Patient leaflet in accordance with the
Pharmacists' Regulations (Preparations) – 1986
The medicine is dispensed according to a physician's prescription only

Flixotide Diskus 50 mcg, Powder for Inhalation
Flixotide Diskus 100 mcg, Powder for Inhalation
Flixotide Diskus 250 mcg, Powder for Inhalation
Flixotide Diskus 500 mcg, Powder for Inhalation

Each dose contains 50 microgram fluticasone propionate
Each dose contains 100 microgram fluticasone propionate
Each dose contains 250 microgram fluticasone propionate
Each dose contains 500 microgram fluticasone propionate

A list of the additional ingredients is detailed in section 6.

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the physician or the pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. What is the medicine intended for?

Flixotide Diskus is used as a preventive treatment for asthma and to reduce the symptoms in chronic obstructive pulmonary disease (COPD).

Only the 250 mcg or 500 mcg strength Flixotide Diskus is suitable for the treatment of COPD.

Therapeutic group
Corticosteroids

Flixotide Diskus contains fluticasone propionate, which belongs to a group of medicines called corticosteroids (a group of synthetic hormones, often called steroids). Flixotide Diskus works by reducing swelling and irritation in the lungs. It has an anti-inflammatory action.

2. Before using the medicine

Do not use the medicine if:
- you are sensitive (allergic) to the active ingredient (fluticasone propionate), lactose (which contains milk protein) or to any of the other ingredients contained in this medicine, listed in section 6.

Special warnings regarding use of the medicine
Before beginning treatment with Flixotide Diskus, tell your physician or pharmacist if:
- you have ever been treated for tuberculosis (TB)

- you have ever had thrush in your mouth
- you are using Flixotide Diskus at the same time as taking steroid tablets. Also if you have just finished taking steroid tablets
- you have diabetes mellitus (Flixotide Diskus may increase your blood sugar level)
- Contact your physician if you experience blurred vision or other visual disturbances, which may be caused by cataract or glaucoma.

If you are not sure if any of these apply to you, talk to your physician or pharmacist before using Flixotide Diskus.

If you find that your medicine for treating sudden asthma attacks is not working as well as before, or you need to take it more than usual, refer to your physician.

If your breathing suddenly gets worse, this can be life-threatening, so seek medical advice urgently.

If your breathing or wheezing gets worse straight after using Flixotide Diskus, **stop using it and tell your physician immediately.**

Children and adolescents
Flixotide Diskus 250 micrograms and Flixotide Diskus 500 micrograms are not recommended for children 16 years of age and under.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the physician or the pharmacist.

In particular, tell your physician or pharmacist if you are taking any of the following:
- antiviral medicines called ‘protease inhibitors’ (such as ritonavir) or medicines that contain the active ingredient cobicistat, which may increase the effect of fluticasone propionate. Your physician may wish to monitor your condition carefully if you are taking these medicines.
- medicines used to treat fungal infections (such as ketoconazole).

If you are not sure if any of the above apply to you, talk to your physician or pharmacist before using Flixotide Diskus.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to become pregnant, ask your physician or pharmacist for advice before taking this medicine.

3. How should you use the medicine?

Always use the preparation according to the physician’s instructions.
You should check with the physician or the pharmacist if you are unsure regarding the dosage and treatment regimen of the preparation.

Flixotide Diskus comes in four different dosages. Your physician will decide which dosage you need. You should not increase or decrease your dosage without seeking medical advice.

Using this medicine
Flixotide Diskus should be inhaled using a special kind of inhaler called a Diskus.

- Make sure that you are able to and know how to use it properly.
- Instructions on how to use the Diskus inhaler are given in the **instructions for use** at the end of the leaflet.
- You may not be able to taste or feel the powder on your tongue, even if you have taken it correctly.
- **It may take a few days to a few months until this medicine starts to have an effect and it is very important that you use it regularly every day.** Do not stop treatment, even if you feel better, unless your physician tells you to stop.

The dosage and treatment regimen will be determined only by the physician. The usual dosage is generally:

Asthma
Children 4-16 years of age:
50 to 100 mcg, twice daily.
Adults and children over 16 years of age:
100 to 1,000 mcg, twice daily.

Chronic Obstructive Pulmonary Disease (COPD)
Adults
The usual dose is: 500 mcg twice daily.
Only the 250 mcg or 500 mcg strength Flixotide Diskus is suitable for the treatment of COPD.

Do not exceed the recommended dose.

Flixotide Diskus at a dosage of 250 mcg and 500 mcg are not recommended for children 16 years of age and under.

It is recommended that children being treated with steroids, including Flixotide Diskus, have their height checked regularly by their physician.

Your physician may give you a Flixotide Diskus of a higher strength if your dosage needs to be increased.

If you are using high dosages of inhaled steroids for a long time, you may sometimes need extra steroids, for example, during stressful circumstances, such as a road traffic accident or before an operation. Your physician may decide to give you extra steroid medicines during this time.

Patients who are taking high dosages of steroids, including Flixotide Diskus for a long time, must not stop taking their medicine suddenly without talking to their physician. Suddenly stopping treatment can

make you feel unwell and may cause symptoms such as vomiting, drowsiness, nausea, headache, tiredness, loss of appetite, low blood sugar level and convulsions.

If you have accidentally inhaled a higher dosage
If you use more than you should, **talk to your physician as soon as possible.**
If you have inhaled an overdose or if a child has accidentally inhaled the medicine, refer immediately to a physician or to a hospital emergency room and bring the package of the medicine with you.

If you forgot to use Flixotide Diskus
If you forgot to inhale this medicine at the scheduled time, do not inhale a double dose to compensate for a forgotten dose. Inhale the next dose at the usual time and consult the physician.
Persist with the treatment as recommended by the physician.

If you stop using Flixotide Diskus
Even if your condition improves, **do not stop treatment** with the medicine, unless told to do so by your physician.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the physician or the pharmacist.

4. Side effects

As with any medicine, use of Flixotide Diskus may cause side effects in some of the users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

If you notice any of the following serious side effects, stop using this medicine and talk to your physician straight away. You may need urgent medical treatment.
- allergic reactions (may affect up to 1 in 100 people) – the signs include skin rashes, redness, itching or wheals like nettle rash or hives.
- severe allergic reactions (may affect up to 1 in 10,000 people) – the signs include swelling of your face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, itchy rash, feeling weak, light-headed and collapse.
- your breathing or wheezing gets worse straight after using your inhaler.

Pneumonia (infection of the lung) in COPD patients (common side effect)
Tell your physician if you develop any of the following symptoms during the course of treatment with Flixotide Diskus – these could be signs of a lung infection:
- fever or chills
- increased mucus production, change in mucus colour

- increased cough or increased breathing difficulties

Additional side effects include:
Very common (may affect more than 1 in 10 people)
- thrush in the mouth and throat.

Common (may affect up to 1 in 10 people)
- hoarseness of voice
- bruising.

Side effects in your mouth and throat can be reduced by doing the following straight after inhaling the dose: brushing your teeth, rinsing your mouth or gargling with water and spitting it out. Tell your physician if you have problems with your mouth or throat, but do not stop treatment unless you are told to.

Rare (may affect up to 1 in 1,000 people)
- thrush (candidiasis) in the oesophagus.

Very rare (may affect up to 1 in 10,000 people)
- sleeping problems or feeling worried, restless, nervous, over-excited or irritable. These effects are more likely to occur in children.
- level of sugar (glucose) in your blood may be increased.
- the way steroids are produced by your body may change during the course of treatment with Flixotide Diskus (adrenal suppression). This is more likely to happen if you use high dosages for a long period of time. This may cause:
  - children and young people to grow more slowly.
  - 'Cushing's syndrome' – This happens when you have too much steroids in your body and it can cause reduced bone density and eye problems (such as cataracts and glaucoma, which is high pressure in the eye).

  Your physician will help stop this happening by making sure you use the lowest dose of steroids which controls your symptoms.

Frequency not known, but may also occur
- depression or aggression. These effects are more likely to occur in children.
- nosebleeds.
- blurred vision (which may be due to cataract or glaucoma).

Talk to your physician as soon as possible if:
- after 7 days of treatment with Flixotide Diskus your shortness of breath or wheezing does not get better, or gets worse.
- you or your child use high doses of inhaled steroids and are feeling unwell with symptoms such as tummy ache, sickness, diarrhoea, headache or drowsiness. This can happen during an infection such as a viral infection or stomach upset. It is important that your steroid therapy is not stopped suddenly as this could make your asthma worse and could also cause problems with the body's hormones.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult the physician.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il/

5. How to store the medicine?

- Flixotide Diskus is packaged 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.
- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
- Store in a dry place, below 30°C.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

6. Additional information

- In addition to the active ingredient the medicine also contains lactose monohydrate.
- **What does the medicine look like and what is the content of the package –**
  Flixotide Diskus contains a white to off-white powder. The Diskus inhaler is made out of plastic and contains foil strips with blisters containing the active substance fluticasone propionate and lactose. The blisters protect the powder for inhalation from environmental conditions.
  Each Diskus inhaler contains 60 doses.
- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: Glaxo Wellcome Production, Evreux, France.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health:
  Flixotide Diskus 50 mcg: 069-98-28477
  Flixotide Diskus 100 mcg: 069-97-28478
  Flixotide Diskus 250 mcg: 069-96-28479
  Flixotide Diskus 500 mcg: 069-95-28480

Instructions for use

- Your physician or pharmacist should show you how to use your Diskus inhaler. They should check from time to time that you are using the Diskus inhaler properly. Not using the Flixotide Diskus properly or as prescribed for you, may mean that the medicine will not help your asthma as it should.
- The Diskus inhaler holds blisters containing Flixotide as a powder.
- On top of the Diskus inhaler there is a dose counter which tells you how many doses are left. It counts down to 0. The numbers 5 to 0 will appear in

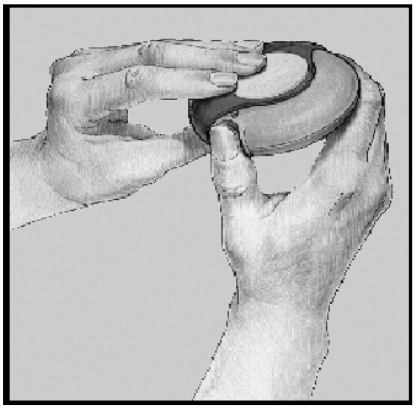
red to warn you when there are only a few doses left. Once the dose counter shows 0, your Diskus inhaler is empty.

Do not use your Diskus inhaler more often than the physician told you to. Tell your physician if your medicine does not seem to be working as well as usual, as your chest problem may be getting worse and you may need a different medicine.

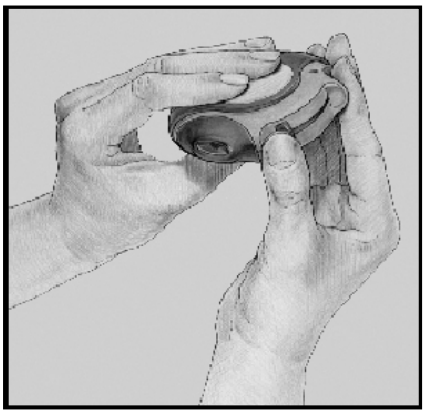
It is very important that you keep to your physician's instructions as to how many doses to take and how often to use your Diskus inhaler.

Using your Diskus inhaler

1 To open your Diskus inhaler, 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. You will hear a click.
This will open a small hole in the mouthpiece.



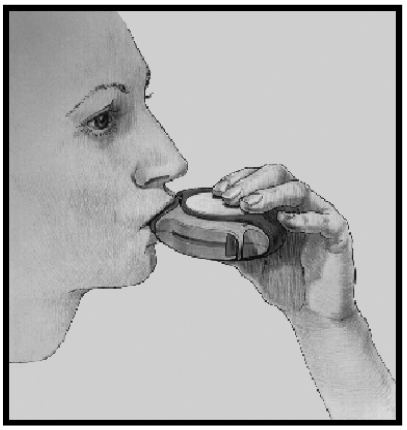
2 Hold your Diskus inhaler with the mouthpiece towards you.
You can hold it in either your right or left hand.
Slide the lever away from you as far as it will go. You will hear a click.
This places a dose of your medicine in the mouthpiece.



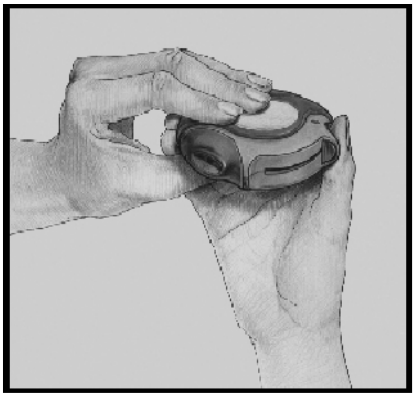
Every time the lever is pulled back a blister is opened inside and the powder is made ready for you to inhale. Do not play with the lever as this opens the blisters and wastes medicine.

3 Hold the Diskus inhaler away from your mouth, breathe out as far as is comfortable. Do not breathe into your Diskus inhaler. Do not breathe in again yet.

4 Put the mouthpiece to your lips; breathe in steadily and deeply through the Diskus inhaler with your mouth, not through your nose. Remove the Diskus inhaler 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.



5 To close the Diskus inhaler, slide the thumbgrip back towards you, as far as it will go. You will hear a click. The lever will return to its original position and is reset.
Your Diskus inhaler is now ready for you to use again.



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

Cleaning your Diskus inhaler
Wipe the mouthpiece of the Diskus inhaler with a dry tissue to clean it.

Revised in January 2021 according to MOH guidelines.