SCHEDULING STATUS: **S2**

PROPRIETARY NAME AND DOSAGE FORM:

CLENIL AQ (Nasal Spray)

COMPOSITION:

Each 100 mℓ suspension contains beclomethasone dipropionate 38,50 mg.

Each metered spray contains 50 µg beclomethasone dipropionate.

Other excipients: 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).

PHARMACOLOGICAL CLASSIFICATION:

A 21.5.1 Corticosteroids and analogues

PHARMACOLOGICAL ACTION:

Pharmacodynamic properties:

Beclomethasone dipropionate is a synthetic glucocorticoid which exerts a local anti-inflammatory action on the respiratory tract.

Pharmacokinetic properties:

Following nasal administration it is rapidly absorbed through the nasal mucosa with an onset of action usually ranging from 5 to 7 days and a half-life of 15 hours.

It is excreted predominantly in the faeces with small amounts being excreted in the urine.

INDICATIONS:

Prophylactic treatment of symptoms of seasonal allergic rhinitis (hay fever).

CONTRAINDICATIONS:

- Hypersensitivity to any of the ingredients.
- Severe nasal infection, especially candidiasis.
- Untreated fungal, bacterial or viral infections.
- History of recurrent nasal bleeding.
- Unhealed nasal wounds.
- Quiescent or active tuberculosis.

WARNINGS AND SPECIAL PRECAUTIONS:

Use of corticosteroids such as CLENIL AQ Nasal Spray is associated with a higher risk of infection.

Infections should be appropriately treated.

Care should be taken to avoid exposure to viral infections.

Systemic effects, including hypothalamic-pituitary-adrenal axis suppression, may occur when more than the recommended doses are used.

Patients using CLENIL AQ Nasal Spray for several months should be assessed periodically due to possible changes in the nasal mucosa. If localised infection develops in the nose or throat, appropriate treatment should be instituted or the medicine should be discontinued.

Growth retardation in children may occur.

If the patient is particularly sensitive or has recently used systemic adrenocorticoids prior to using the CLENIL AQ Nasal Spray, the patient may also be predisposed to hypercorticism.

Patients on high doses should be assessed periodically for signs of systemic absorption.

Infections of the nasal passage and para-nasal sinuses should be appropriately treated but do not constitute a specific contraindication to treatment with beclomethasone dipropionate nasal spray.

CLENIL AQ Nasal Spray withdrawal should always be gradual since an abrupt withdrawal or reduction of dosage of exogenous corticosteroids can produce a hypoadrenal state.

Replacement of systemic steroid treatment with intranasal therapy may unmask allergies such as allergic asthma or eczema previously controlled by the systemic drug. These allergic conditions should be appropriately treated.

CLENIL AQ Nasal Spray contains glucose monohydrate. Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take CLENIL AQ Nasal Spray.
CLENIL AQ Nasal Spray contains glucose monohydrate which may have an effect on the glycaemic control of patients with diabetes mellitus.

INTERACTIONS:

Significant medicinal interactions are unlikely to occur with the usual doses CLENIL AQ Nasal Spray. If used in high doses over a long time, systemic absorption may occur and subsequently some of the interactions seen with systemic corticosteroids.

PREGNANCY AND LACTATION:

Safety of CLENIL AQ Nasal Spray has not been established. It should not be administered to pregnant or lactating women.

DOSAGE AND DIRECTIONS FOR USE:

CLENIL AQ Nasal Spray is to be administered intra-nasally only.
Vigorously shake the bottle before each administration.
Before starting therapy, remove the protective cap and protective ring.
Spray the device a few times, until a visible stream of liquid is dispensed from the pump.
The device is now ready for use.

Should the pump become obstructed during use, remove it from the bottle and rinse it carefully with lukewarm water.

Do not tamper with the opening of the device with sharp objects.

Adults and children over 12 years:

Two sprays (100 µg) into each nostril twice daily or 1 spray (50 µg) into each nostril 3 or 4 times daily.

A total of 8 sprays daily should not be exceeded.

A maximum daily dose of 200 µg per nostril should not be exceeded.

Regular use is required to obtain full therapeutic benefit.

Medication should be discontinued if improvement is not evident after 10 days, and a doctor should be consulted.

SIDE EFFECTS:

Adverse events are listed below by system organ class and frequency according to the following convention:

Frequencies have been reflected as less frequent or more frequent as the exact frequencies are unknown.

Disorders:	***Frequent***	***Less frequently***
Infections and infestations		Candidiasis – pharyngeal or nasal, oesophageal candidiasis, fever.
Immune system		Hypersensitivity reactions (e.g. rashes, oedema of the face or tongue, bronchospasm, watery eyes).
Endocrine		Adrenal insufficiency, hypercorticism, hyperglycaemia.

Psychiatric		Aggressive reactions, anxiety, behavioural changes, depression, psychosis, restlessness.
Nervous system		Dizziness, headache, lethargy, lightheadedness, unpleasant taste, unpleasant smell, syncope.
Eye		Cataracts, ocular hypertension.
Vascular		Palpitations or tachycardia, hypertension, rectal haemorrhage.
Respiratory, thoracic & mediastinal	Transient burning, nasal dryness, throat dryness, nasal irritation, throat irritation, sneezing, cough.	Epistaxis, inner nose crusting, sore throat, ulceration nasal mucosa, cough, hoarseness, rhinorrhoea, nasal congestion, rhinitis, bronchospasm, pneumonia, dyspnoea, nasal septum perforation.
Gastrointestinal		Nausea or vomiting, stomach pain, gastroenteritis.

Skin and subcutaneous tissue		Rash, urticaria, numbness.
Renal and urinary		Cystitis.
Reproductive system and breast		Menstrual changes.
General disorders and administration site disorders		Nasal septum perforation chest pain, malaise, loss of taste or smell.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF TREATMENT:

Symptoms of chronic overdosing include acneform lesions; Cushing's syndrome (fullness or rounding of face) and menstrual changes.

Withdraw medicine gradually to avoid precipitation of acute adrenal insufficiency.

Treatment should be symptomatic and supportive.

IDENTIFICATION:

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

PRESENTATION:

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.

STORAGE INSTRUCTIONS:

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

KEEP OUT OF THE REACH OF CHILDREN.

REGISTRATION NUMBER:

34/21.5.1/0208

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Sandoz SA (Pty) Ltd[1]

72 Steel Road

Spartan

Kempton Park, 1619

South Africa

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

Date of registration: 27 November 2001

Date of most recent approval of professional information: 25 November 2011

Additional countries registration details:

Country	*Product name*	*Scheduling status (or Category of distribution)*	*Registration number*
Namibia	Clenil AQ	NS1	05/21.5.1/0285
Zambia	Clenil AQ	POM	039/062

ATC Code: R01AD01 – Corticosteroids

Name and address of manufacturer:

Chiesie Farmaceutici S.p.A

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