PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

FLUTICASONE 50 µg NASAL SPRAY UNICORN

Each actuation contains 0,050 mg of fluticasone propionate.

Metered-dose nasal spray (aqueous suspension)

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

FLUTICASONE 50 µg NASAL SPRAY UNICORN is available without a doctor's prescription, for you to treat a condition. Nevertheless, you still need to use FLUTICASONE 50 µg NASAL SPRAY UNICORN carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share FLUTICASONE 50 µg NASAL SPRAY UNICORN with any other person.
- Ask your pharmacist if you need more information or advice.

What is in this leaflet:

1. What **FLUTICASONE 50 µg NASAL SPRAY UNICORN** is and what it is used for.
2. What you need to know before you take **FLUTICASONE 50 µg NASAL SPRAY UNICORN**.
3. How to take **FLUTICASONE 50 µg NASAL SPRAY UNICORN**.
4. Possible side effects.
5. How to store **FLUTICASONE 50 µg NASAL SPRAY UNICORN**.
6. Contents of the pack and other information.

1 What FLUTICASONE 50 µg NASAL SPRAY UNICORN is and what it is used for

FLUTICASONE 50 µg NASAL SPRAY UNICORN contains a corticosteroid, fluticasone propionate.

This medicine works by reducing inflammation, swelling and irritation in your nose.

FLUTICASONE 50 µg NASAL SPRAY UNICORN is used in adults and children over 12 years to prevent and treat:

- Inflammation in the lining of your nose (rhinitis) due to seasonal allergies, such as hay fever.
- Inflammation in the lining of your nose (rhinitis) due to year round (perennial) allergies, such as animal allergies.

FLUTICASONE 50 µg NASAL SPRAY UNICORN is for short term use in children 4 to 11 years old to prevent and treat:

- Inflammation in the lining of the nose due to seasonal allergies such as hay fever.
- Use of FLUTICASONE 50 µg NASAL SPRAY UNICORN to prevent and treat inflammation in the lining of the nose due to year round allergies such as animal fever has not been established.

2 What you need to know before you take FLUTICASONE 50 µg NASAL SPRAY UNICORN:

Do not take FLUTICASONE 50 µg NASAL SPRAY UNICORN:

If you are hypersensitive (allergic) to fluticasone proprionate or any of the other ingredients of FLUTICASONE 50 µg NASAL SPRAY UNICORN (see “WHAT FLUTICASONE 50 µg NASAL SPRAY UNICORN CONTAINS”).

Warnings and precautions

Take special care with FLUTICASONE 50 µg NASAL SPRAY UNICORN:

- If you have a nose infection. Your healthcare professional will first treat your infection before you start using FLUTICASONE 50 µg NASAL SPRAY UNICORN.
- If you are planning to have any type of surgery.
- Contact your doctor if you experience blurred vision or other visual disturbances.

Children and adolescents

- Do not administer FLUTICASONE 50 µg NASAL SPRAY UNICORN to children below 4

years of age.

Other medicines with FLUTICASONE 50 µg NASAL SPRAY UNICORN:

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines).

- Ritonavir and cobicistat-containing medicines (medicines used to assit with the management of HIV/AIDs).
- Ketoconazole and itraconazole (medicine used to treat fungal infections).
- Erythromycin (an antibiotic).

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 health care provider for advice before taking this medicine.

The safety and efficacy of FLUTICASONE 50 µg NASAL SPRAY UNICORN during pregnancy and lactation have not been established.

Driving and using machines

It is not always possible to predict to what extent FLUTICASONE 50 µg NASAL SPRAY UNICORN may interfere with your daily activities. Do not engage in the above activities until you are aware of the measure to which FLUTICASONE 50 µg NASAL SPRAY UNICORN affects you.

Important information about some of the ingredients of FLUTICASONE 50 µg NASAL SPRAY UNICORN:

This medicine contains 0,040 mg benzalkonium chloride in each 100 g actuation which is equivalent to 0,040 % w/w.

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

Benzalkonium chloride may cause wheezing and breathing difficulties (bronchospasm), especially if you have asthma.

3 How to use FLUTICASONE 50 µg NASAL SPRAY UNICORN:

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

Always use FLUTICASONE 50 µg NASAL SPRAY UNICORN exactly as your doctor or pharmacist has instructed you. You should check with your doctor or pharmacist if you are unsure.

FLUTICASONE 50 µg NASAL SPRAY UNICORN must be shaken before use.

FLUTICASONE 50 µg NASAL SPRAY UNICORN may only be administered intra-nasally.

Regular use is essential for full therapeutic benefit. Maximum relief may only be obtained after 3 to 4 days of treatment, as such the delay in effect should be explained to the patient.

Adults and children over 12 years of age:

The usual dose is two sprays in each nostril once a day (in the morning).

If required, your doctor may suggest two sprays in each nostril twice a day may be required.

Once symptoms are under control a maintenance dose of one spray once a day may be required.

The maximum daily dose is four sprays in each nostril.

Children aged 4 to 11 years:

The usual dose is one spray in each nostril once a day (in the morning).

The most you would use over 24 hours is normally 4 sprays (2 sprays per nostril).

Your doctor will tell you how long your treatment with FLUTICASONE 50 µg NASAL SPRAY UNICORN will last. Do not stop treatment early without consulting your doctor.

If you have the impression that the effect of FLUTICASONE 50 µg NASAL SPRAY UNICORN is too strong or too weak, tell your doctor or pharmacist.

Use in elderly:

The normal adult dose is applicable.

If you use more FLUTICASONE 50 µg NASAL SPRAY UNICORN than you should:

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

Tell your doctor if you use more FLUTICASONE 50 µg NASAL SPRAY UNICORN than you should.You may experience the side-effects (see POSSIBLE SIDE EFFECTS and Take special care with FLUTICASONE 50 µg NASAL SPRAY UNICORN if).

If you forget to use FLUTICASONE 50 µg NASAL SPRAY UNICORN:

It is important that you do not miss any doses. If you miss a dose of FLUTICASONE 50 µg NASAL SPRAY UNICORN, use it as soon as you remember. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule once daily.

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

If you stop using FLUTICASONE 50 µg NASAL SPRAY UNICORN

Do not stop using FLUTICASONE 50 µg NASAL SPRAY UNICORN unless your doctor tells you to do so. If you have further questions on the use of FLUTICASONE 50 µg NASAL SPRAY UNICORN, ask your doctor or pharmacist.

4 Possible side effects

FLUTICASONE 50 µg NASAL SPRAY UNICORN can have side effects.

Not all side effects reported for FLUTICASONE 50 µg NASAL SPRAY UNICORN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using FLUTICASONE 50 µg NASAL SPRAY UNICORN, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using FLUTICASONE 50 µg NASAL SPRAY UNICORN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Redness and itching of the skin.
- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Difficulty in breathing.
- Coughing and becoming very wheezy.
- Suddenly feeling weak or light-headed (which may lead to collapse or loss of consciousness).

These are all very serious side effects. If you have them, you may have had a serious reaction to FLUTICASONE 50 µg NASAL SPRAY UNICORN. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

The following side effects have frequently been reported:

- Headache.
- Unpleasant taste.
- Unpleasant smell.
- Nose bleeds.
- A dry or painful nose or throat.

Other side effects may include:

- Problems with your eyes such as pain due to pressure or blurred vision.
- Damage to your nose such as holes in the nasal septum or nose ulcers.

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

If you get side effects, talk to your doctor 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 SAHPRA website.

Side effects must also be reported to Unicorn Pharmaceuticals (Pty) Ltd to vigilance@unicornpharma.co.za.

By reporting side effects, you can help provide more information on the safety of FLUTICASONE 50 µg NASAL SPRAY UNICORN.

5 How to store FLUTICASONE 50 µg NASAL SPRAY UNICORN:

Store at or below 25 ºC.

Store in the original packaging.

Do not use FLUTICASONE 50 µg NASAL SPRAY UNICORN after the expiry date stated on the carton.

Return all unused FLUTICASONE 50 µg NASAL SPRAY UNICORN to your pharmacist.

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

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

6 Contents of the pack and other information

What FLUTICASONE 50 µg NASAL SPRAY UNICORN contains

The active ingredient is fluticasone propionate.

Preservatives: Benzalkonium chloride (50 %) 0,04 % *w/w*

Other ingredients include citric acid monohydrate, dextrose monohydrate, disodium hydrogen phosphate, microcrystalline cellulose and sodium carboxymethyl cellulose (Avicell RC 591) and polysorbate 80.

What FLUTICASONE 50 µg NASAL SPRAY UNICORN looks like and contents of the pack

Nasal Spray (aqueous suspension).

White homogenous aqueous suspension.

Holder of Certificate of Registration

Unicorn Pharmaceuticals (Pty) Ltd

4th Floor Offices, Block A, The District Building,

41 Sir Lowry Road, Woodstock, Cape Town,

Western Cape, 7925, Republic of South Africa

enquiries@unicornpharma.co.za

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