Applicant: Teva Pharmaceuticals (Pty) Ltd	Product name: Mysteva OTC (nasal spray, suspension) Each spray actuation delivers 27,5 micrograms of fluticasone furoate.
Registration date: 21.10.2025 **Reg No:** 58/21.5.1/0117	

PATIENT INFORMATION LEAFLET:

SCHEDULING STATUS: **S2**

MYSTEVA OTC (27,5 micrograms/spray, nasal spray suspension)

Fluticasone furoate

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

MYSTEVA OTC is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use MYSTEVA OTC carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share MYSTEVA OTC with any other person.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

What is in this leaflet:

1. WHAT MYSTEVA OTC IS AND WHAT IT IS USED FOR

2. WHAT YOU NEED TO KNOW BEFORE YOU USE MYSTEVA OTC

3. HOW TO USE MYSTEVA OTC

4. POSSIBLE SIDE EFFECTS

5. HOW TO STORE MYSTEVA OTC

6. CONTENTS OF THE PACK AND OTHER INFORMATION

1. WHAT MYSTEVA OTC IS AND WHAT IT IS USED FOR:

MYSTEVA OTC (fluticasone furoate) belongs to a group of medicines called glucocorticoids. MYSTEVA OTC works to decrease inflammation caused by allergy (rhinitis) and therefore reduce

symptoms of allergy.

MYSTEVA OTC nasal spray is a short-term treatment (less than 6 months) used to prevent or treat the symptoms of seasonal allergic rhinitis (certain times of the year) including stuffy, runny or itchy nose, sneezing and watery, itchy or red eyes, in adults and children aged 12 years and over.

Allergy symptoms can occur at specific times of the year and be caused by allergy to pollen from grass or trees (hay fever).

2. WHAT YOU NEED TO KNOW BEFORE YOU USE MYSTEVA OTC:

Do not use MYSTEVA OTC:

- if you are hypersensitive (allergic) to fluticasone furoate or any of the other ingredients of MYSTEVA OTC (listed in **section 6)**.

Warnings and precautions:

Take special care with MYSTEVA OTC:

- when taken for a long time, it may cause children to grow more slowly. MYSTEVA OTC should only be used in children older than 12 years and for less than 6 months. The doctor will check your child's height regularly, and make sure he or she is taking the lowest possible effective dose
- if you experience blurred vision or other visual disturbances such as glaucoma (increase in pressure in the eye) or cataracts (clouding of the lens of the eye), speak to your doctor.

Children:

MYSTEVA OTC is not recommended for use in children below 12 years of age.

Other medicines and MYSTEVA OTC:

Always tell your healthcare provider if you are taking any other medicine. (This includes all

complementary or traditional medicines).

Tell your doctor or pharmacist if you are taking:

- medicines for asthma
- any medicines containing a steroid. These may include some eczema creams, injections, tablets, nasal sprays and eye or nose drops
- ritonavir (a medicine used in the treatment of HIV)
- ketoconazole (a medicine used to treat fungal infections).

Pregnancy and breastfeeding:

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 using MYSTEVA OTC.

Do not use MYSTEVA OTC if you are pregnant or breastfeeding your baby.

Driving and using machines:

MYSTEVA OTC is unlikely to affect your ability to drive and use machines.

It is not always possible to predict to what extent MYSTEVA OTC may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which MYSTEVA OTC affects you.

MYSTEVA OTC contains benzalkonium chloride:

Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.

3. HOW TO USE MYSTEVA OTC:

Do not share medicines prescribed for you with any other person.

Always use MYSTEVA OTC exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

When to use MYSTEVA OTC:

- Use once a day.
- Use at the same time each day.

This will treat your symptoms throughout the day and night.

Some people will not feel the full effects until several days after first using MYSTEVA OTC. However, it is usually effective within 8 to 24 hours of use.

MYSTEVA OTC is sprayed into the nose as a fine mist.

Adults and children over 12 years of age:

The usual starting dose is 2 sprays in each nostril once every day.

Once symptoms are controlled you may be able to decrease your dose to 1 spray in each nostril once every day.

How to use the nasal spray:

MYSTEVA OTC has virtually no taste or smell. It is sprayed into the nose as a fine mist. Be careful not to get any spray into your eyes. If you do, rinse your eyes with water.

There is a ***step-by-step guide to using the nasal spray after Section 6*** of this leaflet. Follow the guide carefully to get the full benefit from using MYSTEVA OTC.

If you use more MYSTEVA OTC 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 MYSTEVA OTC:

Do not use a double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS:

MYSTEVA OTC can have side effects.

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

If any of the following happens, stop using MYSTEVA OTC and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting
- shortness of breath
- blurred vision or temporary changes to vision with long term use
- chest tightness causing difficulty in breathing.

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

Tell your doctor if you notice any of the following:

Frequent side effects include:

- minor nosebleeds – nosebleeds are more likely to occur if you use MYSTEVA OTC for more than 6 weeks continuously
- nasal ulceration - which may cause irritation or discomfort in your nose. You may also get streaks of blood when you blow your nose
- headache.

Less frequent side effects include:

- pain, burning, irritation, soreness or dryness in the inside of the nose
- small holes (perforations) in the ridge inside the nose that separates the nostrils.

Side effects with unknown frequency:

- slowing of growth in children.

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

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website. By reporting side effects, you can help provide more information on the safety of MYSTEVA OTC.

5. HOW TO STORE MYSTEVA OTC:

Store all medicines out of reach of children.

Store at or below 25 ºC. Do not refrigerate or freeze.

Store upright.

Always keep the cap on after use.

Do not use after the expiry date stated on the label/carton/bottle.

MYSTEVA OTC should be used within 2 months after first opening.

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 MYSTEVA OTC contains:

- The active substance is fluticasone furoate. Each spray delivers 27,5 micrograms of fluticasone furoate.
- The other ingredients are benzalkonium chloride 0,015 % w/w (preservative), disodium edetate, glucose, microcrystalline cellulose, carmellose sodium, polysorbate 80, water for injections.

What MYSTEVA OTC looks like and contents of the pack:

MYSTEVA OTC is a white nasal spray suspension contained in a 12 ml Type III amber glass bottle fitted with a metering spray pump, white nasal applicator (actuator) and a clear cap.

MYSTEVA OTC is available in one pack size: 1 bottle of 120 sprays.

Holder of Certificate of Registration:

Teva Pharmaceuticals (Pty) Ltd.

Maxwell Office Park

Magwa Crescent West

Waterfall City, Midrand

Gauteng, South Africa

2090

Tel. no: +27 11 055 0200

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STEP-BY-STEP GUIDE TO USING THE NASAL SPRAY:

What the nasal spray looks like:

The nasal spray comes in an amber glass bottle fitted with a spray pump, applicator and a protective cap. It will contain 120 sprays.

Five important things you need to know about using the nasal spray:

- MYSTEVA OTC comes in an amber glass bottle. If you need to check how much is left hold the nasal spray upright against a bright light. You will then be able to see the level through the bottle.
- When you **first use the nasal spray** you will need to **shake it vigorously** with the cap on for about 10 seconds. This is important as MYSTEVA OTC is a thick suspension that becomes liquid when you shake it well. It will only spray when it becomes liquid.
- The pump must be pressed all the way down, to release the mist through the nozzle.
- **Always keep the cap on the nasal spray** when you are not using it. The cap keeps the dust out, seals in the pressure and stops the nozzle from blocking up.
- **Never use a pin** or anything sharp to clear the nozzle. It will damage the nasal spray.

PREPARING THE NASAL SPRAY FOR USE:

You must prepare the nasal spray:

- before you use it for the first time
- if you have left the cap off for 5 days or the intranasal device has not been used for 30 days or more.

Preparing the nasal spray helps to make sure you always get the full dose of medicine. Follow these steps:

1. **Shake the nasal spray vigorously** with the cap on for about 10 seconds.
2. Remove the cap - see **Picture 1**.

Picture 1



3. Hold the nasal spray upright, then tilt and **point the nozzle away from you.**
4. Prime the pump by putting two fingers on either side of the spray pump and place your thumb on the bottom of the bottle. Press down and release the pump. Do this at least 10 times until it releases a fine mist of spray into the air - see **Picture 2**.

Picture 2



5. The nasal spray is now ready for use.

USING THE NASAL SPRAY:

1. **Shake the nasal spray** vigorously.

2. **Remove the cap.**
3. **Blow your nose** to clear your nostrils, then tilt your head forward a little bit.
4. Place the nozzle in one of your nostrils and close the other nostril with your finger - see P**icture 3**. Point the end of the nozzle slightly outwards, away from the centre ridge of your nose. This helps to get the medicine to the correct part of your nose.
5. **Press the pump** firmly all the way down, **while you breathe in through your nose.**

Picture 3



6. Take the nozzle out and **breathe out through your mouth.**
7. If your dose is 2 sprays in each nostril repeat steps 4 to 6.
8. Repeat steps 4 to 7 to treat the other nostril.
9. **Replace the cap on the nasal spray.**

CLEANING THE NASAL SPRAY:

After each use:

1. Wipe the nozzle and inside of the cap with a clean, dry tissue.
2. Do not use water to clean it.
3. Never use a pin or anything sharp on the nozzle.
4. Always replace the cap once you have finished.

If the nasal spray does not seem to be working:

- Check you still have medicine left. Look at the level through the bottle. If the level is very low there

may not be enough left to work the nasal spray.

- Check the nasal spray for damage.
- If you think the nozzle may be blocked, don't use a pin or anything sharp to clear it.
- Try to reset it by following the instructions under 'Preparing the nasal spray for use'.
- If it is still not working, or if it produces a jet of liquid, take the nasal spray back to the pharmacy to get advice.