Teva Pharmaceuticals (Pty) Ltd.	**Product:** **Fluticasone OTC Teva** **Dosage Form:** Nasal spray **Strength**: Each metered nasal spray contains 50 µg fluticasone propionate.
Reg. No.: 48/21.5.1/0960	

PATIENT INFORMATION LEAFLET:

SCHEDULING STATUS:

S2

FLUTICASONE OTC TEVA (nasal spray)

Read all of this leaflet carefully because it contains important information for you.

FLUTICASONE OTC TEVA is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use **FLUTICASONE OTC TEVA** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **FLUTICASONE OTC TEVA** with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 3-4 days.

WHAT IS IN THIS LEAFLET:

1. WHAT FLUTICASONE OTC TEVA IS AND WHAT IT IS USED FOR

2. WHAT YOU NEED TO KNOW BEFORE YOU USE FLUTICASONE OTC TEVA

3. HOW TO USE FLUTICASONE OTC TEVA

4. POSSIBLE SIDE EFFECTS

5. HOW TO STORE FLUTICASONE OTC TEVA

6. CONTENTS OF THE PACK AND OTHER INFORMATION

1. WHAT FLUTICASONE OTC TEVA IS AND WHAT IT IS USED FOR:

FLUTICASONE OTC TEVA contains a medicine called fluticasone propionate. This belongs to a group of medicines called corticosteroids.

FLUTICASONE OTC TEVA has anti-inflammatory properties. When sprayed into your nose it will reduce swelling and irritation.

It is used for short term prevention and treatment of the symptoms of allergic rhinitis (e.g. hay fever) in adults and children over 12 years.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE FLUTICASONE OTC TEVA:

Do not use FLUTICASONE OTC TEVA:

- If you are hypersensitive (allergic) to fluticasone propionate or to any of the other ingredients of **FLUTICASONE OTC TEVA** (listed in **section 6**).

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Warnings and precautions:

Tell your doctor or healthcare provider before using FLUTICASONE OTC TEVA:

- if you are suffering or have recently suffered from an infection of the nasal airways
- if you have recently been treated with injected steroids, or you have been taking oral steroids for a long time.

FLUTICASONE OTC TEVA will usually control seasonal allergic rhinitis (hay fever) however if you are exposed to excessive amounts of pollen, additional therapy may be helpful for controlling other symptoms such as itching eyes. Please consult your doctor in such an event.

Inform your doctor if you are using **FLUTICASONE OTC TEVA** at high doses over a long period of time and you experience Cushing's syndrome (which has symptoms such as thinning of the skin, the apearance of pinkish stretch marks and weight gain particularly around the face, stomach, upper back and between the shoulders), adrenal suppression (which has symptoms such as tiredness, nausea, low blood pressure and dizziness) or behavioural effects such as hyperactivity, sleep problems, anxiety, depression or aggression (particularly in children).

Inform your doctor if you notice any slowed growth in children using **FLUTICASONE OTC TEVA**.

Contact your doctor if you experience blurred vision or other visual disturbances.

The full benefit of **FLUTICASONE OTC TEVA** may not be achieved until treatment has been administered for several days.

Other medicines and FLUTICASONE OTC TEVA:

Always tell your healthcare provider if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Tell your doctor if you are taking any of the following medicines:

- ritonavir (a protease inhibitor) or cobicistat which are anti-viral medicines used in HIV treatment, since they may increase the effects of **FLUTICASONE OTC TEVA** and your doctor may wish to monitor you carefully if you are taking these medicines
- ketoconazole or itraconazole (medicines used in the treatment of fungal infections)
- erythromycin (an antibiotic used to treat bacterial infections).

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking **FLUTICASONE OTC TEVA**.

Safety during pregnancy and breastfeeding has not been established.

Driving and using machines:

FLUTICASONE OTC TEVA may cause blurred vision therefore you should not drive or operate machinery until you know how **FLUTICASONE OTC TEVA** affects you.

FLUTICASONE OTC TEVA contains benzalkonium chloride solution:

FLUTICASONE OTC TEVA contains the preservative benzalkonium chloride solution (40 micrograms per delivered dose).

Benzalkonium chloride is an irritant and may cause skin reactions. If used for longer periods, the preservative benzalkonium chloride may cause nasal mucosa swelling (persistently congested nose).

3. HOW TO USE FLUTICASONE OTC TEVA:

Do not share **FLUTICASONE OTC TEVA** with any other person.

Always use **FLUTICASONE OTC TEVA** exactly as described in this leaflet or as your healthcare provider has

told you. Check with your healthcare provider if you are not sure.

- Only use in your nose, contact with eyes should be avoided.
- It may take a few days for **FLUTICASONE OTC TEVA** to work. Do not stop using **FLUTICASONE OTC TEVA** unless you are told to do so by a doctor.
- Use the spray every day as instructed.

The recommended dose is as follows:

Adults (including the elderly) and children over 12 years of age:

For the prevention and treatment of hay fever: two sprays into each nostril once a day, preferably in the morning.

If your hay fever symptoms do not improve despite using **FLUTICASONE OTC TEVA**, tell your doctor. He/she may be able to give you additional medicine to treat your symptoms.

Before you use your nasal spray:

FLUTICASONE OTC TEVA has a dust cap that protects the nozzle and keeps it clean – this must be taken off prior to using the spray and then replaced after use.

When your **FLUTICASONE OTC TEVA** is new, the bottle must be primed as follows:

1. Shake the bottle gently and then remove the dust cap.

2. Hold the bottle upright with your thumb under the bottle and your index finger and middle finger on either side of the nozzle. Ensure that the nozzle is pointing away from you when you do this.

3. Press down with fingers in order to pump the spray.



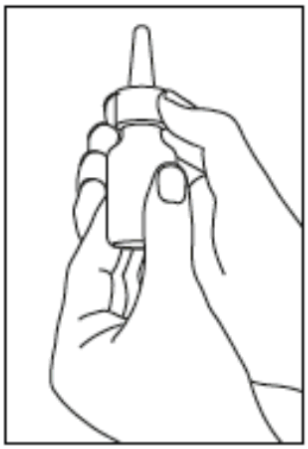
4. Repeat steps 2 and 3 until a further five times – the bottle is now primed.

If you have not used your **FLUTICASONE OTC TEVA** for 7 days, prime until a fine mist is produced. If, after attempting to prime the bottle, the spray still does not work and you think it may be blocked you may clean the spray using the following procedure:

Cleaning your nasal spray:

1. Remove the dust cap.

2. Pull the white collar upwards to remove the nozzle.



3. Place the nozzle and dust cap in warm water and soak for a few minutes, and then rinse by placing under a running tap.

4. Shake off the excess water and allow the nozzle and dust cap to dry in a warm (not hot) place.

5. Re-fit the nozzle.

6. 'Prime' the bottle as necessary by pumping the spray a few times until a fine mist is produced.

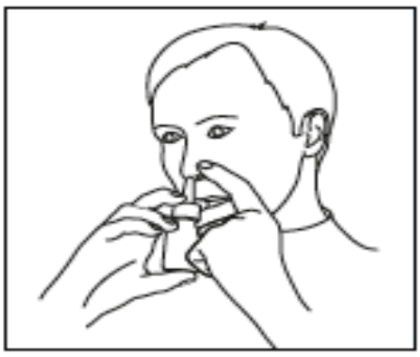
- You should clean your nasal spray at least once a week to stop it from getting blocked up. Additional cleaning is required when your spray becomes blocked.
- You must NEVER attempt to unblock or enlarge the spray hole with a pin or other sharp object because this will destroy the spray mechanism.

Using your nasal spray:

1. Shake the bottle and remove the dust cap.

2. Gently blow your nose.

3. Close one nostril by pressing your finger against it and place the nozzle of the spray in your other nostril. Tilt your head forward slightly so that the bottle is kept upright.



4. Breathe in slowly through your open nostril and, at the same time, press the collar of the nozzle down firmly with your fingers to squirt a spray of fine mist into your nostril.

5. Breathe out through your mouth. Repeat step 4 to take a second spray into the same nostril.

6. Remove the nozzle from this nostril and breathe out through your mouth.

7. Repeat steps 3 to 6 with your other nostril.



After using your nasal spray:

- Wipe the nozzle carefully with a clean tissue and put the dust cap back on.

If you use more FLUTICASONE OTC TEVA than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use FLUTICASONE OTC TEVA:

If you miss a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and take only a single dose as usual. Do not take a double dose to make up for forgotten individual doses.

If you stop using FLUTICASONE OTC TEVA:

Your nose symptoms may only start to improve after you have been using **FLUTICASONE OTC TEVA** for a few days; therefore it is very important that you use **FLUTICASONE OTC TEVA** regularly as instructed.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS:

FLUTICASONE OTC TEVA can have side effects.

Not all side effects reported for **FLUTICASONE OTC TEVA** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **FLUTICASONE OTC TEVA**, please consult your healthcare provider for advice.

If any of the following happens, stop taking **FLUTICASONE OTC TEVA** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- becoming very wheezy, coughing or having difficulty with breathing
- suddenly feeling weak or light-headed (which may lead to collapse or loss of consciousness)
- swelling around the face, mouth or tongue
- skin rashes or skin redness

These are all very serious side effects. If you have them, you may have had a serious reaction to **FLUTICASONE OTC TEVA**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- blurred vision or visual disturbances

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following which may occur frequently:

- headache, unpleasant taste, unpleasant smell
- nose bleeds, nasal dryness and irritation of the throat and nasal passages

Tell your doctor if you notice any of the following which may occur less frequently:

- glaucoma (raised pressure in the eye) and cataracts (clouding of the lens in the eye) have been reported following prolonged treatment
- nasal septal perforation (might make a whistling sound when you breathe and causes nose bleeds, trouble breathing, blocked nose)

Tell your doctor if you notice any of the following which may also occur:

- sores in the nose

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get any side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the '**6.04 Adverse Drug Reaction Reporting Form'**, found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of **FLUTICASONE OTC TEVA**.

5. HOW TO STORE FLUTICASONE OTC TEVA:

Store at or below 25 °C.

Discard 3 months after opening the bottle.

Store all medicines out of reach of children.

Do not use this medicine after the expiry date which is stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION:

What FLUTICASONE OTC TEVA contains:

The active substance is fluticasone propionate.

FLUTICASONE OTC TEVA: Each metered nasal spray contains 50 µg fluticasone propionate.

The other ingredients are: dispersible cellulose, glucose anhydrous, polysorbate 80, purified water, benzalkonium chloride solution (40 micrograms per delivered dose) and phenylethyl alcohol (0,25 % m/m).

Contains sugar (glucose anhydrous 5 mg per spray).

What FLUTICASONE OTC TEVA looks like and contents of the pack:

A white to off-white, opaque aqueous suspension for nasal inhalation via a metering pump.

Packaging material and pack size:

12 ml (60 sprays) or 15 ml (120 sprays) amber glass bottle (Type III) fitted with an atomising metering pump and a nasal adaptor with a dust cap, packed in an outer carton.

Each bottle will provide 60 or 120 sprays respectively with each spray delivering 50 microgram of fluticasone propionate in 100 mg of formulation through the nasal adaptor.

Pack sizes: 60 and 120 metered sprays.

Not all pack sizes may be marketed.

Holder of Certificate of Registration:

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