Flixotide Diskus 100 mcg
Flixotide Diskus 250 mcg
Flixotide Diskus 500 mcg

1. NAME OF THE MEDICINAL PRODUCT

Flixotide Diskus 100 mcg
Flixotide Diskus 250 mcg
Flixotide Diskus 500 mcg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each blister each contains, 100 micrograms fluticasone propionate.
Excipients: Each blister contains 11.9mg lactose (as monohydrate)

Each blister each contains ,250 micrograms fluticasone propionate.
Excipients: Each blister contains 11.6mg lactose (as monohydrate)

Each blister each contains, 500 micrograms fluticasone propionate.
Excipients: Each blister contains 11.4mg lactose (as monohydrate)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Inhalation powder, pre-dispensed
Fine, white to off-white powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Flixotide diskus 100, 250, 500 mcg are indicated for the Prophylactic management of all grades of **Asthma.**

Flixotide diskus 250 mcg and 500 mcg are also indicated for the management of **Chronic Obstructive Pulmonary Disease (COPD**) when used in combination with long-acting bronchodilators (e.g. long-acting beta agonists (LABAs)).

4.2 Posology and Method of Administration

Flixotide Diskus is for inhalation by oral inhalation only.

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

The dosage of fluticasone propionate should be adjusted according to the individual response.

Asthma

The onset of therapeutic effect is 4 to 7 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 1000 micrograms twice daily.

Patients should be given a starting dose of inhaled fluticasone propionate 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 1000 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 over 4 years of age:-

50 to 100 micrograms twice daily.

Children should be given a starting dose of inhaled fluticasone propionate which is appropriate for the severity of their disease, this may be 50 to 100 micrograms twice daily.

Many children's asthma will be well controlled using the 50 to 100 mcg twice daily dosing regimen. For those patients whose asthma is not sufficiently controlled, additional benefit may be obtained by increasing the dose up to 200 mcg twice daily.

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

Chronic Obstructive Pulmonary Disease (COPD)

Adult dose:-

500 micrograms twice daily, used as an adjunct to long-acting bronchodilators (e.g. LABAs).

Medication must be used daily for optimum benefit which may take three to six months. If there is no improvement after three to six months then the patient should undergo medical assessment.

Only the 250 or 500 microgram devices are suitable for the administration of this dose.

Special patient groups

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

4.3 Contraindications

Contraindicated in patients with severe milk-protein allergy or who have demonstrated hypersensitivity to the active substance or to any of the excipients listed in section 6.1 .

4.4 Special Warnings and Precautions for Use

The management of asthma should follow a stepwise programme and patient response should be monitored clinically and by lung function tests.

Increasing use of short-acting inhaled β_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.

Flixotide Diskus is not for use in acute asthma attacks, but for routine long-term management. Patients will require a fast- and short-acting inhaled bronchodilator to relieve acute asthmatic symptoms.

Lack of response or severe exacerbations of asthma should be treated by increasing the dose of inhaled fluticasone propionate and, if necessary, by giving a systemic steroid and/or an antibiotic if there is an infection.

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 section 4.9). Possible systemic effects include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children). It is important, therefore, that the dose of inhaled corticosteroid is reduced to the lowest dose at which effective control of asthma is maintained (see section 4.8).

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

Certain individuals can show greater susceptibility to the effects of inhaled corticosteroid than do most patients.

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

Following introduction of inhaled fluticasone propionate, withdrawal of systemic therapy should be gradual.

Similarly replacement of systemic steroid treatment with inhaled therapy may unmask allergies such as allergic rhinitis or eczema previously controlled by the systemic drug. These allergies should be symptomatically treated with antihistamine and/or topical preparations, including topical steroids.

Treatment with Flixotide Diskus should not be stopped abruptly.

There have been very rare reports of increases in blood glucose levels (see section 4.8) 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 section 4.5).

The possibility of impaired adrenal response should always be borne in mind in emergency situations, including surgery, and elective situations likely to produce stress and appropriate corticosteroid treatment must be considered (see section 4.9).

Adrenal function and adrenal reserve usually remain within the normal range on recommended doses of fluticasone propionate therapy. The benefits of inhaled fluticasone propionate therapy should minimise the need for oral steroids. However, the possibility of adverse effects in patients, resulting from prior or intermittent administration of oral steroids, may persist for some time. The extent of the adrenal impairment may require specialist advice before elective procedures.

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 and short-acting inhaled bronchodilator. Fluticasone propionate should be discontinued immediately, the patient assessed and alternative therapy instituted if necessary (see section 4.8).

Pneumonia in patients with COPD

An increase in the incidence of pneumonia, including pneumonia requiring hospitalisation, has been observed in patients with COPD receiving inhaled corticosteroids. There is some evidence of an increased risk of pneumonia with increasing steroid dose but this has not been demonstrated conclusively across all studies.

There is no conclusive clinical evidence for intra-class differences in the magnitude of the pneumonia risk among inhaled corticosteroid products.

Physicians should remain vigilant for the possible development of pneumonia in patients with COPD as the clinical features of such infections overlap with the symptoms of COPD exacerbations.

Risk factors for pneumonia in patients with COPD include current smoking, older age, low body mass index (BMI) and severe COPD.

Visual disturbance

Visual disturbance may be reported with systemic and topical 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, which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy which have been reported after use of systemic and topical corticosteroids.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

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.

Co-treatment with other potent CYP3A inhibitors, including cobicistat-containing products, is expected to increase the risk of systemic side-effects. Combinations should be avoided unless the benefit outweighs the potential increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects. Other inhibitors of CYP3A4 produce negligible (erythromycin) and minor (ketoconazole) increases in systemic exposure to fluticasone propionate without notable reductions in serum cortisol concentrations.

4.6 Fertility, 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 fluticasone propionate 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 Section 5.1).

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.

Breast-feeding
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.

4.7 Effects on Ability to Drive and Use Machines

Fluticasone propionate has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable Effects

Adverse events are listed below by system organ class and frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1000 to <1/100), rare (≥1/10,000 to <1/1000) and very rare (<1/10,000) including isolated reports and not known (cannot be estimated from the available data). 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 anti-fungal therapy whilst still continuing with Flixotide Diskus.

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 (see section 4.4) include:

Very rare: Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation, decreased bone mineral density, cataract, glaucoma.

Eye Disorders

Not known: Vision, blurred (see section 4.4)

Metabolism and nutrition disorders

Very rare: Hyperglycaemia.

Psychiatric disorders

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

Not known: Depression, aggression (predominantly in children)

Respiratory, Thoracic and Mediastinal Disorders

Common: Hoarseness.

In some patients inhaled fluticasone propionate may cause hoarseness. It may be helpful to rinse out the mouth with water immediately after inhalation.

Very rare: Paradoxical bronchospasm (see section 4.4).

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. Fluticasone propionate should be discontinued immediately, the patient assessed, and if necessary alternative therapy instituted.

Not known: Epistaxis

Skin and subcutaneous tissue disorders

Common: Contusions

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form
https://sideeffects.health.gov.il/
Additionally, you should also report to GSK Israel (il.safety@gsk.com).

4.9 Overdose

Symptoms and Signs
Acute inhalation of fluticasone propionate 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 1000 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.

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

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Fluticasone propionate given by inhalation at recommended doses has a glucocorticoid anti-inflammatory action within the lungs, resulting in reduced symptoms and exacerbations of asthma, without the adverse effects observed when corticosteroids are administered systemically.

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 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 5362 first trimester ICS-exposed pregnancies, 131 diagnosed MCMs were identified; 1612 (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).

COPD clinical trials

TORCH was a 3-year study to assess the effect of treatment with Seretide Diskus 50/500mcg bd, salmeterol Diskus 50mcg bd, fluticasone propionate (FP) Diskus 500mcg bd or placebo on all-cause mortality in patients with COPD. COPD patients with a baseline (pre-bronchodilator) FEV_1 <60% of predicted normal were randomised to double-blind medication. During the study, patients were permitted usual COPD therapy with the exception of other inhaled corticosteroids, long-acting bronchodilators and long-term

systemic corticosteroids. Survival status at 3 years was determined for all patients regardless of withdrawal from study medication. The primary endpoint was reduction in all cause mortality at 3 years for Seretide vs. Placebo.

	Placebo N = 1524	**Salmeterol 50 N = 1521**	**FP 500 N = 1534**	**Seretide 50/500 N = 1533**
All cause mortality at 3 years				
Number of deaths (%)	231 (15.2%)	205 (13.5%)	246 (16.0%)	193 (12.6%)
Hazard Ratio vs. Placebo (CIs) p value	N/A	0.879 (0.73, 1.06) 0.180	1.060 (0.89, 1.27) 0.525	0.825 (0.68, 1.00) 0.052[1]
Hazard Ratio Seretide 50/500 vs. components (CIs) p value	N/A	0.932 (0.77, 1.13) 0.481	0.774 (0.64, 0.93) 0.007	N/A

1. Non significant P value after adjustment for 2 interim analyses on the primary efficacy comparison from a log-rank analysis stratified by smoking status

There was a trend towards improved survival in subjects treated with Seretide compared with placebo over 3 years however this did not achieve the statistical significance level $p \leq 0.05$.

The mean number of moderate to severe exacerbations per year was significantly reduced with Seretide as compared with treatment with salmeterol, FP and placebo (mean rate in the Seretide group 0.85 compared with 0.97 in the salmeterol group, 0.93 in the FP group and 1.13 in the placebo). This translates to a reduction in the rate of moderate to severe exacerbations of 25% (95% CI: 19% to 31%; $p<0.001$) compared with placebo, 12% compared with salmeterol (95% CI: 5% to 19%, $p=0.002$) and 9% compared with FP (95% CI: 1% to 16%, $p=0.024$). Salmeterol and FP significantly reduced exacerbation rates compared with placebo by 15% (95% CI: 7% to 22%; $p<0.001$) and 18% (95% CI: 11% to 24%; $p<0.001$) respectively.

Health Related Quality of Life, as measured by the St George's Respiratory Questionnaire (SGRQ) was improved by all active treatments in comparison with placebo. The average improvement over three years for Seretide compared with placebo was -3.1 units (95% CI: -4.1 to -2.1; $p<0.001$), compared with salmeterol was -2.2 units ($p<0.001$) and compared with FP was -1.2 units ($p=0.017$). A 4-unit decrease is considered clinically relevant.

The estimated 3-year probability of having pneumonia reported as an adverse event was 12.3% for placebo, 13.3% for salmeterol, 18.3% for FP and 19.6% for Seretide (Hazard ratio for Seretide vs. placebo: 1.64, 95% CI: 1.33 to 2.01, $p<0.001$). There was no significant difference in probability of bone fracture (5.1% placebo, 5.1% salmeterol, 5.4% FP and 6.3% Seretide; Hazard ratio for Seretide vs. placebo: 1.22, 95% CI: 0.87 to 1.72, $p=0.248$.

5.2 Pharmacokinetic Properties

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 Diskus (7.8%) and fluticasone propionate Inhaler (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.

The disposition of fluticasone propionate is characterised by high plasma clearance (1150ml/min), a large volume of distribution at steady-state (approximately 300l) and a terminal half-life of approximately 8 hours.

Plasma protein binding is 91%.

Fluticasone propionate is cleared very rapidly from the systemic circulation. The main pathway is metabolism to an inactive carboxylic acid metabolite, by the cytochrome P450 enzyme CYP3A4. Other unidentified metabolites are also found in the faeces.

The renal clearance of fluticasone propionate is negligible. Less than 5% of the dose is excreted in urine, mainly as metabolites. The main part of the dose is excreted in faeces as metabolites and unchanged drug.

5.3 Preclinical Safety Data

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Lactose monohydrate (which contains milk proteins)

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

The expiry date of the product is indicated on the packaging materials.

6.4 Special Precautions for Storage

Store in a dry place, below 30ºC.

The Diskus is sealed in a foil overwrap which should only be opened when it is to be used for the first time. Once opened the foil overwrap should be discarded.

6.5 Nature and Contents of Container

The inhalation powder is contained in blisters held on a formed PVC coated base, with a peelable foil laminate lid. The strip is contained in a moulded plastic device. The plastic device is packaged within a foil overwrap. The plastic devices are available in cardboard containers, which hold a 1 x 60 dose Diskus.

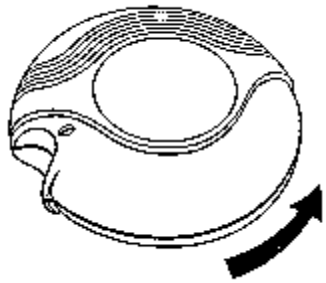
6.6 Special precautions for disposal and other handling

The Diskus is sealed in a foil overwrap. The overwrap provides moisture protection and should only be opened when you are ready to use it for the first time. Once opened the foil overwrap should be discarded.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

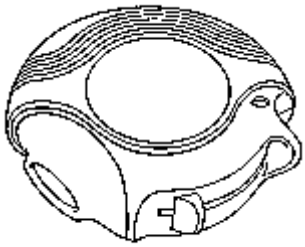
CLOSED:

When you take your Diskus out of its box and remove the foil overwrap, it will be in the closed position.



OPENED:

A new Diskus contains 60 doses of your medicine. The dose indicator tells you how many doses are left.



This Diskus contains 60 individually protected doses of your medicine, in powder form.

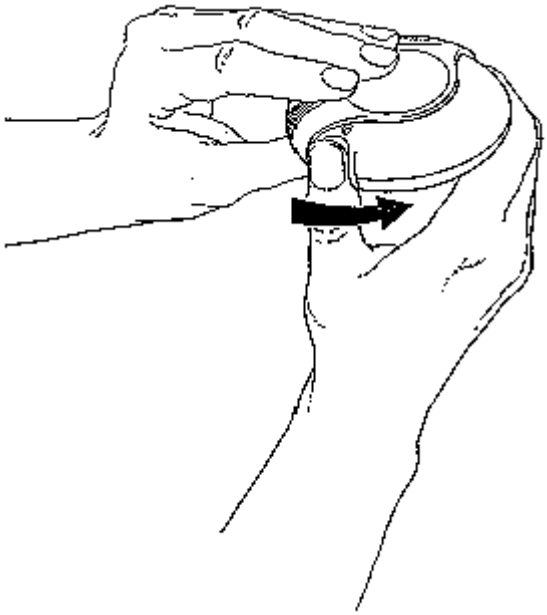
Each dose is accurately measured and hygienically protected. It requires no maintenance and no refilling. The dose indicator on top of your Diskus tells you how many doses are left. Numbers 5 to 0 will appear in RED, to warn you when there are only a few doses left.

The Diskus is easy to use. When you need a dose, just follow the five simple steps illustrated:
1. Open.
2. Slide.
3. Inhale.
4. Close.
5. Rinse.

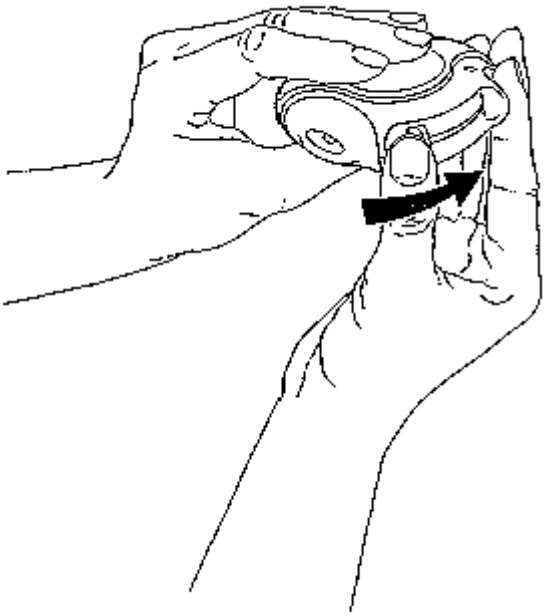
How your Diskus works:

Sliding the lever of your Diskus opens a small hole in the mouthpiece and unwraps a dose, ready for you to inhale it. When you close the Diskus, the lever automatically moves back to its original position, ready for your next dose when you need it. The outer case protects your Diskus when it is not in use.

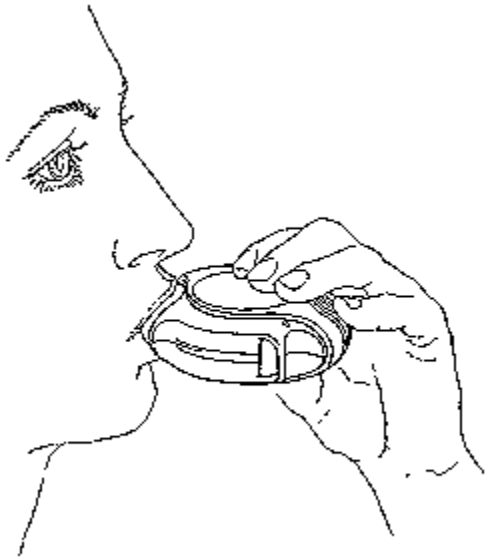
1. Open
To open your Diskus, hold the outer case in one hand and put the thumb of your other hand on the thumbgrip. Push your thumb away from you as far as it will go.



2. Slide
Hold your Diskus with the mouthpiece towards you. Slide the lever away from you, as far as it will go - until it clicks. Your Diskus is now ready to use. Every time the lever is pushed back, a dose is made available for inhaling. This is shown by the dose counter. Do not play with the lever as this releases doses which will be wasted.

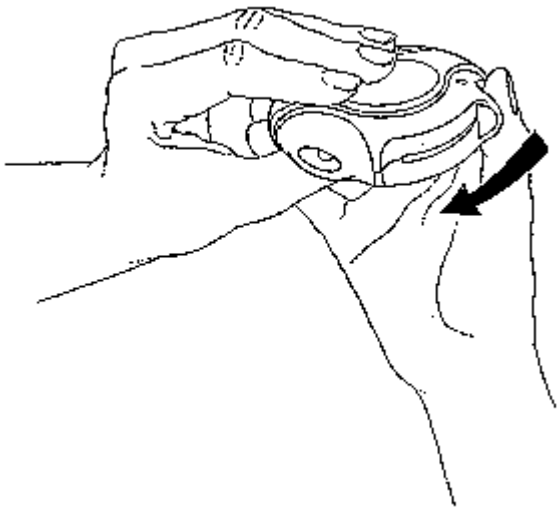


3. Inhale
Before you start to inhale the dose, read through this section carefully.
Hold the Diskus away from your mouth. Breathe out as far as is comfortable. Remember - never breathe into your Diskus.
Put the mouthpiece to your lips. Breathe in steadily and deeply - through the Diskus, not through your nose.
Remove the Diskus from your mouth.
Hold your breath for about 10 seconds, or for as long as is comfortable.



Breathe out slowly.
You may not be able to taste or feel the powder on your tongue, even if you have used the Diskus correctly.

4. Close
To close your Diskus, put your thumb in the thumbgrip, and slide the thumbgrip back towards you, as far as it will go.
When you close the Diskus, it clicks shut. The lever automatically returns to its original position and is reset. Your Diskus is now ready for you to use again.



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

If you have been instructed to take two inhalations you must close the Diskus and repeat stages 1 to 4.

REMEMBER:
- Keep your Diskus dry.
- Keep it closed when not in use.
- Never breathe into your Diskus.
- Only slide the lever when you are ready to take a dose.
- Do not exceed the stated dose.
- Keep out of reach of children.

7. MANUFACTURER

Glaxo Wellcome Production, Evreux, France

8. LICENSE HOLDER AND IMPORTER

GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva

9. LICENSE NUMBER

Flixotide Diskus 100 mcg:069-97-28478
Flixotide Diskus 250 mcg: 069-96-28479
Flixotide Diskus 500 mcg: 069-95-28480

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