FLIXOTIDE INHALER
Fluticasone propionate

QUALITATIVE AND QUANTITATIVE COMPOSITION
Fluticasone propionate 50 micrograms.

FLIXOTIDE 50 Inhaler is pressurised metered-dose inhaler, which delivers 50 micrograms of fluticasone propionate per actuation into the mouthpiece of a specially designed actuator.

Each canister of *FLIXOTIDE* 50 Inhaler supplies 120 actuations.

CLINICAL INFORMATION
Indications
ASTHMA
FLIXOTIDE has a marked anti-inflammatory effect in the lungs.

It reduces symptoms of asthma in patients previously treated with bronchodilator alone or with other prophylactic therapy.

Severe asthma requires regular medical assessment as death may occur. Patients with severe asthma have constant symptoms and frequent exacerbations, with limited physical capacity, and PEF values below 60% predicted at baseline with greater than 30% variability, usually not returning entirely to normal after a bronchodilator. These patients will require high dose inhaled (*see Dosage and Administration*) or oral corticosteroid therapy. Sudden worsening of symptoms may require increased corticosteroid dosage which should be administered under urgent medical supervision.

- **Adults**

Prophylactic management in:
- Mild asthma (PEF values greater than 80% predicted at baseline with less than 20% variability): Patients requiring intermittent symptomatic bronchodilator asthma medication on more than an occasional basis.
- Moderate asthma (PEF values 60-80% predicted at baseline with 20-30% variability): Patients requiring regular asthma medication and patients with unstable or worsening asthma on currently available prophylactic therapy or bronchodilator alone.
- Severe asthma (PEF values less than 60% predicted at baseline with greater than 30% variability): Patients with severe chronic asthma. On introduction of inhaled *FLIXOTIDE* many patients who are dependent on systemic corticosteroids for adequate control of symptoms may be able to reduce significantly or to eliminate their requirement for oral corticosteroids.

- **Children**

Any child who requires to control asthma symptoms, including patients not controlled on currently available prophylactic medication.

Dosage and Administration
Pharmaceutical form: Pressurised metered-dose aerosol.

Patients should be made aware of the prophylactic nature of therapy with inhaled *FLIXOTIDE* and that it should be taken regularly even when they are asymptomatic.

FLIXOTIDE is for inhalation by oral inhalation only.

It is intended that each prescribed dose is given by a minimum of two inhalations.

In patients who find coordination of a pressurised metered dose inhaler difficult a spacer may be used with *FLIXOTIDE* Inhaler.

ASTHMA
The onset of therapeutic effect is four to seven days, although some benefit may be apparent as soon as 24 hours for patients who have not previously received inhaled steroids.

If patients find that relief with short-acting bronchodilator treatment becomes less effective or they need more inhalations than usual, medical attention must be sought.

- **Adults and children over 16 years of age**

100 to 1,000 micrograms twice daily.

Patients should be given a starting dose of inhaled *FLIXOTIDE* which is appropriate for the severity of their disease:

Mild asthma:	100 to 250 micrograms twice daily.
Moderate asthma:	250 to 500 micrograms twice daily.
Severe asthma:	500 to 1,000 micrograms twice daily.

The dose may then be adjusted until control is achieved or reduced to the minimum effective dose, according to the individual response.

Alternatively, the starting dose of fluticasone propionate may be gauged at half the total daily dose of beclomethasone dipropionate or equivalent as administered by metered-dose inhaler.

- **Children 4 years of age and over**

Many children's asthma will be well controlled using the 50 to 100 micrograms twice daily dosing regime.

Children should be given a starting dose of inhaled *FLIXOTIDE* which is appropriate for the severity of their disease.

The dose may then be adjusted until control is achieved or reduced to the minimum effective dose according to individual response.

- **Children aged 1 to 4 years**

Inhaled *FLIXOTIDE* is of benefit to younger children in the control of frequent and persistent asthma symptoms.

Clinical trials in 1 to 4 years old children have shown that the optimal control of asthma symptoms is achieved with 100 micrograms twice daily, administered via a paediatric spacer device with a face mask (such as the *BABYHALER*).

The diagnosis and treatment of asthma should be kept under regular review.

- **Special patient groups**

There is no need to adjust the dose in elderly patients or in those with hepatic or renal impairment.

Contraindications

Hypersensitivity to any ingredient of the preparation *(see Pharmaceutical Particulars – List of Excipients)*.

Warnings and Precautions

Increasing use of short-acting inhaled $beta_2$-agonists to control asthma symptoms indicates deterioration of asthma control. Under these conditions, the patient's therapy plan should be reassessed.

Sudden and progressive deterioration in asthma control is potentially life-threatening and consideration should be given to increasing corticosteroid dosage. In patients considered at risk, daily peak flow monitoring may be instituted.

There was an increased reporting of pneumonia in studies of patients with COPD receiving *FLIXOTIDE* 500 micrograms (*see Adverse Reactions*). Physicians should remain vigilant for the possible development of pneumonia in patients with COPD as the clinical features of pneumonia and exacerbation frequently overlap.

Systemic effects may occur with any inhaled corticosteroid, particularly at high doses prescribed for long periods; these effects are much less likely to occur than with oral corticosteroids (*see Overdose*). Possible systemic effects include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density,

cataract, glaucoma, and central serous chorioretinopathy. It is important, therefore, that the dose of inhaled corticosteroid is titrated to the lowest dose at which effective control is maintained (*see Adverse Reactions*).

It is recommended that the height of children receiving prolonged treatment with inhaled corticosteroid is regularly monitored.

Because of the possibility of impaired adrenal response, patients transferring from oral steroid therapy to inhaled *FLIXOTIDE* therapy should be treated with special care, and adrenocortical function regularly monitored.

Following introduction of inhaled *FLIXOTIDE*, withdrawal of systemic therapy should be gradual and patients encouraged to carry a steroid warning card indicating the possible need for additional therapy in times of stress.

The possibility of impaired adrenal response should always be considered in emergency situations (including surgery), and also in elective situations likely to produce stress, especially in patients taking high doses for an extended duration of time. Additional corticosteroid treatment appropriate to a given clinical situation must be considered (*see Overdose*).

Similarly, replacement of systemic steroid treatment with inhaled therapy may unmask allergies such as allergic rhinitis or eczema previously controlled by the systemic drug.

Treatment with *FLIXOTIDE* should not be stopped abruptly.

There have been very rare reports of increases in blood glucose levels (*see Adverse Reactions*) and this should be considered when prescribing to patients with a history of diabetes mellitus.

As with all inhaled corticosteroids, special care is necessary in patients with active or quiescent pulmonary tuberculosis.

During post-marketing use, there have been reports of clinically significant drug interactions in patients receiving fluticasone propionate and ritonavir, resulting in systemic corticosteroid effects including Cushing's syndrome and adrenal suppression. Therefore, concomitant use of fluticasone propionate and ritonavir should be avoided, unless the potential benefit to the patient outweighs the risk of systemic corticosteroid side effects *(see Interactions)*.

As with other inhalation therapy, paradoxical bronchospasm may occur with an immediate increase in wheezing after dosing. This should be treated immediately with a fast-acting inhaled bronchodilator. *FLIXOTIDE* Inhaler should be discontinued immediately, the patient assessed, and alternative therapy instituted if necessary (*see Adverse Reactions*).

Patients' inhaler technique should be checked to make sure that inhaler actuation is synchronised with inspiration to ensure optimum delivery of the drug to the lungs.

Interactions
Under normal circumstances, low plasma concentrations of fluticasone propionate are achieved after inhaled dosing, due to extensive first pass metabolism and high systemic clearance mediated by cytochrome P450 3A4 in the gut and liver. Hence, clinically significant drug interactions mediated by fluticasone propionate are unlikely.

A drug interaction study in healthy subjects has shown that ritonavir (a highly potent cytochrome P450 3A4 inhibitor) can greatly increase fluticasone propionate plasma concentrations, resulting in markedly reduced serum cortisol concentrations. During post-marketing use, there have been reports of clinically significant drug interactions in patients receiving intranasal or inhaled fluticasone propionate and ritonavir, resulting in systemic corticosteroid effects including Cushing's syndrome and adrenal suppression. Therefore, concomitant use of fluticasone propionate and ritonavir should be avoided, unless the potential benefit to the patient outweighs the risk of systemic corticosteroid side effects.

Studies have shown that other inhibitors of cytochrome P450 3A4 produce negligible (erythromycin) and minor (ketoconazole) increases in systemic exposure to fluticasone propionate without notable reductions in serum cortisol concentrations. Nevertheless, care is advised when

co-administering potent cytochrome P450 3A4 inhibitors (e.g. ketoconazole) as there is potential for increased systemic exposure to fluticasone propionate.

Pregnancy and Lactation
Fertility
There are no data on human fertility. Animal studies indicate no effects of fluticasone propionate on male or female fertility.

Pregnancy
There are limited data in pregnant women. Administration of *FLIXOTIDE* during pregnancy should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus.

Results from a retrospective epidemiological study did not find an increased risk of major congenital malformations (MCMs) following exposure to fluticasone propionate when compared to other inhaled corticosteroids, during the first trimester of pregnancy (*see Clinical Studies)*.

Reproductive studies in animals have shown only those effects characteristic of glucocorticosteroids at systemic exposures in excess of those seen at the recommended inhaled therapeutic dose.

Lactation
The excretion of fluticasone propionate into human breast milk has not been investigated. When measurable plasma levels were obtained in lactating laboratory rats following subcutaneous administration there was evidence of fluticasone propionate in the breast milk. However, plasma levels in patients following inhaled application of fluticasone propionate at recommended doses are likely to be low.

Administration during lactation should only be considered if the expected benefit to the mother is greater than any possible risk to the child.

Effects on Ability to Drive and Use Machines
FLIXOTIDE is unlikely to produce an effect.

Adverse Reactions
Adverse events are listed below by system organ class and frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100 and <1/10), uncommon (≥1/1,000 and <1/100), rare (≥1/10,000 and <1/1,000) and very rare (<1/10,000) including isolated reports. Very common, common and uncommon events were generally determined from clinical trial data. Rare and very rare events were generally determined from spontaneous data.

Infections and infestations
Very common: Candidiasis of mouth and throat.
Candidiasis of the mouth and throat (thrush) occurs in some patients. Such patients may find it helpful to rinse out their mouth with water after using their medication. Symptomatic candidiasis can be treated with topical antifungal therapy whilst still continuing with *FLIXOTIDE*.
Common: Pneumonia (in COPD patients).
Rare: Oesophageal candidiasis.

Immune system disorders
Hypersensitivity reactions with the following manifestations have been reported:
Uncommon: Cutaneous hypersensitivity reactions.
Very rare: Angioedema (mainly facial and oropharyngeal oedema), respiratory symptoms (dyspnoea and/or bronchospasm) and anaphylactic reactions.

Endocrine disorders
Possible systemic effects include (*see Warnings and Precautions*):
Very rare: Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation, decreased bone mineral density, cataract, glaucoma.

Metabolism and nutrition disorders
Very rare: Hyperglycaemia.

Psychiatric disorders
Very rare: Anxiety, sleep disorders and behavioural changes, including hyperactivity and irritability (predominantly in children).

Respiratory, thoracic and mediastinal disorders
Common: Hoarseness.
In some patients inhaled *FLIXOTIDE* may cause hoarseness. It may be helpful to rinse out the mouth with water immediately after inhalation.
Very rare: Paradoxical bronchospasm (*see Warnings and Precautions*).

Skin and subcutaneous tissue disorders
Common: Contusions.

Overdose
Acute inhalation of *FLIXOTIDE* doses in excess of those approved may lead to temporary suppression of the hypothalamic-pituitary-adrenal axis. This does not usually require emergency action, as normal adrenal function typically recovers within a few days.

If higher than approved doses are continued over prolonged periods, significant adrenocortical suppression is possible. There have been very rare reports of acute adrenal crisis occurring in children exposed to higher than approved doses (typically 1,000 micrograms daily and above), over prolonged periods (several months or years); observed features included hypoglycaemia and sequelae of decreased consciousness and/or convulsions. Situations which could potentially trigger acute adrenal crisis include exposure to trauma, surgery, infection or any rapid reduction in dosage.

Patients receiving higher than approved doses should be managed closely and the dose reduced gradually.

PHARMACOLOGICAL PROPERTIES
Pharmacodynamics
Pharmacodynamic Properties
FLIXOTIDE given by inhalation at recommended doses has a potent glucocorticoid anti-inflammatory action within the lungs, resulting in reduced symptoms and exacerbations of asthma.

Pharmacokinetics
Absorption
The absolute bioavailability of fluticasone propionate for each of the available inhaler devices has been estimated from within and between study comparisons of inhaled and intravenous pharmacokinetic data. In healthy adult subjects the absolute bioavailability has been estimated for fluticasone propionate Accuhaler/Diskus (7.8%), fluticasone propionate Diskhaler (9.0%) and fluticasone propionate Evohaler (10.9%) respectively. In patients with asthma or COPD a lesser degree of systemic exposure to inhaled fluticasone propionate has been observed. Systemic absorption occurs mainly through the lungs and is initially rapid then prolonged. The remainder of the inhaled dose may be swallowed but contributes minimally to systemic exposure due to the low aqueous solubility and pre-systemic metabolism, resulting in oral availability of less than 1%. There is a linear increase in systemic exposure with increasing inhaled dose.

Distribution
Fluticasone propionate has a large volume of distribution at steady-state (approximately 300 L). Plasma protein binding is moderately high (91%).

Metabolism
Fluticasone propionate is cleared very rapidly from the systemic circulation, principally by metabolism to an inactive carboxylic acid metabolite, by the cytochrome P450 enzyme CYP3A4. Care should be taken when co-administering known CYP3A4 inhibitors, as there is potential for increased systemic exposure to fluticasone propionate.

Elimination
The disposition of fluticasone propionate is characterised by high plasma clearance (1,150 mL/min) and a terminal half-life of approximately 8 hours. The renal clearance of fluticasone propionate is negligible (less than 0.2%) and less than 5% as the metabolite.

Clinical Studies
Fluticasone propionate containing medications in asthma during pregnancy
An observational retrospective epidemiological cohort study utilising electronic health records from the United Kingdom was conducted to evaluate the risk of MCMs following first trimester exposure to inhaled fluticasone propionate (FP) alone and salmeterol-FP combination relative to non-FP containing ICS. No placebo comparator was included in this study.

Within the asthma cohort of 5,362 first trimester ICS-exposed pregnancies, 131 diagnosed MCMs were identified; 1,612 (30%) were exposed to FP or salmeterol-FP of which 42 diagnosed MCMs were identified. The adjusted odds ratio for MCMs diagnosed by 1 year was 1.1 (95%CI: 0.5 – 2.3) for FP exposed vs non-FP ICS exposed women with moderate asthma and 1.2 (95%CI: 0.7 – 2.0) for women with considerable to severe asthma. No difference in the risk of MCMs was identified following first trimester exposure to FP alone versus salmeterol-FP combination. Absolute risks of MCM across the asthma severity strata ranged from 2.0 to 2.9 per 100 FP-exposed pregnancies which is comparable to results from a study of 15,840 pregnancies unexposed to asthma therapies in the General Practice Research Database (2.8 MCM events per 100 pregnancies).

Non-clinical Information
Toxicology has shown only those class effects typical of potent corticosteroids, and these only at doses in excess of those proposed for therapeutic use. No novel effects were identified in repeat dose toxicity tests, reproductive studies or teratology studies.

Fluticasone propionate is devoid of mutagenic activity *in vitro* and *in vivo* and showed no tumorigenic potential in rodents. It is both non-irritant and non-sensitising in animal models.

The non-CFC propellant, HFA134a, has been shown to have no toxic effect at very high vapour concentrations, far in excess of those likely to be experienced by patients, in a wide range of animal species exposed daily for periods of two years.

PHARMACEUTICAL INFORMATION
List of Excipients
Hydroxyfluoroalkane 134a, 1, 1, 1, 2-tetrafluoroethane (HFA 134a).

Shelf Life
The expiry date is indicated on the packaging.

Storage
The storage conditions are detailed on the packaging.

Replace the mouthpiece cover firmly and snap it into position.

FLIXOTIDE Inhaler should not be stored above 30 oC

Protect from frost and direct sunlight.
As with most inhaled medications in pressurised canisters, the therapeutic effect of this medication may decrease when the canister is cold.

Pressurised container. Do not expose to temperatures higher than 50°C. The canister should not be punctured, broken or burnt even when apparently empty.

Nature and Contents of Container
FLIXOTIDE Inhaler comprises a suspension of fluticasone propionate in the non-CFC propellant HFA 134a. The suspension is contained in an aluminium alloy can sealed with a metering valve. The canisters are fitted into plastic actuators incorporating an atomizing orifice and fitted with dustcaps.

Incompatibilities
None reported.

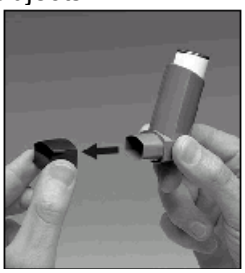
Use and Handling
Instructions for use of your *FLIXOTIDE* Inhaler
Testing your inhaler:

Before using for the first time or if your inhaler has not been used for a week or more remove the mouthpiece cover by gently squeezing the sides of the cover, shake the inhaler well, and release two puff into the air to make sure that it works.

Using your inhaler:

1. Remove the mouthpiece cover by gently squeezing the sides of the cover.

2. Check inside and outside of the inhaler including the mouthpiece for the presence of loose objects.



3. Shake the inhaler well to ensure that any loose objects are removed and that the contents of the inhaler are evenly mixed.

4. Hold the inhaler upright between fingers and thumb with your thumb on the base, below the mouthpiece.

5. Breathe out as far as is comfortable and then place the mouthpiece in your mouth between your teeth and close your lips around it but do not bite it.

6. Just after starting to breathe in through your mouth press down on the top of the inhaler to release *FLIXOTIDE* while still breathing in steadily and deeply.

7. While holding your breath, take the inhaler from your mouth and take your finger from the top of the inhaler. Continue holding your breath for as long as is comfortable.

8. If you are to take further puffs keep the inhaler upright and wait about half a minute before repeating steps 3 to 7.

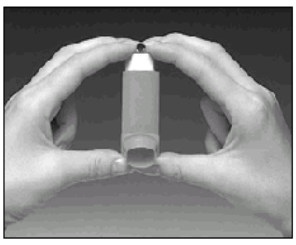
9. Afterwards, rinse your mouth with water and spit it out.

10. Replace the mouthpiece cover by firmly pushing and snapping the cap into position.

IMPORTANT:
Do not rush stages 5, 6 and 7. It is important that you start to breathe in as slowly as possible just before operating your inhaler. Practise in front of a mirror for the first few times. If you see "mist" coming from the top of your inhaler or the sides of your mouth you should start again from stage 2.

If your doctor has given you different instructions for using your inhaler, please follow them carefully. Tell your doctor if you have any difficulties.

Children:
Young children may need help and an adult may need to operate the inhaler for them. Encourage the child to breathe out and operate the inhaler just after the child starts to breathe in. Practice the technique together. Older children or people with weak hands should hold the inhaler with both hands. Put the two forefingers on top of the inhaler and both thumbs on the base below the mouthpiece.



Cleaning:
Your inhaler should be cleaned at least once a week.
1. Remove the mouthpiece cover.
2. Do not remove the canister from the plastic casing.
3. Wipe the inside and outside of the mouthpiece with a dry cloth or tissue.
4. Replace the mouthpiece cover.

DO NOT PUT THE METAL CANISTER INTO WATER.

HARUS DENGAN RESEP DOKTER

FLIXOTIDE Inhaler 50 mcg/dose, Box, 1 canister @ 120 doses Reg. No. DKI1585100739A1

Manufactured by
Glaxo Wellcome Production
Evreux, France

Imported by
PT Glaxo Wellcome Indonesia
Jakarta, Indonesia

Version number: GDS36/IPI12
Date of issue: 05 November 2020

INFORMASI UNTUK PASIEN

FLIXOTIDE INHALER

Fluticasone propionate

Baca semua informasi dalam petunjuk berikut sebelum menggunakan *FLIXOTIDE* Inhaler karena petunjuk ini mengandung informasi penting untuk Anda.
- Simpan petunjuk ini. Kemungkinan Anda membutuhkannya untuk dibaca kembali.
- Jika Anda memiliki pertanyaan lebih lanjut, tanyakan kepada dokter, perawat, atau apoteker.
- *FLIXOTIDE* Inhaler ini hanya diresepkan kepada Anda. Jangan diberikan kepada orang lain. Hal tersebut dapat membahayakan mereka, meskipun gejala penyakit mereka sama dengan gejala Anda.
- Jika Anda merasakan efek samping, bicarakan dengan dokter, perawat, atau apoteker. Termasuk kemungkinan efek samping lain yang tidak tertulis dalam petunjuk ini. Lihat *Bagian 4*.

Apa saja yang ada dalam petunjuk ini:

1 Apa itu *FLIXOTIDE* dan digunakan untuk apa

Fluticasone propionate masuk dalam kelompok obat kortikosteroid (biasa hanya disebut steroid). Karena obat ini dihirup langsung ke paru Anda, maka hanya dibutuhkan dosis yang sangat kecil.

FLIXOTIDE bekerja dengan cara mengurangi pembengkakan dan iritasi pada paru-paru. Cara kerja inilah yang biasa disebut dengan 'aksi anti-inflamasi'.

FLIXOTIDE membantu untuk pencegahan serangan asma pada pasien yang memerlukan terapi teratur. Hal inilah yang menyebabkan obat ini disebut sebagai 'pencegah/*preventer*'. *FLIXOTIDE* dibutuhkan untuk penggunaan secara teratur, setiap hari.

FLIXOTIDE tidak ditujukan untuk mengobati serangan asma mendadak dimana Anda merasa tidak dapat bernapas.
- Obat lain yang digunakan untuk terapi serangan asma (obat ini disebut 'pelega/*reliever*').
- Jika Anda memiliki lebih dari satu obat, berhati-hatilah supaya tidak tertukar penggunaannya.

2 Apa yang perlu Anda ketahui sebelum menggunakan *FLIXOTIDE*

Jangan menggunakan:
- Jika Anda alergi terhadap fluticasone propionate atau bahan lain dari obat ini (tertulis di *Bagian 6*).

Peringatan dan Pencegahan

Bicarakan kepada dokter, perawat, atau apoteker sebelum menggunakan *FLIXOTIDE* jika:
- Anda pernah menjalani pengobatan tuberculosis (TB).
- Anda menggunakan *FLIXOTIDE* bersamaan dengan penggunaan tablet steroid. Dan juga jika Anda baru saja selesai meminum tablet steroid.

Proses pembentukan steroid tubuh Anda dapat terpengaruh ketika menggunakan *FLIXOTIDE*. Hal ini kemungkinan terjadi jika Anda menggunakan dosis tinggi dalam jangka panjang. Hal ini dapat menyebabkan:
- Pertumbuhan anak-anak dan remaja melambat.
- *Cushing's syndrome* terjadi ketika Anda memiliki steroid yang terlalu banyak di dalam darah dan menyebabkan penipisan tulang, dan masalah mata (seperti katarak, glaukoma, dan *central serous chorioretinopathy*).

Dokter Anda akan mencegah kejadian ini dengan memastikan Anda menggunakan dosis terendah yang dapat mengontrol gejala asma Anda (Lihat *Bagian 4*).

Jika Anda tidak yakin kondisi di atas berlaku terhadap Anda, bicarakan kepada dokter, perawat, atau apoteker sebelum menggunakan *FLIXOTIDE*.

Obat Lain dan *FLIXOTIDE*

Beritahukan dokter, perawat, dan apoteker jika Anda sedang, baru saja atau akan menggunakan obat lain, termasuk obat yang didapat tanpa resep. Termasuk obat herbal. Ingatlah untuk membawa obat ini jika Anda harus dirawat di rumah sakit.

Khususnya beritahukan dokter atau apoteker jika Anda sedang menggunakan obat berikut:
- Obat tipe antiviral yang dikenal sebagai '*inhibitor protease*' (seperti ritonavir).
- Obat yang digunakan untuk mengobati infeksi jamur (seperti ketoconazole).

Jika Anda tidak yakin apakah kondisi di atas berlaku terhadap Anda, bicarakan kepada dokter atau apoteker sebelum menggunakan *FLIXOTIDE*.

***FLIXOTIDE* dengan Makanan dan Minuman**
Anda dapat menggunakan *FLIXOTIDE* setiap saat, sebelum atau sesudah makan.

Kehamilan dan Menyusui
Jika Anda sedang hamil atau menyusui, menduga hamil, atau merencanakan kehamilan, harap berkonsultasi dengan dokter sebelum menggunakan obat ini.

Berkendara atau Menjalankan Mesin
FLIXOTIDE tidak akan mempengaruhi kemampuan Anda mengemudi atau menggunakan alat atau mesin.

3 Bagaimana menggunakan *FLIXOTIDE*

Dokter akan menentukan jumlah dosis yang Anda butuhkan. Selalu gunakan obat ini sesuai dengan yang dokter katakan kepada Anda. Periksakan ke dokter, perawat, atau apoteker jika Anda tidak yakin.

Menggunakan Obat Ini
Obat dalam *FLIXOTIDE* harus dihirup dengan cara yang benar.
- Pastikan Anda memiliki inhaler dan mampu menggunakannya dengan baik.
- Petunjuk penggunaan inhaler diberikan dalam bentuk panduan per tahap.
- **Obat ini memerlukan waktu beberapa hari untuk bekerja dan sangat penting untuk Anda menggunakannya secara teratur.**

Dewasa dan Anak-Anak Berumur di Atas 16 Tahun
100 hingga 1.000 mikrogram dua kali sehari tergantung tingkat keparahan yang dinilai oleh dokter.

Anak-Anak 4 Tahun ke Atas
Asma pada anak-anak akan terkontrol dengan baik menggunakan dosis 50 hingga 100 mikrogram dua kali sehari.

Anak-Anak Umur 1 Hingga 4 Tahun
Kontrol optimal untuk gejala asma tercapai dengan 100 mikrogram dua kali sehari digunakan dengan alat bantu *BABYHALER*.

Disarankan anak yang diobati dengan steroid, termasuk *FLIXOTIDE* Inhaler diukur tinggi badannya secara teratur oleh dokter.

Dokter mungkin akan memberikan *FLIXOTIDE* Inhaler dengan dosis yang lebih tinggi apabila dosis obat Anda ditingkatkan.

Jika Anda menggunakan steroid inhalasi dosis tinggi dalam jangka waktu lama, terkadang Anda akan butuh tambahan steroid misalnya pada kondisi dengan tingkat kecemasan yang tinggi seperti kecelakaan lalu lintas atau sebelum tindakan operasi. Dokter Anda akan memutuskan untuk memberi obat steroid tambahan selama kondisi tersebut.

Pasien yang sedang menjalani terapi menggunakan steroid dosis tinggi, termasuk *FLIXOTIDE* Inhaler dalam jangka lama, tidak boleh menghentikan terapi secara tiba-tiba tanpa memberi tahu dokter. Penghentian terapi secara tiba-tiba dapat membuat Anda tidak enak badan atau dapat menyebabkan gejala seperti muntah, mengantuk, mual, sakit kepala, kelelahan, hilang nafsu makan, kadar gula darah rendah, dan kesehatan menurun.

Cara Penggunaan
Dokter, perawat, dan apoteker harus menunjukkan cara menggunakan inhaler kepada Anda. Mereka harus memeriksa bagaimana Anda menggunakan inhaler tiap waktu. Penggunaan *FLIXOTIDE* Inhaler

yang tidak benar atau tidak sesuai dengan yang diresepkan, bisa mengakibatkan obat tidak dapat mengatasi kondisi asma Anda sebagaimana mestinya.

Obat terdapat dalam *canister* di wadah plastik dengan sebuah *mouthpiece*.

Cara Mencoba Inhaler
Dilakukan sebelum menggunakan inhaler untuk yang pertama kalinya atau jika inhaler tidak digunakan selama satu minggu atau lebih. Buka penutup *mouthpiece* dengan menarik bagian sisi penutupnya, kocok inhaler dengan baik, dan lepaskan dua semprot (*puff*) ke udara untuk memastikan bahwa inhaler dapat digunakan.

Cara Menggunakan Inhaler
1. Buka penutup *mouthpiece* dengan menarik bagian sisi penutupnya.

2. Pastikan bagian luar dan dalam inhaler termasuk bagian *mouthpiece* bebas dari debu dan kotoran.


3. Kocok inhaler beberapa kali agar isi inhaler tercampur dengan merata.


4. Pegang inhaler menghadap ke atas di antara telunjuk dan ibu jari, dengan posisi ibu jari di bagian bawah *mouthpiece*.


5. Keluarkan napas semaksimal mungkin kemudian letakkan *mouthpiece* pada mulut di antara gigi Anda dan tutup bibir Anda melingkari bagian *mouthpiece* namun jangan digigit.


6. Bersamaan dengan Anda mulai menarik napas kembali, tekan bagian atas inhaler untuk melepaskan semprotan *FLIXOTIDE*. Lakukan hal ini ketika menghirup napas dengan teratur dan dalam.

7. Tahan napas Anda, ambil inhaler dari mulut dan lepaskan telunjuk Anda dari ujung inhaler. Tetap tahan napas Anda selama beberapa detik atau sepanjang Anda merasa nyaman.

8. Jika dokter menganjurkan untuk melakukan beberapa semprotan (*puff*), tunggu sekitar setengah menit sebelum Anda mengulang tahap nomor 3 hingga 7.

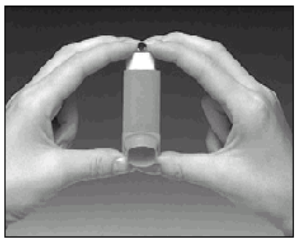
9. Setelah itu, berkumur-kumurlah menggunakan air dan buang air tersebut.

10. Tutup kembali *mouthpiece* dengan menekan secara halus dan mengatupkan penutup ke tempat semula.

PENTING
Jangan tergesa-gesa pada tahap nomor 5, 6, dan 7. Penting untuk bernapas sepelan mungkin sebelum menggunakan inhaler. Berlatihlah di depan cermin saat awal-awal penggunaan. Jika Anda melihat 'uap' berasal dari ujung atas inhaler atau dari sisi mulut, Anda harus mengulang kembali dari tahap 2.

Jika dokter memberikan petunjuk penggunaan yang berbeda, ikutilah petunjuk dokter dengan hati-hati. Beritahukan dokter jika Anda mengalami kesulitan.

Anak-Anak:
Anak-anak akan memerlukan bantuan dan orang tuanya perlu memakaikan inhaler untuk mereka. Anjurkan anak untuk mengeluarkan napas dan pakaikan inhaler bersamaan dengan anak memulai napas kembali. Latih teknik tersebut bersama-sama. Remaja atau orang dewasa dengan tangan yang lemah akan lebih mudah menggunakan inhaler dengan kedua tangan. Letakkan kedua telunjuk di bagian atas inhaler dan kedua ibu jari di bagian bawah *mouthpiece*.



Membersihkan Inhaler
Inhaler harus dibersihkan minimal satu kali dalam seminggu.
1. Lepaskan penutup *mouthpiece.*
2. Jangan melepaskan *canister* logam dari pembungkus plastik.
3. Lap bagian dalam serta bagian luar *mouthpiece* dengan kain atau tisu kering.
4. Tutup kembali penutup *mouthpiece*.

JANGAN MERENDAM *CANISTER* LOGAM DI DALAM AIR.

Jika Anda Menggunakan *FLIXOTIDE* Lebih dari Seharusnya
Jika Anda menggunakan lebih dari seharusnya, **laporkan ke dokter sesegera mungkin**.

Sangat penting bagi Anda untuk menggunakan sesuai dosis yang tertera pada etiket dosis obat dari apotek atau sesuai dengan saran dokter. Anda tidak seharusnya menambah atau mengurangi dosis tanpa saran dokter.

Jika Anda Lupa Menggunakan *FLIXOTIDE*
- Gunakan dosis di jadwal selanjutnya.

- Jangan menggunakan dosis ganda untuk menebus dosis yang terlupakan.

Jika Anda Berhenti Menggunakan *FLIXOTIDE*
- **Jangan menghentikan terapi** meskipun Anda merasa lebih baik kecuali disarankan oleh dokter.

Jika Anda memiliki pertanyaan lebih jauh pada penggunaan obat ini, tanyakan ke dokter, perawat, atau apoteker.

4 Efek samping yang mungkin terjadi

Seperti obat lainnya, obat ini dapat menyebabkan efek samping, meski tidak semua pasien mengalaminya.

Jika Anda merasakan efek samping serius berikut, hentikan penggunaan obat ini dan laporkan segera mungkin ke dokter. Anda mungkin membutuhkan tindakan medis darurat.
- Reaksi alergi (dapat terjadi pada 1 dari 100 pasien) - gejala termasuk ruam kulit, kemerahan, gatal-gatal, atau luka seperti ruam jelatang, atau bintik kemerahan.
- Reaksi alergi parah (dapat terjadi pada 1 dari 10.000 pasien) - gejala termasuk pembengkakan pada muka, bibir, mulut, lidah, atau tenggorokan yang mana menyebabkan kesulitan dalam menelan dan bernapas, ruam yang gatal, merasa akan pingsan, melayang, dan akhirnya jatuh.
- Napas atau mengi semakin memburuk segera setelah penggunaan inhaler.

Efek Samping Lain Termasuk:
Sangat umum (dapat terjadi pada ≥1/10 pasien)
- Sariawan di mulut dan tenggorokan.

Umum (dapat terjadi pada ≥1/100 dan <1/10 pasien)
- Suara serak.
- Memar.

Masalah suara serak dapat dikurangi dengan menggosok gigi, berkumur kemudian dibuang airnya setelah menghirup obat sesuai dosis Anda. Beri tahu dokter jika Anda memiliki masalah dengan mulut atau tenggorokan, namun jangan menghentikan terapi kecuali diperintahkan oleh dokter.

Efek samping pada pasien dengan Penyakit Paru Obstruktif Kronik (PPOK):
- Pneumonia dan *bronchitis* (infeksi paru). Segera laporkan ke dokter apabila Anda menemukan gejala sebagai berikut: peningkatan produksi dahak, perubahan warna dahak, demam, menggigil, peningkatan batuk, meningkatnya masalah pernapasan.
- Memar.

Tidak umum terjadi (dapat terjadi pada ≥1/1.000 dan <1/100 pasien)
- Reaksi hipersensitivitas pada kulit.

Jarang terjadi (dapat terjadi pada ≥1/10.000 dan <1/1.000 pasien)
- Kandidiasis esofagus.

Sangat jarang terjadi (dapat terjadi pada <1/10.000 pasien)
- Angioedema (terutama udem wajah dan orofaring), gejala pernapasan (dispnea dan/atau bronkospasme), dan reaksi anafilaksis.
- Proses pembentukan steroid tubuh Anda dapat terpengaruh ketika menggunakan *FLIXOTIDE*. Hal ini kemungkinan terjadi jika Anda menggunakan dosis tinggi dalam jangka panjang (misalnya 400 mikrogram per hari pada anak-anak). Hal ini dapat menyebabkan:
  - Pertumbuhan anak-anak dan remaja melambat.
  - *Cushing's syndrome* terjadi ketika Anda memiliki steroid yang terlalu banyak di dalam darah dan menyebabkan penipisan tulang, dan masalah mata (seperti katarak dan glaukoma yaitu tekanan yang tinggi pada mata).

  Dokter Anda akan mencegah kejadian ini dengan memastikan Anda menggunakan dosis terendah yang dapat mengontrol gejala asma Anda.
- Kadar gula (glukosa) dalam darah meningkat (hiperglikemia).
- Merasa cemas, gangguan tidur dan perubahan perilaku termasuk hiperaktivitas dan mudah marah (terutama pada anak-anak).
- Bronkospasme paradoksal.

Hubungi Dokter Anda Segera Apabila:

- Setelah 7 hari menggunakan *FLIXOTIDE* keadaan sesak napas atau mengi tidak membaik, atau semakin memburuk.
- Anda atau anak anda menggunakan dosis tinggi inhalasi steroid dan merasa tidak enak badan yang disertai dengan gejala-gejala seperti sakit perut, mual, diare, sakit kepala, atau mengantuk. Hal ini dapat terjadi apabila Anda mengalami infeksi seperti infeksi virus atau sakit perut. Sangatlah penting steroid Anda tidak dihentikan tiba-tiba mengingat hal ini dapat membuat asma Anda semakin memburuk dan dapat menyebabkan permasalahan pada hormon tubuh Anda.

Pelaporan Efek Samping
Jika Anda merasakan efek samping, laporkan ke dokter, apoteker, atau perawat. Termasuk kemungkinan efek samping lain yang tidak tertulis dalam informasi ini.

Dengan melaporkan efek samping, Anda dapat membantu memberikan informasi lebih terhadap keamanan obat ini.

5 Bagaimana cara penyimpanan *FLIXOTIDE*

- Simpan obat ini jauh dari jangkauan anak-anak.
- Bersihkan inhaler seminggu sekali dan jika terjadi penyumbatan seperti dijelaskan pada bagian 'Membersihkan Inhaler'.
- Jangan menggunakan obat setelah tanggal kedaluwarsa, yang ditulis pada label dan karton setelah kata 'EXP'. Tanggal kedaluwarsa merujuk pada hari terakhir bulan tersebut.
- Jangan disimpan pada suhu diatas 30 oC. Lindungi dari pembekuan dan sinar matahari langsung.
- Jika inhaler menjadi sangat dingin, lepas *canister* logam dari pembungkus plastik dan hangatkan dengan tangan Anda beberapa menit sebelum digunakan. Jangan pernah menggunakan sesuatu yang lain untuk menghangatkannya.
- *Canister* logam merupakan wadah bertekanan (*pressurised*). Jangan menusuk, memecah, atau membakarnya meskipun tampak kosong.
- Jangan terpapar suhu lebih dari 50^{o}C.
- Jangan membuang obat apapun di air limbah atau limbah rumah tangga. Tanyakan pada apoteker bagaimana membuang obat yang tidak digunakan lagi. Langkah ini membantu dalam menjaga lingkungan.
- Jika Anda diperintahkan untuk menghentikan penggunaan obat ini, kembalikan inhaler ke apoteker untuk dimusnahkan.

6 Isi dari kemasan dan informasi lain

Apa Kandungan *FLIXOTIDE*
- Zat aktif obat adalah fluticasone propionate.
- Bahan lain adalah HFA 134a.

Seperti Apa Bentuk *FLIXOTIDE* Inhaler dan Isi dari Kemasan
- *FLIXOTIDE* Inhaler terdiri dari *canister*, *actuator*, dan penutup.
- Setiap *canister* mengandung 120 dosis dari 50 mikrogram fluticasone propionate.

HARUS DENGAN RESEP DOKTER

FLIXOTIDE Inhaler 50 mikrogram/dosis, Dus, 1 *canister* @ 120 dosis No. Reg. DKI1585100739A1

Diproduksi oleh
Glaxo Wellcome Production
Evreux, Perancis

Diimpor oleh
PT Glaxo Wellcome Indonesia
Jakarta, Indonesia

Version 4 – 31 May 2021