1. NAME OF THE MEDICINAL PRODUCT

Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation) contains Mometasone Furoate 50 mcg/actuation.

0.05173mg of Mometasone Furoate Monohydrate is equivalent to 0.05mg of Mometasone Furoate

Excipient(s) with known effect

This medicine contains less than 1 mmol sodium (23 mg) per actuation, that is to say essentially 'sodium-free'.

This medicine contains 0.02 mg benzalkonium chloride in each actuation. Benzalkonium chloride may cause irritation or swelling inside the nose, specially if used for a long time.

3. PHARMACEUTICAL FORM

Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation) is a white colored, homogenous, viscous suspension filled in a white opaque high density 20 ml polyethylene (HDPE) bottle fitted with a crimp on metered dose pump & with a white opaque actuator & transparent dust cap.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation) is indicated for use in adults, adolescents and children between the ages of 3 and 11 years to treat the symptoms of seasonal or perennial rhinitis.

In patients who have a history of moderate to severe symptoms of seasonal allergic rhinitis, prophylactic treatment with Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation) is recommended two to four weeks prior to the anticipated start of the pollen season.

Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation) is also indicated for the treatment of nasal polyps in patients 18 years of age and older.

Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation) is indicated for the treatment of symptoms associated with acute rhinosinusitis in patients 12 years of age and older without signs or symptoms of severe bacterial infection.

4.2 Posology and method of administration

Posology
Method of administration

After initial priming of the Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation) pump (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 micrograms mometasone furoate. If the spray pump has not been used for 14 days or longer, it should be reprimed with 2 actuations, until a uniform spray is observed, before next use.

Shake container well before each use.

Seasonal allergic or perennial rhinitis: Adults (including geriatric patients) and adolescents: The usual recommended dose for prophylaxis and treatment is two sprays (50 micrograms/spray) in each nostril once daily (total dose 200 micrograms). Once symptoms are controlled, dose reduction to one spray in each nostril (total dose 100 micrograms) may be effective for maintenance.

If symptoms are inadequately controlled, the dose may be increased to a maximum daily dose of four sprays in each nostril once daily (total dose 400 micrograms). Dose reduction is recommended following control of symptoms.

Clinically significant onset of action occurs as early as 12 hours after the first dose.

Children between the ages of 3 and 11 years: The usual recommended dose is one spray (50 micrograms/spray) in each nostril once daily (total dose 100 micrograms).

Administration to young children should be aided by an adult.

Nasal polyposis: Adults (including geriatric patients) and adolescents 18 years of age and older: The usual recommended dose for polyposis is two sprays (50 micrograms/spray) in each nostril twice daily (total daily dose of 400 mcg). Once symptoms are adequately controlled, dose reduction to two sprays in each nostril once daily (total daily dose 200 mcg) is recommended.

Acute Rhinosinusitis: Adults (including geriatric patients) and adolescents 12 years of age or older: The usual recommended dose for acute rhinosinusitis is two actuations (50 micrograms/actuation) in each nostril twice daily (total daily dose of 400 micrograms). If no improvement is seen after 15 days of twice daily administration, alternative therapies should be considered. If symptoms worsen during treatment, the patient should be advised to consult their physician.

4.3 Contraindications

Hypersensitivity to any ingredients of Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation); severe nasal infection especially candidiasis; persons with hemorrhagic diathesis or with a history of recurrent nasal bleeding.

4.4 Special warnings and precautions for use

Mometasone Furoate aqueous nasal spray should not be used in the presence of untreated localized infection involving the nasal mucosa.

Because of the 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.

Following 12 months of treatment with Mometasone Furoate aqueous nasal spray, there was no evidence of atrophy of the nasal mucosa; also, mometasone furoate tended to reverse the nasal mucosa closer to a normal histologic phenotype. As with any long-term

treatment, patients using Mometasone Furoate aqueous nasal spray 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 Mometasone Furoate aqueous nasal spray therapy or appropriate treatment may be required. Persistence of nasopharyngeal irritation may be an indication for discontinuing Mometasone Furoate aqueous nasal spray.
Mometasone Furoate aqueous nasal spray should be used with caution, if at all, in patients with active or quiescent tuberculous infections of the respiratory tract, or in untreated fungal, bacterial, systemic viral infections or ocular herpes simplex.

There is no evidence of hypothalamic-pituitary-adrenal (HPA) axis suppression following prolonged treatment with Mometasone Furoate aqueous nasal spray. However, patients who are transferred from long-term administration of systemically active corticosteroids to Mometasone Furoate aqueous nasal spray require careful attention. Systemic corticosteroid withdrawal in such patients may result in adrenal insufficiency for a number of months until recovery of 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.

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.
In a placebo-controlled clinical trial in which pediatric patients were administered Mometasone Furoate aqueous nasal spray 100 micrograms daily for one year, no reduction in growth velocity was observed.

Safety and efficacy of Mometasone Furoate aqueous nasal spray for the treatment of nasal polyposis in children and adolescents less than 18 years of age have not been studied.
During transfer from systemic corticosteroids to Mometasone Furoate aqueous nasal spray, 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 Mometasone Furoate aqueous nasal spray therapy. Such transfer may also unmask pre-existing allergic conditions such as allergic conjunctivitis and eczema, previously suppressed by systemic corticosteroid therapy.

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 aerosolized 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 of visual disturbances 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.

Acute Rhinosinusitis
If signs or symptoms of severe bacterial infection are observed (such as fever, persistent severe unilateral facial/tooth pain, orbital or peri-orbital facial swelling, or worsening of symptoms after an initial improvement), the patient should be advised to consult their physician immediately.
Safety and efficacy of Mometasone Furoate aqueous nasal spray for the treatment of symptoms of rhinosinusitis in children under 12 years of age have not been studied.

General Nasal Corticosteroid Warning: Systemic effects of nasal corticosteroids may occur, particularly at high doses prescribed for prolonged periods. Growth retardation has been reported in children receiving nasal corticosteroids at licensed doses.

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 corticosteroid, if possible, to the lowest dose at which effective control of symptoms is maintained. In addition, consideration should be given to referring patient to a paediatric specialist.

4.5 Interaction with other medicinal products and other forms of interaction

Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation) has been administered concomitantly with loratadine with no apparent effect on plasma concentrations of loratadine or its major metabolite. In these studies mometasone furoate plasma concentrations were not detectable using an assay with a LLOQ of 50 pg/ml. The combination therapy was well tolerated.

Mometasone furoate is metabolized by CYP3A4.

Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin, ritonavir, cobicistat-containing products) may lead to increased plasma concentrations of corticosteroids and potentially increase the risk for systemic corticosteroid side-effects. Consider the benefit of coadministration versus the potential risk of systemic corticosteroid effects, in which case patients should be monitored for systemic corticosteroid side-effects.

4.6 Fertility, pregnancy and lactation

There are no adequate or well controlled studies in pregnant women.
As with other nasal corticosteroid preparations, Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation) should be used in pregnant women, nursing mothers or women of childbearing age only if the potential benefit justifies the potential risk to the mother, fetus or infant. Infants born of mothers who received corticosteroids during pregnancy should be observed carefully for hypoadrenalism.

4.7 Effects on ability to drive and use machines

The effect of Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation) on ability to drive or use machinery has not been studied.

4.8 Undesirable effects

Seasonal allergic or perennial rhinitis: Treatment-related local adverse events reported in clinical studies in adult patients and adolescents include headache (8%), epistaxis (i.e., frank bleeding, blood-tinged mucus, and blood flecks (8%), pharyngitis (4%), nasal burning (2%), nasal irritation (2%), and nasal ulceration (1%), which are typically observed with use of a corticosteroid nasal spray. Epistaxis was generally self-limiting and mild in severity, and occurred at a higher incidence compared to placebo (5%), but at a comparable or lower incidence compared to the active control nasal corticoids studied (up to 15%). The incidence of all other effects was comparable with that of placebo.

In the pediatric population, the incidence of adverse effects, e.g., headache (3%), epistaxis (6%), nasal irritation (2%) and sneezing (2%) was comparable to placebo (4%). Rarely, immediate hypersensitivity reactions (e.g. bronchospasm, dyspnea) may occur after intranasal administration of mometasone furoate monohydrate. Very rarely,

anaphylaxis and angioedema have been reported.

Disturbances of taste and smell have been reported very rarely.

Nasal Polyposis: In patients treated for nasal polyposis, the overall incidence of adverse events was comparable to placebo and similar to that observed for patients with allergic rhinitis.

Acute Rhinosinusitis: In patients treated for acute rhinosinusitis, the overall incidence of adverse events was comparable to placebo and similar to that observed for patients with allergic rhinitis.

Post-Market
The following additional adverse reactions have been reported in post-marketing use: vision blurred.

4.9 Overdose

Because the systemic bioavailability of Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation) is <1% (using a sensitive assay with a lower quantitation limit of 0.25 pg/ml), overdose is unlikely to require any therapy other than observation, followed by initiation of the appropriate prescribed dosage.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

In studies utilizing nasal antigen challenge, Mometasone Furoate aqueous nasal spray has shown anti-inflammatory activity in both the early- and late- phase allergic responses. This has been demonstrated by decreases (vs placebo) in histamine and eosinophil activity and reductions (vs baseline) in eosinophils, neutrophils, and epithelial cell adhesion proteins.

In clinical trials with nasal polyposis, Mometasone Furoate aqueous nasal spray showed significant improvement when compared to placebo in the clinically relevant endpoints of congestion, nasal polyp size and loss of smell.

5.2 Pharmacokinetic properties

Mometasone furoate, administered as a nasal spray, has a systemic bioavailability of <1% in plasma, using a sensitive assay with a lower quantitation limit (LLOQ) of 0.25 pg/ml. Mometasone furoate suspension is very poorly absorbed from the gastrointestinal tract, and the small amount that may be swallowed and absorbed undergoes extensive first-pass metabolism prior to excretion mostly as metabolites in the bile and to a limited extent in the urine.

5.3 Preclinical safety data

Not applicable for generic product

5.4 Shelf life

Please refer to the expiry date on the bottle or outer carton.
Discard after 60 days from first opening.

5.5 Storage

Keep in a dry place, below 30°C. Protect from light. Store away from heat. Do not freeze.

5.6 Nature and contents of container

Bexomet Aqueous Nasal Spray (Mometasone Furoate 50 mcg/actuation):
Each bottle contains 140 metered sprays.
Each actuation delivers 50 mcg of Mometasone Furoate BP.

6. MANUFACTURED BY

Beximco Pharmaceuticals PLC
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