PROFESSIONAL INFORMATION LEAFLET: MONACT AQUEOUS NASAL SPRAY

SCHEDULING STATUS S2

1. NAME OF THE MEDICINE

Monact™ 50 micrograms **Aqueous Nasal Spray**

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each metered dose pump actuation of MONACT delivers approximately 100 mg of mometasone furoate suspension, containing 50 micrograms of mometasone furoate (as mometasone furoate monohydrate).
MONACT contains 0,02 mg of benzalkonium chloride per actuation (0,02 % *m/m*) as preservative.
For the full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Metered dose aqueous nasal spray.
White homogenous aqueous suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

MONACT is indicated for use in adults, adolescents and children between the ages of 2 and 11 years to treat the symptoms of seasonal allergic or perennial allergic rhinitis.
In patients who have a history of moderate to severe symptoms of seasonal allergic rhinitis, prophylactic treatment with MONACT is recommended prior to the anticipated start of the pollen season.

4.2 Posology and method of administration

After initial priming of the MONACT nasal pump (usually 10 actuations, until a uniform spray is observed), each actuation delivers approximately 100 mg of mometasone furoate suspension, containing mometasone furoate monohydrate equivalent to 50 mcg mometasone furoate.

Seasonal or Perennial Allergic Rhinitis

- Adults (including geriatric patients) and adolescents:

The usual recommended dose for prophylaxis and treatment is 2 sprays (50 micrograms /spray) into each nostril once daily (total dose 200 micrograms). Once symptoms are controlled, dose reduction to 1 spray into each nostril (total dose 100 micrograms) may be effective in some patients for maintenance.
If symptoms are inadequately controlled, the dose may be increased to a maximum daily dose of 4 sprays into each nostril once daily (total dose 400 micrograms).

Dose reduction is recommended following control of symptoms.

- Children between the ages of 2 and 11 years:

The usual recommended dose is 1 spray (50 micrograms /spray) into each nostril once daily (total dose 100 micrograms).
Administration to young children should be aided by an adult.

Method of administration

Prior to administration of the first dose, shake container well and actuate pump 10 times (until a uniform spray is obtained). If pump is not used for 14 days or longer, re-prime the pump with 2 sprays until a uniform spray is observed, before next use. Shake container well
before each use.

4.3 Contraindications

- Known hypersensitivity to mometasone furoate or to any excipients of MONACT listed under Section 6.1.
- Pregnancy and lactation (see Section 4.6).
- Children under 2 years, as safety and efficacy have not been demonstrated.

4.4 Special warnings and precautions for use

MONACT should not be used in the presence of untreated localized infection involving the nasal mucosa. Due to inhibitory effect of corticosteroids on wound healing, patients who have experienced recent nasal surgery or trauma should not use a nasal corticosteroid until healing has occurred.

Patients using MONACT over several months or longer should be examined periodically for possible changes in the nasal mucosa. If localized fungal infection of the nose or pharynx develops, discontinuance of MONACT therapy or appropriate treatment may be required. Persistence of nasopharyngeal irritation may require cessation of treatment with MONACT.

MONACT should be used with caution, if at all, in patients with active or quiescent tuberculosis infections of the respiratory tract, or in untreated fungal, bacterial, systemic viral infections or ocular herpes simplex.

Patients who are transferred from long-term administration of systemically active corticosteroids to MONACT require careful attention. Systemic corticosteroid withdrawal in such patients may result in adrenal insufficiency for a number of months until recovery of hypothalamic-pituitary-adrenal HPA axis function. If these patients exhibit signs and symptoms of adrenal insufficiency, systemic corticosteroid administration should be resumed and other modes of therapy and appropriate measures instituted.

During transfer from systemic corticosteroids to MONACT some patients may experience symptoms of withdrawal from systemically active corticosteroids (e.g., joint and/or muscular pain, lassitude, and depression initially) despite relief from nasal symptoms and will require encouragement to continue MONACT therapy. Such transfer may also unmask pre-existing allergic conditions, such as allergic conjunctivitis and eczema, previously suppressed by systemic corticosteroid therapy.

Systemic effects of nasal corticosteroids may occur, particularly at high doses prescribed for prolonged periods. These effects are much less likely to occur than with oral corticosteroids and may vary in individual patients and between different corticosteroid preparations. Potential systemic effects may include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, cataract, glaucoma and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children).

Patients receiving corticosteroids who are potentially immunosuppressed should be warned of the risk of exposure to certain infections (e.g., chickenpox, measles) and of the importance of obtaining medical advice if such exposure occurs.

Following the use of intranasal aerosolised corticosteroids, instances of nasal septum perforation or increased intraocular pressure have been reported very rarely.

Visual disturbance may be reported with systemic and topical (including intranasal, inhaled and intraocular) corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

It is recommended that the height of children receiving prolonged treatment with nasal corticosteroids is regularly monitored. If growth is slowed, therapy should be reviewed with the aim of reducing the dose of nasal corticosteroids if possible, to the lowest dose at which effective control of symptoms is maintained. In addition, consideration should be given to referring the patient to a paediatric specialist.

Treatment with higher than recommended doses may result in clinically significant adrenal suppression. If there is evidence for higher than recommended doses being used, then additional systemic corticosteroid cover should be considered during periods of stress or elective surgery.

Although MONACT will control the nasal symptoms in most patients, the concomitant use of appropriate additional therapy may provide additional relief of other symptoms, particularly ocular symptoms.

MONACT is not recommended in case of nasal septum perforation (see Section 4.8).
Clinical studies revealed that epistaxis occurred at a higher incidence compared to placebo. Epistaxis was generally self-limiting and mild in severity (see Section 4.8).

MONACT contains benzalkonium chloride which may cause nasal irritation.

4.5 Interaction with other medicines and other forms of interaction

Concomitant administration with loratadine did not appear to affect plasma concentrations of loratadine or its major metabolite. Mometasone furoate plasma concentrations were not detectable.

Mometasone furoate is metabolised by CYP3A4.
Co-administration with strong CYP3A4 inhibitors (e.g. ketoconazole, itraconazole, clarithromycin, ritonavir, cobicistat-containing medicines) may lead to increased plasma concentrations of corticosteroids and potentially increase the risk for systemic corticosteroid side effects. Consider the benefit of co-administration versus the potential risk of systemic corticosteroid effects, in which case patients should be monitored for systemic corticosteroid side effects.

4.6 Pregnancy and lactation

Pregnancy

MONACT **should not be used** during pregnancy (see Section 4.3).
There are no adequate or well-controlled studies in pregnant women.
Infants born of mothers who received corticosteroids during pregnancy should be observed carefully for hypoadrenalism.

Lactation

MONACT should not be used during lactation (see Section 4.3).

Fertility

There are no clinical data concerning the effect of mometasone furoate on fertility. Animal studies have shown reproductive toxicity, but no effects on fertility.

4.7 Effects on ability to drive and use machines

Dizziness may occur following administration of MONACT, which may affect the ability to drive and use machines (see Section 4.8).

4.8 Undesirable effects

System organ class	**MONACT Side effects**
Infections and infestations	
Frequent:	Pharyngitis, upper respiratory tract infection
Immune system disorders	
Frequency not known:	Hypersensitivity including anaphylactic reactions, angioedema, bronchospasm and dyspnoea
Nervous system disorders	
Frequent:	Headache
Frequency not known:	Dizziness
Eye disorders	
Frequency not known:	Glaucoma, increased intraocular pressure, cataracts, blurred vision, central serous chorioretinopathy, conjunctivitis, dry eyes
Respiratory, thoracic and mediastinal disorders	
Frequent:	Epistaxis, nasal burning sensation, nasal irritation, nasal ulceration, sneezing
Frequency not known:	Nasal septum irritation/perforation, rhinitis, sinusitis, cough, rhinorrhoea
Gastrointestinal disorders	
Frequent:	Throat irritation
Frequency not known:	Disturbances of taste and smell, nausea
Skin and sub-cutaneous tissue disorders	
Frequency not known:	Skin rash

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions. Suspected adverse reactions can be reported to Actor Pharma

(Pty) Ltd via email: pharmacovigilance@actorpharma.co.za or telephonically on 011 312 3812. Suspected adverse reactions can also be reported to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

Due to the negligible (≤ 0,1 %) systemic bioavailability of intranasal mometasone furoate, overdose is unlikely to require any therapy other than observation, followed by initiation of the appropriate prescribed dosage. Inhalation or oral administration of excessive doses of corticosteroids may lead to suppression of HPA axis function.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A.21.5.1. Corticosteroids and analogues

Mometasone furoate is a topical glucocorticosteroid with local anti-inflammatory properties.

5.2 Pharmacokinetic properties

Absorption

Mometasone furoate, administered as an aqueous nasal spray, has a systemic bioavailability of < 1 % in plasma, using a sensitive assay with a lower quantitation limit of 0,25 pg/ml.

Distribution

Not applicable as mometasone is poorly absorbed via the nasal route.

Biotransformation

The small amount that may be swallowed and absorbed undergoes extensive first-pass hepatic metabolism.

Elimination

Metabolites are excreted in urine and bile.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride
Citric acid monohydrate
Glycerol
Polysorbate 80
Sodium carboxymethyl cellulose
Sodium citrate dihydrate
Water for injection

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years. Use within 2 months of first use.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

MONACT Aqueous Nasal Spray is supplied in a 26 ml HDPE crimp on bottle with a metered dose micro pump, nasal adaptor and transparent dust protective cap. Each bottle contains 18 g (140 actuations) of nasal spray suspension and is enclosed in an outer is carton.

6.6 Special precautions for disposal

None

7. HOLDER OF CERTIFICATE OF REGISTRATION

Actor Pharma (Pty) Ltd[1]
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8. REGISTRATION NUMBER(S)

47/21.5.1/1223

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

14 September 2021

10. DATE OF REVISION OF THE TEXT

29 September 2021

[1] Company Registration number.: 2008/008787/07

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