PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

PROPRIETARY NAME, STRENGTH, AND PHARMACEUTICAL FORM:

CLENIL AQ (Nasal Spray)

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

CLENIL AQ Nasal Spray is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless you still need to use CLENIL AQ Nasal Spray carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share CLENIL AQ 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 or do not improve after 10 days.

1. WHAT CLENIL AQ NASAL SPRAY CONTAINS:

- The active substance is beclomethasone dipropionate.
- The other ingredients are dispersible cellulose (microcrystalline cellulose and carboxymethylcellulose), glucose monohydrate, polysorbate 20, purified water.
- Preservatives: benzalkonium chloride 0,027 % *m/v*; phenylethyl alcohol 0,255 % *m/v*.
- Contains sugar (glucose monohydrate 5100 mg/100 mℓ).

2. WHAT CLENIL AQ NASAL SPRAY IS USED FOR:

CLENIL AQ Nasal Spray helps to relieve the symptoms of seasonal allergic rhinitis (hay fever).

3. BEFORE YOU USE CLENIL AQ NASAL SPRAY:

Do not use CLENIL AQ Nasal Spray:

- If you are hypersensitive (allergic) to beclomethasone dipropionate or any of the other ingredients of CLENIL AQ Nasal Spray (see **"WHAT CLENIL AQ NASAL CONTAINS").**
- If you have a severe nasal infection, especially candidiasis (a yeast infection).
- If you suffer from recurrent nasal bleeding.
- If you have dormant or active tuberculosis (TB).
- If you are younger than 12 years of age.
- If you are pregnant or breastfeeding.

Take special care with CLENIL AQ Nasal Spray:

- If you've just had surgery or an injury to the nose, or ulcers in the nose.
- If you have a cold or sinus infection or another infection around the nose.
- If you have recently been switched over from an oral steroid, you may need to take supplementary oral steroids during a period of major stress or trauma.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking CLENIL AQ Nasal Spray.

Driving and using machinery:

CLENIL AQ Nasal Spray will not cause drowsiness, so you can still drive or use machines.

Important information about some of the ingredients of CLENIL AQ Nasal Spray:

CLENIL AQ Nasal Spray contains glucose monohydrate which may have an effect on the control of your blood sugar if you have diabetes mellitus. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take CLENIL AQ Nasal Spray.

Using other medicines with CLENIL AQ Nasal Spray:

Always tell your healthcare professional if you are taking any other medicine

(this includes complementary or traditional medicines).

Please consult your doctor, pharmacist or other healthcare professional, for advice, if you are taking:

- Other corticosteroid medicines – these may include some eczema creams, asthma-inhalers, tablets, injections, nasal sprays and eye or nose drops.
- Ritonavir – an anti-HIV medicine.
- Ketoconazole – used to treat fungal infections.
- Immunosuppressants like cyclosporin, methotrexate or cyclophosphamide as taking them together with CLENIL AQ Nasal Spray may mask symptoms of infections or may worsen the infection.

4. HOW TO USE CLENIL AQ NASAL SPRAY:

Always take CLENIL AQ Nasal Spray exactly as instructed. You should check with your doctor or pharmacist if you are unsure.

If you have the impression that the effect of CLENIL AQ Nasal Spray is too strong or too weak, tell your doctor or pharmacist.

- Use as little as you need to keep allergy symptoms under control. The usual dose for persons older than 12 years, is 2 sprays into each nostril, up to twice daily, or 1 spray into each nostril 3 or 4 times daily.
- Never use more than 2 sprays per nostril and do not use more than 4 sprays into each nostril in a day.

You may not get benefit straight away. It can take 3 or 4 days for the spray to have its full effect. Use the medicine regularly to obtain full therapeutic effect.

- If your allergy symptoms do not get any better in 10 days, stop using the spray and tell your doctor.
- Do not use CLENIL AQ Nasal Spray for more than 3 months continuously, except on the advice of a doctor.
- Do not swallow CLENIL AQ Nasal Spray.

Instructions for use:

1. Vigorously shake the bottle before each administration.
2. Before starting therapy, remove the protective cap and protective ring.
3. Spray the device a few times, until a visible puff of liquid is dispensed from the pump.
4. The device is now ready for use.
5. Blow your nose gently.
6. Close one nostril and put the nozzle in the other nostril. Tilt your head slightly forward keeping the nozzle in the upright position.
7. While breathing in, press down once to release a spray.
8. Breathe out through your mouth.
9. Repeat steps 6 and 7 for the other nostril.

After use:

1. Wipe the nozzle with a clean cloth and replace the cap.
2. Should the pump become obstructed during use, remove it from the bottle and rinse it carefully with lukewarm water.
3. Do not tamper with the opening of the device with sharp objects.

NOTE:

The first time you use CLENIL AQ Nasal Spray, you may sneeze a few times, because the lining of your nose is very sensitive. This is not likely to happen after the first few doses. The medicine will take effect within a few days.

Cleansing:

Your CLENIL AQ Nasal Spray should be cleaned at least once a week.

1. Push the nozzle upwards to detach from the bottle.
2. Wash the nozzle and dust cap in warm water. Shake off excess water and leave to dry in a warm place. Avoid excessive heat.
3. Replace the nozzle and dust cap.

4. If the nozzle becomes blocked, remove as above and soak in warm water. Rinse under a cold tap. Allow to dry and refit. Do not use a pin or other sharp object to unblock the nozzle.

If you use more CLENIL AQ Nasal Spray than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center.

If you forget to take CLENIL AQ Nasal Spray:

Inhale the dose as soon as you remember and any remaining doses for that day at recommended intervals. Do not take a double dose.

5. POSSIBLE SIDE EFFECTS:

CLENIL AQ Nasal Spray can have side effects.

Not all side effects reported for CLENIL AQ Nasal Spray are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CLENIL AQ Nasal Spray, please consult your doctor, pharmacist or other healthcare professional for advice.

The following side effects may occur:

Frequent:

Dryness and irritation of the nose and throat, transient burning, throat irritation and sneezing.

Less frequent:

- *Allergic reactions:*

Some people have allergies to medicines, and can be serious. If you get sudden swelling of the face or tongue, a rash, start wheezing or feeling faint after using the spray, stop using it and see a doctor straight away.

- *Nervous system disorders:*

Headaches, dizziness, sluggishness, light-headedness, an unpleasant taste or smell.

- *Administration site disorders - Nose injuries:*

Following the instructions on the product information leaflet will help you to avoid injuring your nose.

- *Respiratory disorders:*

Nose bleeding, dryness, inner crusting of the nose, ulcers inside the nose, runny nose, stuffy nose. If you get a bad nose bleed, that won't stop, and/or a painful nose after using the spray, stop using it and see a doctor straight away.

Sore throat, coughing, hoarseness.

- *Stomach disorders:*

Nausea or vomiting, stomach pain.

- *Infections:*

Yeast growth (candidiasis) in the nose or throat.

- *General:*

Chest pain, feeling unwell, mild sickness.

6. STORING AND DISPOSING OF CLENIL AQ NASAL SPRAY:

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C. Do not refrigerate.

Keep the container in the outer carton.

Keep the container tightly closed.

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

Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF CLENIL AQ NASAL SPRAY:

Clenil Aq Nasal Spray is supplied in amber plastic bottles with a special metering pump and nasal applicator.

Pack sizes of 200 doses are available.

8. IDENTIFICATION OF CLENIL AQ NASAL SPRAY:

A white opalescent suspension, homogenous or with a residue easily redispersible by gentle shaking.

9. REGISTRATION NUMBER:

34/21.5.1/0208

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Sandoz SA (Pty) Ltd[1]

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11. DATE OF PUBLICATION:

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