NASONEX® Aqueous Nasal Spray

Mometasone Furoate

COMPOSITION

NASONEX® Aqueous Nasal Spray is a metered-dose, manual pump spray unit containing a white to off-white opaque suspension of mometasone furoate. Each metered-dose pump actuation of NASONEX® Aqueous Nasal Spray delivers approximately 100 mg of mometasone furoate suspension, containing mometasone furoate monohydrate equivalent to 50 micrograms mometasone furoate, dispersable cellulose, glycerol, anhydrous citric acid, sodium citrate dihydrate, polysorbate 80, benzalkonium chloride solution and purified water.

ACTIONS

Mometasone furoate is a topical glucocorticosteroid with local anti-inflammatory properties at doses that are not systemically active.

It is likely that much of the mechanism for the anti-allergic and anti-inflammatory effects of mometasone furoate lies in its ability to inhibit the release of mediators of allergic reactions. Mometasone furoate significantly inhibits the release of leukotrienes from leucocytes of allergic patients. In cell culture, mometasone furoate demonstrated potency in inhibition of synthesis and release of IL-I, IL-5, IL-6 and TNFα. It is also a potent inhibitor of leukotriene production. In addition, it is an inhibitor of the production of the Th 2 cytokines IL-4 and IL-5, from human CD 4 + T-cells. In studies utilizing nasal antigen challenge, NASONEX® Aqueous Nasal Spray has shown anti-inflammatory activity in both the early and late-phase allergic responses. This has been demonstrated by decreases (vs placebo) in histamine and eosinophil activity and reductions (vs baseline) in eosinophils, neutrophils and ephithelial cell adhesion proteins. In patients with seasonal allergic rhinitis, NASONEX® Aqueous Nasal Spray demonstrated a clinically significant onset of action within 12 hours after the first dose.

Pharmacokinetic Properties

Mometasone furoate, administered as an aqueous nasal spray, has a systemic bioavailability of <1% in plasma, using sensitive assay with a lower quantitation limit (LLOQ) of 0.25 pg/ml. Mometasone furoate suspension is very poorly absorbed from the gastrointestinal tract, and the small amount that may be swallowed and absorbed undergoes extensive first-pass hepatic metabolism prior to excretion in urine and bile.

INDICATIONS

NASONEX® Aqueous Nasal Spray is indicated for use in adults, adolescents and children between the age of 2 and 11 years to treat the symptoms of seasonal or perennial rhinitis, especially in moderate to severe persistent allergy.

NASONEX® Aqueous Nasal Spray is also indicated for the treatment of nasal polyps in adult patients 18 years of age and older.

NASONEX® Aqueous Nasal Spray is indicated for the treatment of symptoms associated with mild to moderate uncomplicated acute rhinosinusitis in adults and children 12 years of age and older where signs or symptoms of bacterial infection are not present.

DOSAGE AND ADMINISTRATION

Seasonal allergic or perennial rhinitis:

After initial priming of the NASONEX® Aqueous Nasal Spray (usually 6 or 7 actuations, until a uniform spray is released)-, each actuation delivers approximately 100 mg of mometasone furoate suspension, containing mometasone furoate monohydrate equivalent to 50 μg mometasone furoate. Prior to administration of the first dose, shake container well and actuate pump well before each use. If the product has not been used for 14 days or longer, it should be reprimed before next use.

Adults (including geriatric patients) and children 12 years of age and older-:

The usual recommended dose for prophylaxis and treatment is two sprays (50 μg/spray) in each nostril once daily (total dose 200 μg). Once symptoms are controlled, dose reduction to one spray in each nostril (total dose 100 μg) may be effective for maintenance.

If symptoms are inadequately -controlled, the dose may be increased to a maximum daily dose of four sprays in each nostril once daily (total dose 400 μg). Dose reduction is recommended following control of symptoms.

Children between the ages of 2 through 11 years :
The usual recommended dose is one spray (50 μg/spray) in each nostril once daily (total dose 100 μg).

Administration to young children should be aided by an adult

Nasal polyposis: Adults (including geriatric patients) and adolescents 18 years of age and older: The usual recommended dose for polyposis is two sprays (50 micrograms/spray) in each nostril twice daily (total daily dose of 400 mcg). Once symptoms are adequately controlled, dose reduction to two sprays in each nostril once daily (total daily dose 200 mcg) is recommended.
Efficacy and safety studies of NASONEX® for the treatment of nasal polyps were four months in duration.

Treatment of mild to moderate uncomplicated acute rhinosinusitis: The usual recommended dose for acute rhinosinusitis is two actuations (50 micrograms/actuation) in each nostril twice daily (total daily dose of 400 micrograms). If symptoms worsen during treatment, the patient should be advised to consult their physician.
Patients should not use NASONEX® without an antibiotic if bacterial infection of the sinuses is present or suspected.
If signs or symptoms of severe bacterial infection are observed during treatment (such as fever, persistent severe unilateral facial/tooth pain, orbital or peri-orbital facial swelling, or worsening of symptoms after an initial improvement), the patient should be advised to consult their physician immediately, at which time the physician may advise the patient to stop using NASONEX®.
Safety and efficacy of NASONEX® in the treatment of symptoms associated with mild to moderate uncomplicated acute rhinosinusitis beyond 15 days have not been evaluated.
NASONEX® Aqueous Nasal Spray demonstrates a clinically significant onset of action within 12 hours after the first dose in some patients with seasonal allergic rhinitis; this was also shown in a clinical trial with NASONEX® Aqueous Nasal Spray. However full benefit

of treatment may not be achieved in the first 48 hours. Therefore, the patient should continue regular use to achieve full therapeutic benefit.

The therapeutic effects of corticosteroids, unlike those of decongestants, are not immediate. Since the effect of NASONEX® depends on its regular use, patients should be instructed to take the nasal inhalation at regular intervals and not, as with other nasal sprays, as they feel necessary.

In the presence of excessive nasal mucous secretion or edema of the nasal mucosa, the drug may fail to reach the site of action. In such cases, it is adviseable to use a nasal vasoconstrictor for 2 to 3 days prior to starting treatment with NASONEX®. Patients should be instructed on the correct method of use, which is to blow the nose, then insert the nozzle carefully into the nostril, compress the opposite nostril and actuate the spray while inspiring through the nose, with the mouth closed.

PRECAUTIONS

NASONEX® Aqueous Nasal Spray should not be used in the presence of untreated localized infection involving the nasal mucosa.

Because of the inhibitory effect of corticosteroids on wound healing, patients who have experienced recent nasal surgery or trauma should not use a nasal corticosteroid until healing has occurred.

Following 12 months of treatment with NASONEX® Aqueous Nasal Spray, there was no evidence of atrophy of the nasal mucosa; also, mometasone furoate tended to reverse the nasal mucosa closer to a normal histologic phenotype. As with any long-term treatment, patients using NASONEX® Aqueous Nasal Spray over several months or longer should be examined periodically for possible changes in the nasal mucosa. If localized fungal infection of the nose or pharynx develops, discontinuance of NASONEX® Aqueous Nasal Spray or appropriate treatment may be required. Persistence of nasopharyngeal irritation may be an indication for discontinuing NASONEX® Aqueous Nasal Spray.

NASONEX® Aqueous Nasal Spray should be used with caution, if at all, in patients -with active or quiescent tuberculosis infections of the respiratory tract, or in untreated fungal, bacterial, systemic viral infections or ocular herpes simplex.

There is no evidence of hypothalamic-pituitary-adrenal (HPA) axis suppression following prolonged treatment with NASONEX® Aqueous Nasal Spray. However, patients who are transferred from long-term administration of systemically active corticosteroids to NASONEX® Aqueous Nasal Spray require careful attention. Systemic corticosteroid withdrawal in such patients may result in adrenal insufficiency for a number of months until recovery of HPA axis function. If these patients exhibit signs and symptoms of adrenal insufficiency, systemic corticosteroid administration should be resumed and other modes of therapy and appropriate measure instituted.

During transfer from systemic corticosteroids to NASONEX® Aqueous Nasal Spray, some patients may experience symptoms of withdrawal from systemically active corticosteroids (e.g., joint and-/or muscular pain, lassitude, and depression initially) despite relief from nasal symptoms and will require encouragement to continue NASONEX® Aqueous Nasal Spray therapy. Such transfer may also unmask pre-existing allergic conditions, such as allergic conjunctivitis and eczema, previously suppressed by systemic corticosteroid therapy.

Patients receiving corticosteroids who are potentially immunosuppressed should be warned of the risk of exposure to certain infections (e.g., chickenpox, measles) and of the importance of obtaining medical advice if such exposure occurs.

Following the use of intranasal aerosolized corticosteroids, instances of nasal septum perforation or increased intraocular pressure have been reported very rarely.

Visual disturbance may be reported with systemic and topical (including, intranasal, inhaled and intraocular) corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes of visual disturbances which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

Systemic effects of nasal corticosteroids may occur, particularly at high doses prescribed for prolonged periods. Growth retardation has been reported in children receiving nasal corticosteroids at licensed doses.

It is recommended that the height of children receiving prolonged treatment with nasal corticosteroids is regularly monitored. If growth is slowed, therapy should be reviewed with the aim of reducing the dose of nasal corticosteroid if possible, to the lowest dose at which effective control of symptoms is maintained. In addition, consideration should be given to referring patient to a paediatric specialist.

Treatment with higher than recommended doses may result in clinically significant adrenal suppression. If there is evidence for higher than recommended doses being used, then additional systemic corticosteroid cover should be considered during periods of stress or elective surgery.

If signs or symptoms of severe bacterial infection are observed (such as fever, persistent severe unilateral facial/tooth pain, orbital or peri-orbital facial swelling, or worsening of symptoms after an initial improvement), the patient should be advised to consult their physician immediately.

Safety and efficacy of NASONEX® Aqueous Nasal Spray for the treatment of symptoms of rhinosinusitis in children under 12 years of age have not been studied.

The safety and efficacy of NASONEX® has not been studied for use in the treatment of unilateral polyps, polyps associated with cystic fibrosis, or polyps that completely obstruct the nasal cavities.

Unilateral polyps that are unusual or irregular in appearance, especially if ulcerating or bleeding, should be further evaluated.

Safety and efficacy of NASONEX® Nasal Spray for the treatment of nasal polyposis in children and adolescents under 18 years of age have not been studied.

USAGE DURING PREGNANCY & LACTATION

There are no adequate or well-controlled studies in pregnant women.

As with other nasal corticosteroid preparations NASONEX® Aqueous Nasal Spray should not be used in pregnant women, nursing mothers or women of childbearing age unless the potential benefit justifies the potential risk to the mother, fetus or infant. Infants born of mothers who received corticosteroids during pregnancy should be observed carefully for hypoadrenalism.

OVER DOSAGE :

Because the systemic bioavailability of NASONEX® Aqueous Nasal Spray is <1% (using a sensitive assay with a lower quantitation limit of 0.25 pg/ml), overdose is unlikely to require any therapy other than observation, followed by initiation of the appropriate prescribed dosage.

Inhalation or oral administration of excessive doses of corticosteroids may lead to suppression of HPA axis function.

INTERACTION WITH OTHER MEDICATIONS AND OTHER FORMS OF INTERACTION

Mometasone furoate is metabolized by CYP3A4.

Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin, ritonavir, cobicistat-containing products) may lead to increased plasma concentrations of corticosteroids and potentially increase the risk for systemic corticosteroid side-effects. Consider the benefit of coadministration versus the potential risk of systemic corticosteroid effects, in which case patients should be monitored for systemic corticosteroid side-effects.

ADVERSE EFFECTS

Clinical Trials Experience

Seasonal allergic or perennial rhinitis: Treatment-related local adverse events reported in clinical studies include headache (8%), epistaxis (i.e., frank bleeding, blood-tinged mucus,

and blood fleck) (8%), pharyngitis (4%), nasal burning (2%), nasal irritation (2%) and nasal ulceration (1%), which are typically observed with use of a corticosteroid nasal spray. Epistaxis was generally self-limiting and mild in severity, and occurred at a higher incidence compared to placebo (5%), but at a comparable or lower incidence compared to the active control nasal corticosteroids studied (up to 15%). The incidence of all other effects was comparable with that of placebo.

In the pediatric population, the incidence of adverse effects, e.g., headache (3%), epistaxis (6%), nasal irritation (2%) and sneezing (2%) was comparable to placebo.

Rarely, immediate hypersensitivity reactions (e.g. bronchospasm, dyspnea) may occur after intranasal administration of mometasone furoate monohydrate. Very rarely, anaphylaxis and angioedema have been reported.

Disturbances of taste and smell have been reported very rarely.

Nasal Polyposis: In patients treated for nasal polyposis, the overall incidence of adverse events was comparable to placebo and similar to that observed for patients with allergic rhinitis.

Acute rhinosinusitis: In patients treated for mild to moderate acute rhinosinusitis, the overall incidence of adverse events was comparable to placebo and similar to that observed for patients with allergic rhinitis.

Post-Market Experience

The following additional adverse reactions have been reported in post-marketing use with NASONEX: vision blurred.

CONTRA INDICATIONS

Hypersensitivity to any ingredients of NASONEX® Aqueous Nasal Spray.
Should not be used in the presence of untreated localized infection involving the nasal mucosa.

Because of the inhibitory effect of corticosteroids on wound healing patients who have experienced recent nasal surgery or trauma should not use a nasal corticosteroid until healing has occurred.

If there is any Adverse Event (AE) and Product Quality Complaints (PQC), please inform to PT Organon Pharma Indonesia Tbk, Jakarta.
Telephone : (021) 31107001; Email : dpoc.indonesia@organon.com

PRESENTATIONS

Bottle of 60 mettered dose units : Reg. No. DKI0087100256A1
Bottle of 140 mettered dose units ; Reg.No. DKI0087100256A1

Store below 30°C. Do not freeze

HARUS DENGAN RESEP DOKTER

Manufactured by :
Organon Heist bv, Belgium
Registered by :
PT Organon Pharma Indonesia Tbk.,
Pasuruan, Jawa Timur

Ref:

LRN 032088-NSX-NS-PIPB.5
LRN 032088-NSX-NS-CCDS.3
Update Instructions For Use: Do Not Pierce and Cleansing Advisory
PI June 2011
S-CCDS-MK0887-NS-052017
S-CCDS-MK0887-NS-082017

INSTRUCTIONS FOR USE

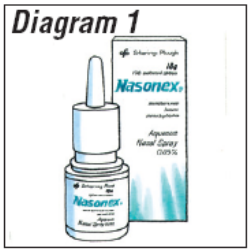
Proper administration of NASONEX is essential to achieve maximum efficacy and minimize the risk of complications. Caution: Do not pierce the nasal applicator (spray pump) with sharp device.

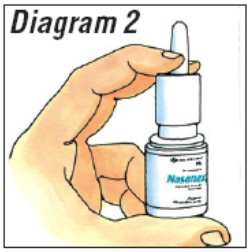
Nasonex Aqueous nasal spray is contained of the teal-blue plastic dust cap, spray pump and bottle (diagram 1)

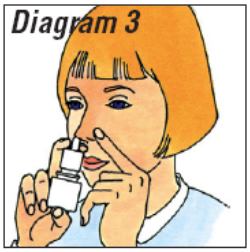
Please read the instructions below carefully and use as recommended.

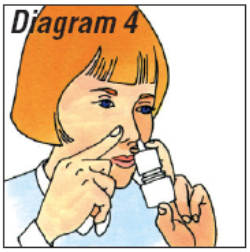
1. Remove the teal-blue plastic dust cap.
2. The very first time the spray is used or it is not used for 14 days or longer, it is necessary to prime the pump before use.

   Instruction: Prime the pump by pressing downwards on the white collar, using your forefinger and middle finger while supporting the base of the bottle with your thumb (diagram 2). Point nozzle away from you, shake container slowly and then press down and release the pump 6 – 7 times or until a fine spray appears.
3. Gently blow your nose to clear the nostrils.
4. Close one nostril, and carefully insert the nasal applicator into the other nostril. Tilt your head forward slightly, keeping the bottle upright. (diagram 3)
5. Start to breathe inward through the nostril and press firmly downward once on the shoulders of the white applicator.
6. Take out the spray from the nostril, then breathe out through the mouth.
7. Repeat steps 3 to 6 in other nostril. (diagram 4)
8. If you need two sprays for each nostril, spray both in one before moving to the other nostril.
9. After use, clean the spray pump and replace the plastic dust cap.









Cleaning your nasal spray

It is important to clean your nasal spray regularly, otherwise it may not work properly. Remove the dust cap and gently pull off the nozzle. Wash the nozzle and dust cap in warm water and then rinse under a running tap. **Do not try to unblock the nasal applicator by inserting a pin or other sharp object as this will damage the applicator and cause you not to get the right dose of medicine**. Allow to dry in a warm place. Push the nozzle back onto the bottle and replace the dust cap. The spray will need to be re-primed with 2 sprays when first used after cleaning.

ORGANON

Informasi Untuk Pasien
Tentang NASONEX® Semprot Hidung

Harap baca leaflet ini dengan seksama sebelum anda mulai minum obat ini, walau anda telah menggunakan obat ini sebelumnya. Beberapa informasi dalam leaflet sebelumnya dapat berubah. Leaflet ini merupakan ringkasan informasi untuk pasien. Dokter atau apoteker Anda dapat memberikan informasi tambahan. Leaflet ini tidak menggantikan pembicaraan dengan dokter Anda tentang kondisi medis atau perawatan Anda.

Ingatlah bahwa dokter anda meresepkan obat ini hanya untuk anda. Jangan berikan kepada orang lain.

NASONEX® semprot hidung merupakan unit dosis terukur dengan pompa semprot manual yang mengandung suspensi dari mometasone furoate yang berwarna putih hingga putih buram.

Apa yang terkandung dalam NASONEX® semprot hidung ?

Setiap unit dosis terukur NASONEX® semprot hidung mengantarkan sekitar 100 mg suspensi mometasone furoate, mengandung mometasone furoate monohidrat setara dengan 50 micrograms mometasone furoate, dispersable cellulose, anhydrous citric acid, sodium citrate, polysorbate 80, benzalkonium chloride solution dan purified water.

Untuk apa NASONEX® semprot hidung digunakan?

NASONEX® semprot hidung ditujukan untuk penggunaan pada orang dewasa, remaja dan anak usia antara 2 dan 11 tahun untuk mengobati gejala rhinitis musiman atau *perennial*, terutama pada alergi persisten sedang hingga berat.

NASONEX® semprot hidung juga dapat digunakan untuk mengobati polip hidung pada pasien dewasa usia 18 tahun atau lebih.

NASONEX® semprot hidung dapat digunakan untuk mengobati gejala yang terkait rhinosinusitis akut ringan hingga sedang tanpa komplikasi pada orang dewasa dan anak usia 12 tahun atau lebih tanpa ada tanda atau gejala infeksi bakteri.

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Berapa banyak dan seberapa sering NASONEX® semprot hidung ini boleh digunakan?

- Alergi Musiman atau rinitis perennial:
  - **Penggunaan pada dewasa dan anak usia 12 tahun atau lebih**
  - Dosis rekomendasi untuk penecegahan atau pengobatan adalah dua semprot pada setiap lubang hidung, sehari sekali.
  - Saat gejala telah terkontrol, dokter mungkin akan menyarankan untuk menurunkan dosis.
  - Jika Anda tidak mulai merasa lebih baik, Anda harus menemui dokter Anda dan dokter Anda mungkin meminta Anda untuk meingkatkan dosis, Dosis harian maksimum adalah empat semprot pada setiap lubang hidung, sehari sekali.

  - **Penggunaan pada anak usia 2 sampai 11 tahun:**
    Dosis rekomendasi adalah satu semprot pada setiap lubang hidung, sehari sekali.
    Penggunaan pada anak-anak harus diawasi oleh orang dewasa.

- Polip Hidung
  - **Penggunaan pada orang dewasa (termasuk lanjut usia) dan remaja usia 18 tahun atau lebih:**
    - Dosis rekomendasi adalah dua semprot pada setiap lubang hidung, dua kali sehari.
    - Saat gejala dapat terkontrol dengan baik, direkomendasikan untuk menurunkan dosis penggunaan menjadi dua semprot untuk setiap hidung, sehari sekali.

- Rinosinusitis akut ringan hingga sedang
  - Dosis rekomendasi adalah dua semprot pada setiap lubang hidung dua kali sehari.
  - Beritahukan kepada dokter Anda apabila gejala memburuk selama pengobatan. Bila anda mengalami gejala seperti demam, nyeri pada bagian wajah dan gigi, wajah bengkak perburukan gejala setelah sebelumnya mengalami perbaikan, segera beritahukan kepada dokter Anda

Bagaimana cara menggunakan NASONEX® ?

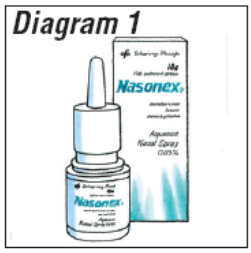
Pemberian NASONEX yang tepat sangat penting untuk mencapai khasiat yang maksimum dan meminimalkan risiko komplikasi. Perhatian: Jangan menusuk aplikator hidung (pompa semprot) dengan alat tajam.

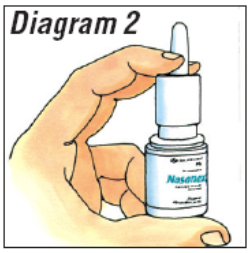
Harap baca petunjuk di bawah ini dengan seksama dan gunakan sesuai anjuran.

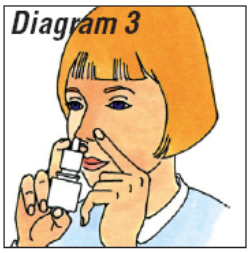
1. Lepaskan tutup plastik berwarna kebiruan.
2. Saat pertama kali semprotan digunakan, atau tidak digunakan selama 14 hari atau lebih, perlu untuk mencoba menyemprotkan pompa sebelum digunakan.

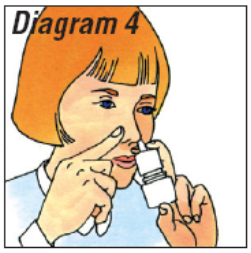
Cara penggunaan: Coba semprotan pompa dengan menekan kebawah pada bagian leher botol, menggunakan jari telunjuk dan jari tengah dan dengan menopang pangkal botol dengan ibu jari Anda (diagram 2). Arahkan nosel menjauh dari Anda, kocok wadah perlahan lalu tekan ke bawah dan semprotkan 6 – 7 kali atau sampai semprotan halus muncul.

3. Tiup hidung Anda dengan lembut untuk membersihkan lubang hidung.
4. Tutup satu lubang hidung, dan masukkan aplikator dengan hati-hati ke lubang hidung lainnya. Miringkan kepala Anda sedikit ke depan, jaga agar botol tetap tegak. (diagram 3)
5. Tarik napas melalui lubang hidung dan tekan sekali pada bagian leher aplikator putih ke bawah dengan kuat
6. Keluarkan aplikator dari lubang hidung, buang napas melalui mulut.
7. Ulangi Langkah 3 sampai 6 pada lubang hidung yang lain. (diagram 4)
8. Jika Anda perlu 2 semprot untuk setiap lubang hidung, semprotkan dua kali sebelum pindah ke lubang hidung yang lain.
9. Setelah penggunaan, bersihkan lubang semprot dan pasang Kembali tutup plastic.









Bagaimana cara membersihkan semprot hidung Anda?

Penting untuk membersihkan semprotan hidung Anda secara teratur, jika tidak maka mungkin tidak berfungsi dengan baik. Lepaskan penutup dan tarik nosel perlahan. Cuci nosel dan tutup dengan air hangat lalu bilas dibawah keran yang mengalir. **Jangan mencoba menghilangkan sumbatan pada aplikator dengan memasukkan pin atau benda tajam lainnya karena ini akan merusak aplikator dan menyebabkan Anda tidak mendapatkan dosis obat yang tepat**. Biarkan kering di tempat yang hangat. Pasang kembali nosel ke botol dan pasang kembali tutup. Semprotan perlu disiapkan kembali dengan 2 semprotan saat pertama kali digunakan setelah dibersihkan.

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Apa yang harus dilakukan bila lupa menggunakan NASONEX® semprot hidung?

Apabila Anda lupa menggunakan semprot hidung pada waktu yang tepat, gunakan segera setelah Anda ingat, kemudian lanjutkan penggunaan seperti sebelumnya.
Jangan menggunakan dengan dosis ganda untuk menggantikan dosis yang terlupakan.

Apa yang harus saya ketahui sebelum dan ketika menggunakan NASONEX® semprot hidung ?

- Beritahukan kepada dokter atau apoteker sebelum menggunakan Nasonex :
  - Jika sedang atau pernah menderita tuberculosis
  - Jika anda menderita infeksi lain
    Jika anda mengonsumsi obat kortikosteroid lainnya baik dalam bentuk peroral ataupun melalui injeksi
- Selama penggunaan Nasonex, Beritahukan pada dokter Anda :
  - Jika sistem imun Anda tidak bekerja dengan baik (kesulitan dalammelawan infeksi) dan anda melakukan kontak dengan penderita campak ataupun cacar air. Anda harus menghindari kontak dengan siapapun yang menderita infeksi ini
  - Jika anda mengalami penglihatan kabur atau gangguan penglihatan lainnya
  - Jika terdapat tanda-tanda atau gejala infeksi bakteri berat (seperti demam, nyeri wajah / gigi unilateral berat yang persisten, pembengkakan wajah orbital atau peri-orbital, atau memburuknya gejala setelah perbaikan awal).
  - Selama perubahan dari kortikosteroid sistemik ke NASONEX semprot hidung, anda mungkin akan mengalami gejala penghentian kortikosteroid sistemik aktif (seperti: nyeri pada sendi dan/atau otot, kelelahan dan depresi awal). Perubahan ini juga dapat menimbulkan kondisi alergi yang sudah ada sebelumnya, seperti konjungtivitis alergi (radang pada mata) dan eksim, yang sebelumnya ditekan oleh terapi kortikosteroid sistemik.

Pada keadaan apa Anda tidak diperbolehkan menggunakan NASONEX® semprot hidung ?

- Jika anda hipersensitif (alergi) terhadap bahan yang terkandung dalam NASONEX semprot hidung
- Jika anda menderita infeksi yang belum terobati pada mukosa hidung
  Jika anda baru menjalani operasi hidung atau mengalami trauma pada hidung. Anda tidak dapat menggunakan semprot hidung hingga benar- benar pulih

Apa yang perlu diperhatikan bila menggunakan NASONEX® semprot hidung ini?

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Penggunaan wanita Hamil dan Menyusui

- Tidak ada studi yang memadai atau terkontrol dengan baik pada wanita hamil. NASONEX semprot hidung tidak direkomendasikan untuk digunakan pada wanita hamil, menyusui atau sedang merencanakan untuk hamil. Informasikan
- kepada dokter atau apoteker anda sebelum anda menggunakan obat iniBayi yang lahir dari ibu yang menerima kortikosteroid selama kehamilan harus diamati dengan hati-hati untuk hipoadrenalisme.

Penggunaan pada anak-anak

- Ketika digunakan pada dosis tinggi untuk jangka waktu yang lama, semprotan hidung kortikosteroid dapat menyebabkan efek samping tertentu, seperti memperlambat laju pertumbuhan pada anak-anak.
- Dianjurkan untuk memantau secara teratur ketinggian anak-anak yang menerima pengobatan jangka panjang dengan kortikosteroid hidung. Hubungi dokter spesialis anak apabila terdapat perubahan yang tercatat.

Obat dan makanan apa yang harus dihindari jika menggunakan NASONEX® semprot hidung ini?

Penggunaan bersama obat-obat penghambat kuat CYP3A4 (seperti: ketoconazole, itraconazole, clarithromycin, ritonavir, produk yang mengandung cobicistat) dapat meningkatkan konsentrasi plasma kortikosteroid dan berpotensi untuk meningkatkan risiko efek samping kortikosteroid sistemik.

Apakah boleh mengendarai dan menjalankan mesin selama minum Obat ini?

Tidak ada informasi yang diketahui tentang efek Nasonex pada kemampuan mengemudi atau menggunakan mesin.

Apa efek yang tidak diinginkan yang mungkin dimiliki NASONEX® semprot hidung ?

Efek samping yang mungkin muncul dari penggunaan NASONEX semprot hidung meliputi :

- Sakit kepala
- Perdarahan pada hidung
- Faringitis (radang tenggorokan)
- Hidung terbakar, iritasi hidung dan luka pada hidung
- Bersin
- Sesak nafas
- Reaksi alergi parah , yang ditunjukkan dengan ruam pada kulit, sesak nafas, pembengkakan di kelopak mata, bibir, lidah dan tenggorokan, penurunan tekanan darah secara drastis yang menyebabkan lemas, pusing, meningkatnya denyut jantung. Segera hubungi Dokter untuk mendapatkan pertolongan medis.

- Angioedema (pembengkakan di bawah kulit)
- Gangguan penciuman dan perasa
- Gangguan penglihatan
- Apabila anda mengalami efek samping, hubungi dokter atau apoteker Anda, termasuk efek samping yang tidak terdaftar dalam informasi produk ini.

Apa yang harus dilakukan bila menggunakan Obat ini melebihi dosis yang dianjurkan?

Hubungi dokter apabila anda mengonsumsi obat ini melebihi dosis yang dianjurkan.

Bagaimana saya bisa mempelajari lebih lanjut tentang NASONEX® semprot hidung dan kondisi saya?

Anda dapat memperoleh informasi lebih lanjut dari dokter atau apoteker Anda

Berapa lama saya harus menyimpan obat saya?

Jangan gunakan obat ini setelah tanggal yang ditunjukkan setelah tanggal kadaluarsa pada kemasan.

Bagaimana saya harus menyimpan NASONEX® semprot hidung ?

Simpan di bawah 30º C. Jangan dibekukan.

Apabila ada keluhan efek samping dan keluhan kualitas produk, silakan hubungi PT Organon Pharma Indonesia Tbk, Jakarta. Telepon : (021) 31107001; Email : dpoc.indonesia@organon.com

HARUS DENGAN RESEP DOKTER

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