PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

ZILFONE NASAL SPRAY

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

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

- Keep this leaflet. You may need to read it again.
- Do not share ZILFONE NASAL SPRAY with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen.

1. WHAT ZILFONE NASAL SPRAY CONTAINS

Active ingredient:

Zilfone Nasal Spray contains the active substance mometasone furoate.

Zilfone Nasal Spray is a metered-dose, manual pump spray unit containing a suspension of mometasone furoate. Each metered dose pump actuation of Zilfone Nasal Spray delivers approximately 100 mg of mometasone furoate suspension, containing mometasone furoate monohydrate equivalent to 50 µg mometasone furoate.

The other ingredients are:

Citric acid monohydrate, glycerol, microcrystalline cellulose and carmellose sodium (Avicel RC-591), polysorbate 80, sodium citrate dihydrate and water for injection.

Preservative:

Benzalkonium chloride 0, 02 % *m/m.*

2. WHAT ZILFONE NASAL SPRAY IS USED FOR

ZILFONE NASAL SPRAY contains mometasone furoate, a cortisone-like medicine.

ZILFONE NASAL SPRAY is used in adults, adolescents and children between the ages of 2 and 11 years to relieve symptoms that may occur with seasonal allergic hay fever or year-round nasal allergies, including stuffiness (congestion) in the nose, discharge, itching and sneezing.

Your doctor may also prescribe ZILFONE NASAL SPRAY before the beginning of the pollen season to help prevent these symptoms.

3. BEFORE YOU USE ZILFONE NASAL SPRAY

Do not use ZILFONE NASAL SPRAY:

- if you are hypersensitive (allergic) to mometasone furoate or any of the other ingredients of ZILFONE NASAL SPRAY (see “WHAT ZILFONE NASAL SPRAY CONTAINS”).
- if you are pregnant or breastfeeding your baby.
- ZILFONE NASAL SPRAY is not recommended for children under 2 years.
- if you have an infection in your nose that is not being treated.
- if you have recently had an operation on your nose or have injured your nose. You should wait till it has healed before you start using ZILFONE NASAL SPRAY.

Take special care with ZILFONE NASAL SPRAY:

- if you have low immunity you should avoid coming into contact with anyone who has measles or chickenpox.
- if you have nose infection, injury or recent nose surgery. You should wait until the infection or wound is completely healed before you start using the ZILFONE NASAL SPRAY as it may affect the healing process.
- if you are using ZILFONE NASAL SPRAY for several months or longer and develop fungal

infection in your nose or pharynx.

- If you use ZILFONE NASAL SPRAY for more than 12 months, you should be examined for any changes in the lining of the nasal cavities.
- If you have a nasal perforation, which is a condition where the membrane that separates your nostrils, has a hole in.
- if you have tuberculosis (TB) or previously had TB.
- if you have fungal, bacterial, viral infection you should avoid using ZILFONE NASAL SPRAY.
- when giving ZILFONE NASAL SPRAY to children for a long period of time it may cause slowed growth rate in children. Contact your doctor if you think your child is not growing at a normal rate.
- if you experience moon-face, unusual hair growth in woman, buffalo hump, flushing, bruise easily, unusual red or purple spots on your skin, stretch marks and acne.
- if you are using other corticosteroid medicines, either by mouth or by injection.
- if you experience weakness, tiredness, loss of appetite, weight loss, nausea, vomiting, diarrhoea or stomach pain, this may be due to corticosteroid withdrawal symptoms due to being transferred from long-term use of ZILFONE NASAL SPRAY.
- if you develop increased pressure in the eye.
- If you experience any changes in your vision, e.g. blurred vision, for some time, you should see an eye specialist.
- If you suffer from nasal polyps, a condition where abnormal tissue growth cause small, mushroom / grape shapes, do not use ZILFONE NASAL SPRAY.
- If you are using ZILFONE NASAL SPRAY, you may find some relief by using concomitant therapy as well, e.g. eye drops to treat symptoms like itching eyes.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using ZILFONE NASAL SPRAY.

If you have been using medicine containing corticosteroids as in ZILFONE NASAL SPRAY, while being pregnant, please inform your doctor in order for them to monitor your baby carefully. This is to monitor for signs of a condition called hypoadrenalism, where symptoms may include weakness, vomiting or feeding problems.

Driving and using machinery:

- ZILFONE NASAL SPRAY may make you feel dizzy.
- Do not operate any tools or machines while you are using ZILFONE NASAL SPRAY or until you know how ZILFONE NASAL SPRAY affects you.

Using other medicines with ZILFONE NASAL SPRAY:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Do not use ZILFONE NASAL SPRAY if you are taking:

- Cimetidine (used to treat stomach ulcers).
- Nelfinavir or ritonavir (used to treat HIV).
- Clarithromycin or erythromycin (used to treat bacterial infections).
- Ketoconazole or fluconazole (used to treat fungal infections).
- Verapamil (used to treat high blood pressure).

4. HOW TO USE ZILFONE NASAL SPRAY

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

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

Shake well before use.

Seasonal or perennial allergic rhinitis

The usual dose in adults and adolescents:

2 sprays (50 mcg/spray) into each nostril once daily (total daily dose 200 mcg). Once symptoms are controlled, dose may be reduced to 1 spray into each nostril once daily (total daily dose 100 mcg) may be effective in some patients for maintenance.
If symptoms are not controlled, the dose may be increased to a maximum daily dose of 4 sprays into each nostril once daily (total daily dose of 400 mcg).
Dose must be reduced after symptoms have been controlled.

The usual dose in children between the ages of 2 and 11 years:

1 spray (50 mcg/ spray) into each nostril once daily (total daily dose 100 mcg). Administration to children should be done by an adult.

How to use the nasal spray:

If you are using the spray for the first time you need to 'prime' the bottle by pumping the spray 10 times until a fine mist is produced.

1. Gently shake the bottle and remove the dust cap as shown in figure 1.



2. Gently blow your nose.
3. Close one nostril and put the nozzle into the other nostril as shown in Figure 2.
4. Tilt your head forward slightly, keeping the bottle upright. Start to breathe in gently or slowly through your nose and whilst you are breathing in squirt a spray of fine mist into your nose by pressing down ONCE with your fingers.
5. Breathe out through your mouth. Repeat step 4 to inhale a second spray in the same nostril if applicable.
6. Remove the nozzle from this nostril and breathe out through the mouth.



7. Repeat step 3 to 6 again with the other nostril as seen in figure 3.



8. Wipe the nozzle clean after each use.

If you have not used the spray for 14 days or more, you need to “re-prime” the bottle by pumping the spray 2 times until a fine mist is produced.

If you use more ZILFONE NASAL SPRAY 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.

If you forget to take a dose of ZILFONE NASAL SPRAY:

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

5. POSSIBLE SIDE EFFECTS

ZILFONE NASAL SPRAY can have side effects.

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

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

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- Rash or itching.

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

Tell your doctor if you notice any of the following:

- Changes in the eye such as glaucoma (pressure in the eye/s) or cataracts (blurred vision).
- Discharge with itching of the eyes and crusty eyelids (signs of pinkeye), dry eyes.
- Severe upper stomach pain, often with nausea and vomiting (signs of acute pancreatitis).
- Joint pain when you put weight on it and while laying down signs of (avascular necrosis of bone).
- Nausea, headache, dizziness, vomiting, double or loss of vision and pain in the eye (signs of benign intracranial hypertension); blurred vision.
- No menstrual periods.
- Mental and neurological changes.
- Skin rash, skin thinning or excessive sweating.
- Painful sores in your nose, nose bleeds or blood in mucus.
- Irritation, dry and burning sensation in your nose.
- Runny nose or stuffy nose, fever or sore or irritation of the throat.
- Sneezing or cough.
- Dizziness.
- Headache.
- Nausea, vomiting, taste and smell disturbances.

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

6. STORING AND DISPOSING OF ZILFONE NASAL SPRAY

Store at or below 25 °C, away from heat.

Do not freeze.

Protect from light/moisture.

Do not store in a bathroom.

Do not use after the expiry date stated on the bottle.

Return all unused medicine to your pharmacist.

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

STORE ALL MEDICINES OUT OF THE REACH OF CHILDREN.

7. PRESENTATION OF ZILFONE NASAL SPRAY

Zilfone Nasal Spray is packed into 20 mℓ white HDPE plastic bottle with a screw. A nasal spray pump with nasal actuator, protection cap (white) and dip tube is fixed to the bottle neck. Bottles containing 17 g of nasal spray (120 metered sprays) or 18 g of nasal spray (140 metered sprays).

8. IDENTIFICATION OF ZILFONE NASAL SPRAY

Zilfone Nasal Spray: a white homogenous suspension.

9. REGISTRATION NUMBER

46/21.5.1/0491.490

10. NAME AND ADDRESS OF THE REGISTRATION HOLDER

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72 Steel Road

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11. DATE OF PUBLICATION:

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