxic doses can produce CNS symptoms, e.g. excitation, tremor, and convulsions. Should these occur in humans, symptomatic and supportive treatment should be provided as there is no specific antidote. Gastric lavage is recommended if the overdose is recent. With the nasal route of administration, overdosage reactions are not anticipated.

Fluticasone Propionate

Use of excessive doses of corticosteroids and/or chronic overdosage may lead to signs or symptoms of hypercorticism and/or suppression of the HPA function.

Storage: Store in a cool place. Protect from light. Keep out of reach of children. Do not freeze. Shake well before each use. For External use only. For Intranasal use only.

Presentation:

EZICAS AZ is available in a pack of 7 ml

Manufactured by: Biodeal Pharmaceuticals Pvt. Ltd.
Village - Sans Majra, Naagarh - Pagar Road,
Nalagarh, Dist. - Solan (H.P.) INDIA - 174 101

Marketed by:

INTAS
INTAS PHARMACEUTICALS LTD.
Matoda-382 210, Dist.: Ahmedabad, INDIA

LLT076

Parts of EZICAS AZ Nasal Spray



Directions for using EZICAS AZ

1. Before each use shake the bottle gently and remove the dust cap.
2. Hold the bottle as shown, by placing your index finger and middle finger on either side of the nozzle with your thumb underneath the base of the bottle.



3. Keep the nozzle pointed away from you.



4. Blow your nose gently.
5. Close the nostril either side and place the nozzle in the other nostril as shown. Tilt your head slightly forward while keeping the nozzle in an upright position.
6. Start breathing in and firmly press down the wings of nozzle with your fingers to release a spray.



7. Exhale to your mouth after nasal inhalation. Repeat steps 6 and 7 to inhale a second spray.

8. Repeat steps 5, 6 and 7 for delivery to the other nostril.



9. After use, wipe the nozzle with a clean cloth and place the protective dust cap back on the nozzle again.



Prescribing Information:
For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.

EZICAS AZ
(AZELASTINE HYDROCHLORIDE AND
FLUTICASONE PROPIONATE NASAL SPRAY)

INTAS

Marketed by:
INTAS PHARMACEUTICALS LTD.
Matoda-382 210, Dist.: Ahmedabad, INDIA

Each Actuation Delivers :

Azelastine
Hydrochloride IP 140 mcg
Fluticasone
Propionate IP 50 mcg

Composition:

Azelastine
Hydrochloride IP 0.14% w/v
Fluticasone
Propionate IP 0.05% w/v
Benzalkonium
Chloride IP 0.01% w/v
(as Preservative)
Phenylethyl
Alcohol IP 0.25% w/v
(as Preservative)
Excipients q.s.

Dose : As directed by the
Physician.

Store in a cool place.

Protect from light.

Keep out of reach of children.

Do not freeze.

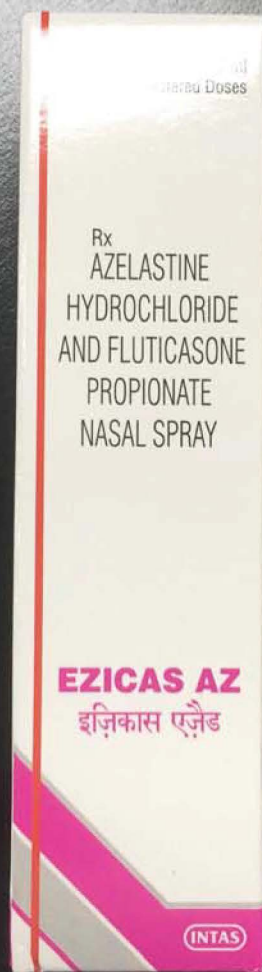
Shake well before each use.

FOR EXTERNAL USE ONLY.

FOR INTRANASAL USE ONLY.

SCHEDULE 'H' DRUG :

Warning : To be sold by



MEDA_APTX03502813

EZICAS AZ

(AZELASTINE HYDROCHLORIDE AND)
FLUTICASON PROPIONATE NASAL SPRAY)

Each Actuation Delivers:	
Azelastine Hydrochloride IP	140 mcg
Fluticasone Propionate IP	50 mcg
Composition:	
Azelastine Hydrochloride IP	0.14% w/v
Fluticasone Propionate IP	0.05% w/v
Benzalkonium Chloride IP (as Preservative)	0.01% w/v
Phenylethyl Alcohol IP (as Preservative)	0.25% w/v
Excipients	q.s.

DESCRIPTION:
EZICAS AZ nasal spray contains two active drugs like azelastine hydrochloride and fluticasone propionate. Azelastine hydrochloride is a second generation H₁ receptor-antagonist with potent topical activity and with anti-inflammatory properties.

PHARMACOLOGY:

Pharmacodynamics

Azelastine hydrochloride
Azelastine hydrochloride, a pivalazinone derivative, exhibits histamine H₁ receptor-antagonist activity in isolated tissues, animal models, and humans. The major metabolite, desmethyl azelastine, also possesses H₁ receptor-antagonist activity. By blocking the actions of histamine at H₁ receptor, it prevents the effects of histamine in allergic rhinitis.

Fluticasone Propionate
The anti-inflammatory effects through which fluticasone propionate acts along rhinitis symptoms is not clear. It is known that allergic rhinitis symptoms have been shown to have a local component. Local effects on multiple cell types (e.g., mast cells, eosinophils, neutrophils, macrophages, and T cells) and mediators (e.g., histamine, leukotrienes, and cytokines) involved in allergic rhinitis.

Pharmacokinetics
Following intranasal administration, the plasma concentration of azelastine hydrochloride is low, with a T_{1/2} of 2-3 hours.

The total blood clearance of fluticasone propionate is high (average, 1,093 ml/min), with renal clearance accounting for less than 0.02% of the total.

Following intravenous dosing, fluticasone propionate showed a terminal elimination half-life of approximately 7.8 hours. Less than 5% of a radiolabeled oral dose was excreted in the urine as parent drug and metabolites.

INDICATIONS:
EZICAS AZ nasal spray is indicated for the management of symptoms of allergic rhinitis, once the need for an antihistamine and corticosteroid has been established. It is recommended for the treatment of moderate to severe persistent symptoms in adults and adolescents above 12 years of age. It can also be used for treating non-allergic rhinitis in adults and adolescents, 12 years of age and older.

Contraindications:
Fluticasone propionate delivered by the intranasal route has an absolute bioavailability averaging less than 2%. Due to the low bioavailability by the intranasal route, the majority of the pharmacokinetic data was obtained via other routes of administration.

Warnings:
Avoid concurrent use of this combination with alcohol or other central nervous system (CNS) depressants or other antihistamines due to additional risk of CNS depression.

The replacement of a systemic corticosteroid with a topical corticosteroid can be accompanied by signs of adrenal insufficiency. Some patients may experience symptoms of withdrawal, e.g., joint and/or muscle pain, lassitude, and depression.

Suppression of the HPA-axis may occur with the use of an intranasal corticosteroid. The concomitant use of an intranasal corticosteroid with other corticosteroids could increase the risk of suppression of the HPA-axis.

During long-term therapy, monitoring of hematological and adrenal functions is advisable.

For children aged 5-12 years, recommended for severe symptoms of allergic rhinitis.

USAGE AND ADMINISTRATION

Adults (Above 12 years of age) and Children (Aged 5-12 years)

The recommended dosage should not be exceeded. One spray per nostril twice daily.

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7 ml
70 Metered Doses

Rx
AZELASTINE
HYDROCHLORIDE
AND FLUTICASON
PROPIONATE
NASAL SPRAY

EZICAS AZ
इज़िकास एज़ेड

INTAS

MEDA_APTX03502814

1899C2

Please read this leaflet carefully
before you start using Azeflo

Azelastine Hydrochloride & Fluticasone Propionate Nasal Spray

Azeflo

Each spray delivers

Azelastine Hydrochloride I.P.	140 mcg
Fluticasone Propionate I.P.	50 mcg

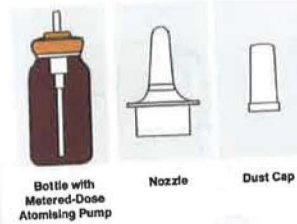
Composition:

Azelastine Hydrochloride I.P.	0.14 % w/v
Fluticasone Propionate I.P.	0.05 % w/v
Benzalkonium Chloride Solution I.P. (As preservative)	0.02 % w/v
Phenyl Ethyl Alcohol I.P. (As preservative)	0.25 % w/v
Excipients	q.s.



LUPIN

Patient Information Leaflet Parts of Azeflo Nasal Spray

Bottle with
Metered-Dose
Atomising Pump

Nozzle

Dust Cap

Important

1. Azeflo is to be used under advice of your doctor. Do not exceed the dose recommended.
2. Since it takes a few days for this medication to work effectively, it is very important that you use it regularly. Do not stop treatment even if you feel better unless otherwise directed by your doctor.
3. Azeflo has been specifically recommended by your doctor for you. Do not allow any other person to use it.
4. Always keep Azeflo out of children's reach.
5. Protect Azeflo from direct light. Store Azeflo in cool, dry place. Use within two months of opening.

Directions for using Azeflo

1. Before each use shake the bottle gently and remove the dust cap
2. Hold the bottle as shown, by placing your forefinger and middle finger on either side of the nozzle with your thumb underneath the base of the bottle



3. If you are using Azeflo for the first time or are using it after a long period, follow the instructions as under:
 - Keep the nozzle pointed away from you.
 - Press several times as shown until a fine mist comes out evenly from the nozzle.



4. Blow your nose gently



5. Close one nostril and place the nozzle in the other nostril as shown. Tilt your head slightly forward while keeping the nozzle in an upright position.

MEDA_APTX03502815

6. Start breathing in and gently press down the wings of nozzle with our fingers to release a spray.



7. Exhale to your mouth after nasal inhalation. Repeat steps 6 & 7 to inhale a second spray.



8. Repeat steps 5,6 and 7 for deliver to the other nostril.



9. After use, wipe the nozzle with a clean cloth & replace the dust cap.



Note

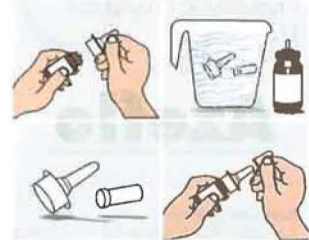
If using Azello for the first time, it may cause you to sneeze for a few times. This is because the lining of your nose is very sensitive. This is not likely to happen after the initial doses.

This medication may cause a few side effects in certain hypersensitive individuals. In case of bleeding from the nose or other discomfort please consult your doctor immediately.

Cleaning

Clean Azello at least once a week

Cleaning procedure:



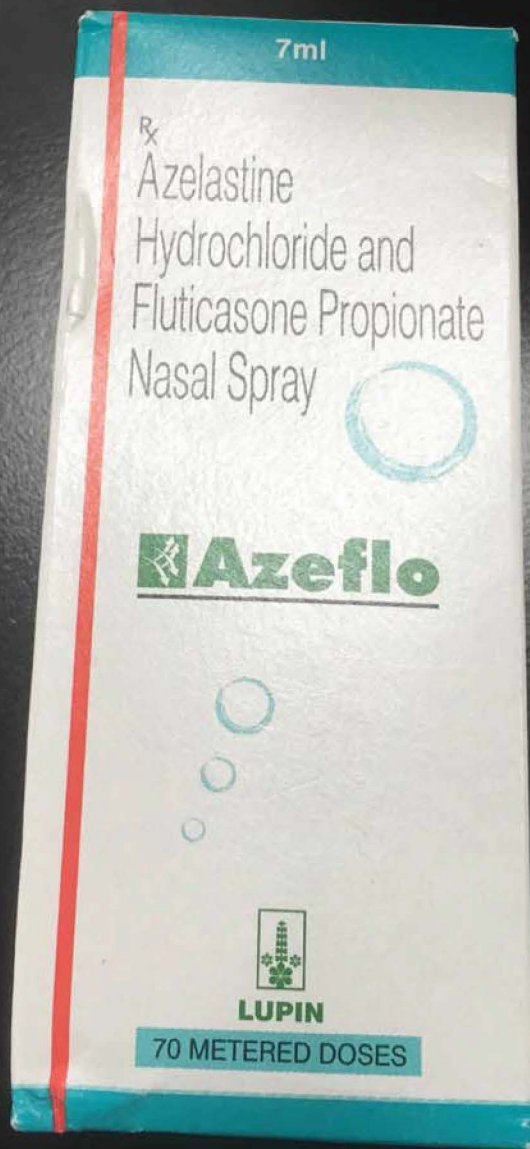
1. Detach the nozzles from the bottle by pushing it up with thumb
2. Clean the nozzle and dust cap in warm water. Shake off excess water allow it to dry in a warm place. Avoid keeping it in places with excessive heat.
3. Re-assemble the nozzle and dust cap for further use.
4. In case the nozzle gets blocked, remove the same way as above and soak in warm water. Rinse under a cold tap, allow it to dry and refit again. Never use a pin or other sharp objects to unblock the nozzle.

Presentation

Azello Nasal Spray pack contains 70 metered doses.

For further information please write to :

LUPIN LTD.
159, C.S.T. Road, Kalina,
Santacruz (E),
Mumbai - 400 096, INDIA.



MEDA_APTX03502817

INTRODUCING IN NEW PACK

Each spray delivers

Azelastine	
Hydrochloride I.P.	140 mcg
Fluticasone	
Propionate I.P.	50 mcg

Composition :

Azelastine	
Hydrochloride I.P.	0.14 % w/v
Fluticasone	
Propionate I.P.	0.05 % w/v
Benzalkonium Chloride	
Solution I.P.	0.02 % w/v
(As Preservative)	
Phenyl Ethyl	
Alcohol I.P.	0.25 % w/v
(As Preservative)	
Excipients	q.s.

Dosage : As directed by the Physician.

SHAKE WELL BEFORE EACH USE

Store below 30°C but do not refrigerate. Protect from light

Keep out of reach of children.

1309002

Please read this patient leaflet
before you start using Azeflo

Azelastine Hydrochloride & Fluticasone Propionate Nasal Spray

Azeflo

Each spray delivers

Azelastine Hydrochloride I.P.	140 mcg
Fluticasone Propionate I.P.	50 mcg
Composition:	
Azelastine Hydrochloride I.P.	0.14 % w/v
Fluticasone Propionate I.P.	0.05 % w/v
Benzalkonium Chloride Solution I.P.	0.02 % w/v
(As preservative)	
Phenyl Ethyl Alcohol I.P.	0.25 % w/v
(As preservative)	
Excipients	q.s.



LUPIN

Patient Information Leaflet Parts of Azeflo Nasal Spray



Bottle with
Metered-Dose
Atomizing Pump

Nozzle

Dust Cap

Important

1. Azeflo is to be used under advice of your doctor. Do not exceed the dose recommended.
2. Since it takes a few days for this medication to work effectively, it is very important that you use it regularly. Do not stop treatment even if you feel better unless otherwise directed by your doctor.
3. Azeflo has been specifically recommended by your doctor for you. Do not allow any other person to use it.
4. Always keep Azeflo out of children's reach.
5. Protect Azeflo from direct light. Store Azeflo in cool, dry place. Use within two months of opening.

Directions for using Azeflo

1. Before each use shake the bottle gently and remove the dust cap.
2. Hold the bottle as shown, by placing your forefinger and middle finger on either side of the nozzle with your thumb underneath the base of the bottle.



3. If you are using Azeflo for the first time or are using it after a long period, follow the instructions as under:
 - Keep the nozzle pointed away from you.
 - Press several times as shown until a fine mist comes out evenly from the nozzle.



4. Blow your nose gently



5. Close one nostril and place the nozzle in the other nostril as shown. Tilt your head slightly forward while keeping the nozzle in an upright position.

MEDA_APTX03502819

6. Start breathing in and gently press down the wings of nozzle with our fingers to release a spray.



7. Exhale to your mouth after nasal inhalation. Repeat steps 6 & 7 to inhale a second spray.



8. Repeat steps 5, 6 and 7 for deliver to the other nostril.



9. After use, wipe the nozzle with a clean cloth & replace the dust cap.



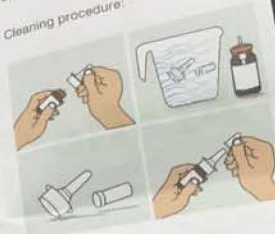
Note

If using Azefio for the first time, it may cause you to sneeze for a few times. This is because the lining of your nose is very sensitive. This is not likely to happen after the initial doses.

This medication may cause a few side effects in certain hypersensitive individuals. In case of bleeding from the nose or other discomfort please consult your doctor immediately.

Cleaning
Clean Azefio at least once a week

Clearing procedure:



1. Detach the nozzles from the bottle by pushing it up with thumb
2. Clean the nozzle and dust cap in warm water. Shake off excess water allow it to dry in a warm place. Avoid keeping it in places with excessive heat.
3. Re-assemble the nozzle and dust cap for further use.
4. In case the nozzle gets blocked, remove the same way as above and soak in warm water. Rinse under a cold tap, allow it to dry and refit again. Never use a pin or other sharp objects to unblock the nozzle.

Presentation
Azefio Nasal Spray pack contains 70 metered doses.

For further information please write to :

LUPIN LTD.
159, C.S.T. Road, Kalina,
Santacruz (E),
Mumbai - 400 098, INDIA.

199902 Please read this leaflet carefully before you start using Azeflo

Azelastine Hydrochloride & Fluticasone Propionate Nasal Spray

Azeflo

Each spray delivers

Azelastine Hydrochloride I.P	140 mcg
Fluticasone Propionate I.P	50 mcg

Composition:

Azelastine Hydrochloride I.P	0.14 % w/v
Fluticasone Propionate I.P	0.05 % w/v
Benzalkonium Chloride Solution I.P	0.02 % w/v
(As preservative)	
Phenyl Ethyl Alcohol I.P	0.25 % w/v
(As preservative)	
Excipients	q.s.


Important

1. Azeflo is to be used under advice of your doctor. Do not exceed the dose recommended.
2. Since it takes a few days for this medication to work effectively, it is very important that you use it regularly. Do not stop treatment even if you feel better unless otherwise directed by your doctor.
3. Azeflo has been specifically recommended by your doctor for you. Do not allow any other person to use it.
4. Always keep Azeflo out of children's reach.
5. Protect Azeflo from direct light. Store Azeflo in cool, dry place. Use within two months of opening.


Directions for using Azeflo

1. Before each use shake the bottle gently and remove the dust cap.
2. Hold the bottle as shown, by placing your forefinger and middle finger on either side of the nozzle with your thumb underneath the base of the bottle.

Parts of Azeflo Nasal Spray




Bottle with Metered-Dose Atomizing Pump Nozzle Dust Cap




3. If you are using Azeflo for the first time or are using it after a long period, follow the instructions as under:

- Keep the nozzle pointed away from you.
- Press several times as shown until a fine mist comes out evenly from the nozzle.

4. Blow your nose gently



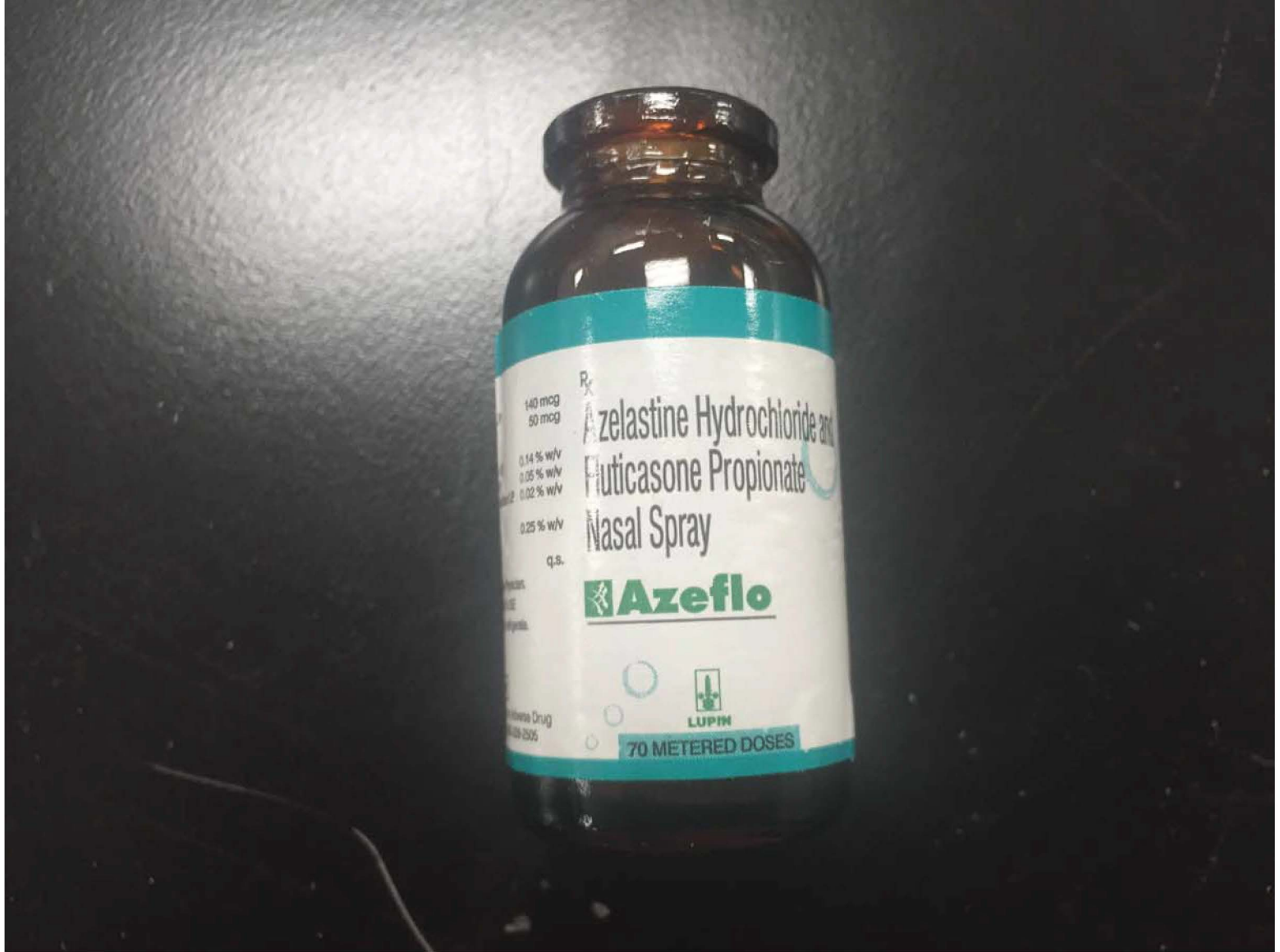
5. Close one nostril and place the nozzle in the other nostril as shown. Tilt your head slightly forward while keeping the nozzle in an upright position.



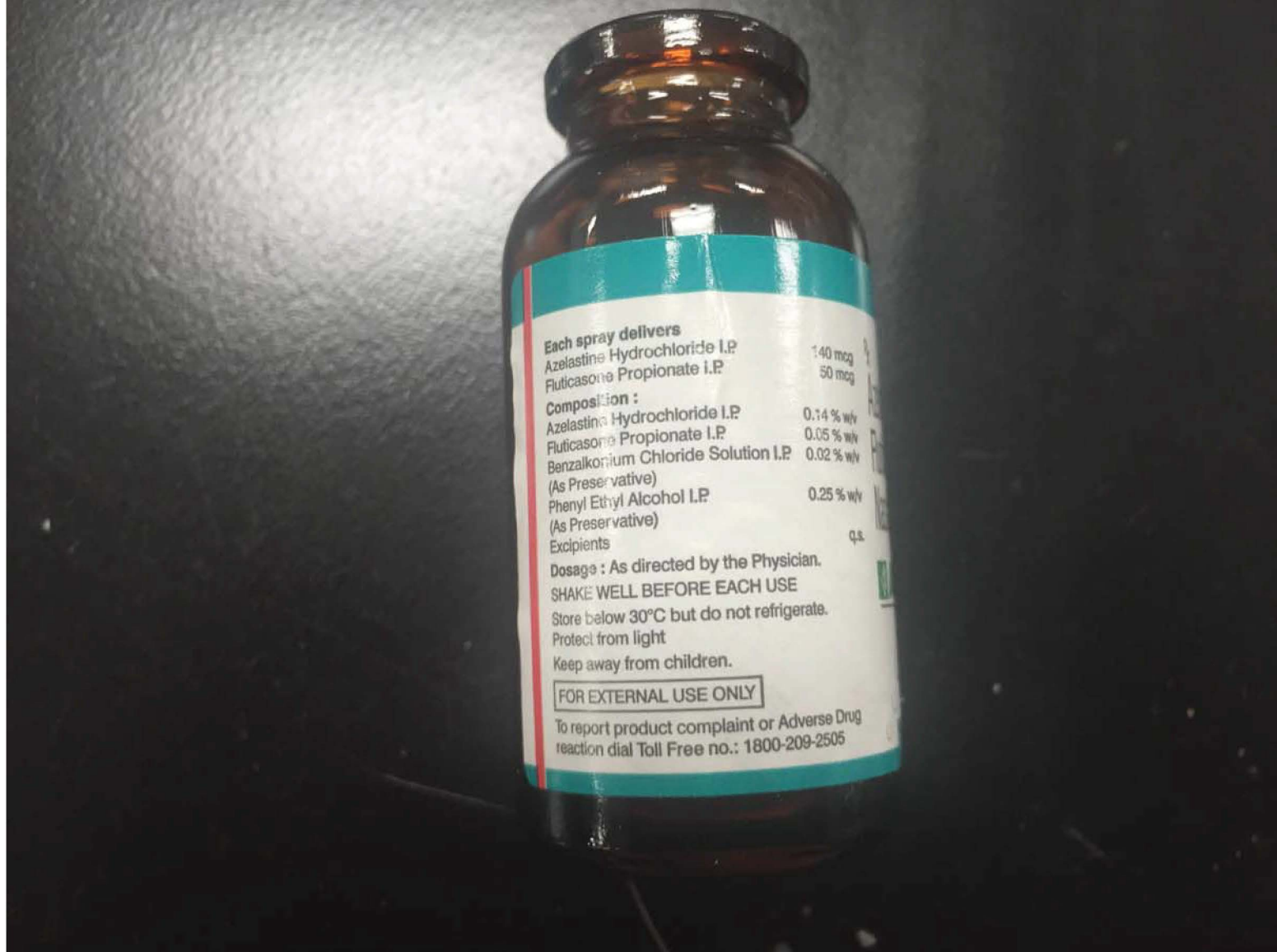
LUPIN



MEDA_APTX03502821



MEDA_APTX03502822



Each spray delivers
Azelastine Hydrochloride I.P. 1.40 mcg
Fluticasone Propionate I.P. 50 mcg

Composition :

Azelastine Hydrochloride I.P.	0.14 % w/v
Fluticasone Propionate I.P.	0.05 % w/v
Benzalkonium Chloride Solution I.P. (As Preservative)	0.02 % w/v
Phenyl Ethyl Alcohol I.P. (As Preservative)	0.25 % w/v
Excipients	q.s.

Dosage : As directed by the Physician.

SHAKE WELL BEFORE EACH USE

Store below 30°C but do not refrigerate.

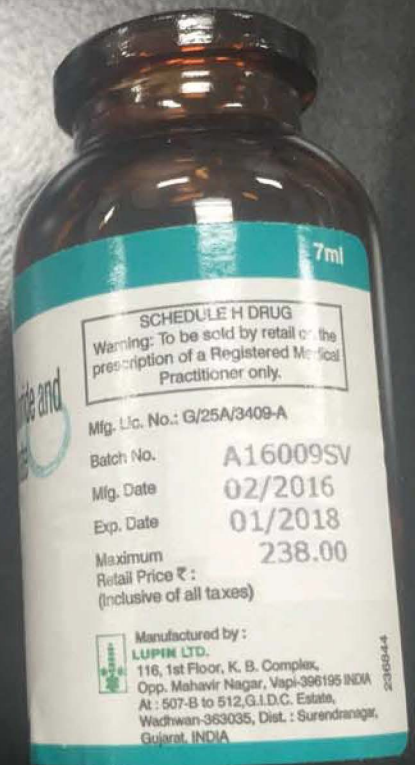
Protect from light

Keep away from children.


FOR EXTERNAL USE ONLY

To report product complaint or Adverse Drug
reaction dial Toll Free no.: 1800-209-2505

MEDA_APTX03502823



MEDA_APTX03502824



Nazomac-AF



Azelastine Hydrochloride &
Fluticasone Propionate Nasal Spray

MACLEOD'S

Patient information leaflet

Nazomac-AF

Azelastine Hydrochloride &
Fluticasone Propionate Nasal Spray

Step 1: Wash the nozzle and the dust cap in lukewarm water.



Step 2: Shake off the excess water and allow nozzle and cap to dry at room temperature before putting it back on the bottom of the nasal spray.



Note: DO NOT USE A PIN OR SHARP OBJECTS TO UNLOCK THE NOZZLE AS THIS MAY DESTROY THE SPRAY MECHANISM.

Step 3: Blow the dust cap off the nozzle and hold the nozzle in the palm of your hand. Blow the dust cap off the nozzle and hold the nozzle in the palm of your hand.




Step 4: Spray the nasal spray into the nostril.




Note: If you are using the nasal spray for the first time, you should spray the nozzle with water before using it.

USAGE INSTRUCTIONS

Step 1: Gently shake the bottle and then remove the protective dust cap.



Step 2: Hold the bottle as shown with your forefinger and middle finger on either side of the nozzle and your thumb at the bottom of the bottle.



CONTRAINDICATIONS
Nasacort Allergy Relief is contraindicated in patients with known hypersensitivity to fluticasone propionate or any of the components of the preparation.

WARNINGS AND PRECAUTIONS
Concurrent use of this combination with alcohol or other central nervous system (CNS) depressants or other anxiolytics should be avoided as additional sedation or impairment of CNS performance may occur due to a synergistic effect.

The replacement of a systemic corticosteroid with a topical corticosteroid can be accompanied by signs of adrenal insufficiency. Some patients may experience symptoms of withdrawal, e.g., pain and/or muscular pain, lassitude, and depression.

The concurrent use of an inhaled corticosteroid with other corticosteroids could increase the risk of signs or symptoms of hypercorticism and/or suppression of the HPA axis. Therefore, such a combination should be used cautiously in patients with other pathological conditions requiring steroids.

Inhaled corticosteroids may cause a reduction in growth velocity when administered at higher dose. The recommended dosage of Nasacort Allergy Relief should not be exceeded.

Special care is needed in patients with lung tuberculosis, and fungal and viral infections. Children who are on immunosuppressant drugs are more susceptible to infections than healthy children. Chicken pox and measles, for example, can have a more serious or even a fatal course in children on immunosuppressant corticosteroids.

no specific antidote available. If these symptoms occur in human symptomatic and supportive treatment should be initiated. Gastric lavage is recommended if the overdose is recent. With the nasal route of administration, overdose reactions are not anticipated.

Fluticasone Propionate
Use of excessive doses of corticosteroids and/or chronic overdosage may lead to signs or symptoms of hypercorticism and/or suppression of the HPA function. Intranasal administration of 2 mg (10 times the recommended dose) of fluticasone propionate, twice daily for 7 days, to healthy human volunteers was well tolerated. Single oral doses of up to 16 mg have been studied in human volunteers with no acute toxic effects reported. Repeat oral doses of up to 80 mg daily for 10 days in volunteers and repeat oral doses of up to 10 mg daily for 14 days in patients were also well tolerated.

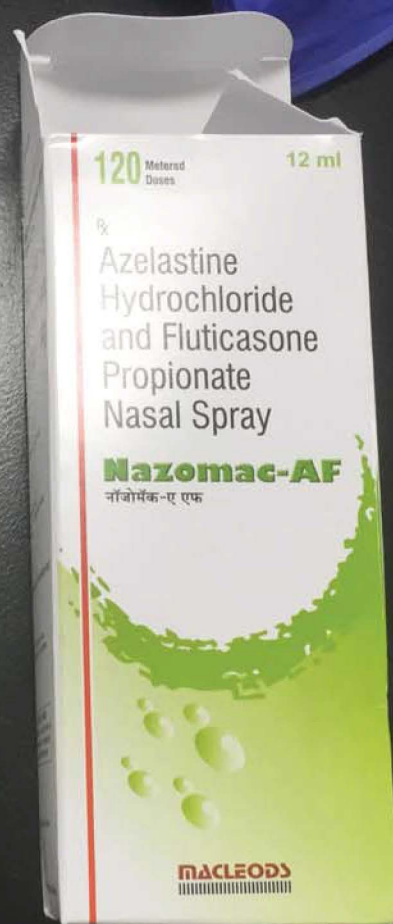
STORAGE
Store in a cool place, protected from light. Do not freeze.

Presentation
A pack contains one Nasal Spray Device.

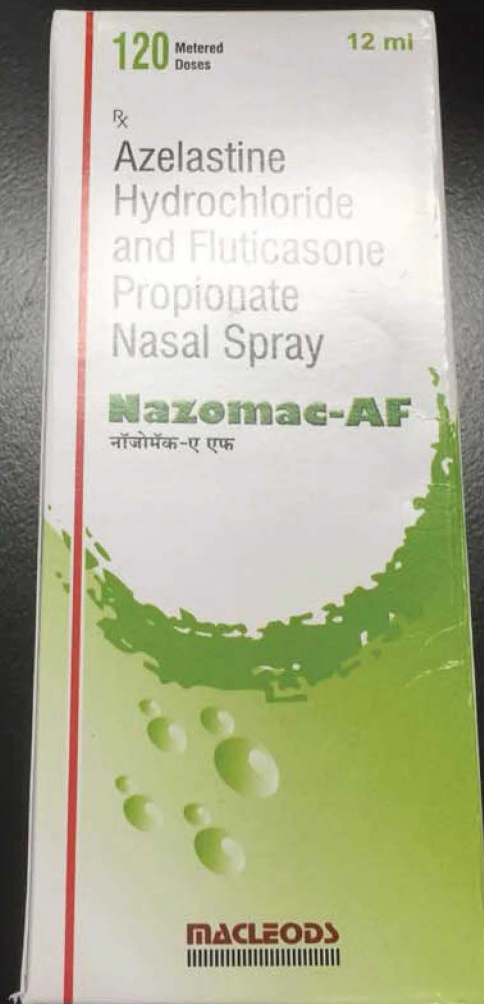
For further information, please write to:

EFCT
PVT. LTD.

MANUFACTURED BY
SAVA HEALTHCARE LIMITED
807-8 to 512, G. I. D. C. Estate,
Pattanam City - 563 035
Dist. Shivamogga
Gulbarga, INDIA
www.savahc.com



MEDA_APTX03502827



MEDA_APTX03502828

Nazomac-AF

नॉजोमॅक-ए एफ

Each Actuation delivers:

Azelastine Hydrochloride IP	140 mcg
Fluticasone Propionate IP	50 mcg

Composition:

Azelastine Hydrochloride IP	0.14% w/v
Fluticasone Propionate IP	0.05%w/v

Preservatives:

Benzalkonium Chloride IP	0.01% w/v
Phenylethyl Alcohol IP	0.25% w/v
Excipients	q.s.

Dosage:

As directed by the physician

Direction for use:

Please refer the enclosed leaflet before use

SHAKE WELL BEFORE EACH USE

Store in a cool and dry place

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