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Alvogen

โมเมทาโซนฟูโรเอต ความแรง 50 ไมโครกรัม ต่อ 1 สูด ชนิดพ่นจมูก ชื่อการค้า Momensa (โมเมนซ่า)

Alvogen

1. ยานี้คืออะไร

1.1 ยานี้มีชื่อว่าอะไร

- ยานี้ชื่อว่า โม-เม-ทา-โซน-ฟู-โร-เอต (Mometasone Furoate) เป็นยาในกลุ่มสเตียรอยด์

1.2 ยานี้ใช้เพื่ออะไร

- รักษาอาการคัดจมูกที่เกิดจากภูมิแพ้ ในผู้ใหญ่ และเด็กที่อายุมากกว่า 3 ปี
- รักษาโรคริดสีดวงจมูก ในผู้ใหญ่อายุ 18 ปี ขึ้นไป

2. ข้อควรรู้ก่อนใช้ยา

2.1 <u>ห้ามใช้</u>ยานี้เมื่อไหร่

⊗ เคยแพ้ยานี้หรือส่วนประกอบของยานี้
⊗ มีภาวะติดเชื้อที่ยังไม่ได้รับการรักษา
⊗ อยู่ในช่วงการพักหลังผ่าตัดจมูก หรือจมูกได้รับบาดเจ็บ

2.2 ข้อควรระวังเมื่อใช้ยานี้

- **ให้ปรึกษาแพทย์หรือเภสัชกร ในกรณีต่อไปนี้**

- ใช้ยา สมุนไพร หรืออาหารเสริมอื่นอยู่
- โรควัณโรค
- โรคติดเชื้อ
- โรคเป็นถุงพังผืด
- ใช้ยาในกลุ่มคอร์ติโคสเตียรอยด์
- มีอาการระคายเคืองจมูกหรือลำคอ
- ตั้งครรภ์ วางแผนตั้งครรภ์ หรืออยู่ระหว่างให้นมบุตร

"สอบถามแพทย์หรือเภสัชกร ถ้าท่านไม่แน่ใจว่ามีภาวะดังกล่าวหรือไม่"

3. วิธีใช้ยา

3.1 ขนาดและวิธีใช้

- **ควรใช้ยาตามคำแนะนำของแพทย์หรือเภสัชกร เท่านั้น** เพราะขนาดและระยะเวลาในการใช้ยานี้ขึ้นกับชนิดและความรุนแรงของโรค
- เด็กอายุมากกว่า 12 ปีและผู้ใหญ่ ใช้ข้างละ 2 สูด วันละ 1 ครั้ง หรือตามแพทย์สั่ง
- เด็กอายุ 3-12 ปี ใช้ข้างละ 1 สูด วันละ 1 ครั้ง หรือตามแพทย์สั่ง
- ศึกษาวิธีใช้เพิ่มเติมจากท้ายเอกสาร

3.2 หากลืมพ่นยาควรทำอย่างไร

- พ่นยาทันทีที่นึกขึ้นได้ แต่ถ้าใกล้กับการใช้ยาครั้งต่อไป ให้ข้ามไป โดยไม่ต้องเพิ่มขนาดยาเป็น 2 เท่า

3.3 ถ้าพ่นยานี้เกินขนาดที่แนะนำ ควรทำอย่างไร

- ให้สังเกตอาการอย่างใกล้ชิด หากมีอาการผิดปกติที่รุนแรง ให้รีบนำส่งโรงพยาบาลทันที

4. ข้อควรปฏิบัติระหว่างใช้ยา

- หากต้องพ่นยาข้างละสองครั้ง ควรพ่นยาข้างละ 1 ครั้งให้ครบทั้งสองข้างก่อน แล้วจึงเริ่มพ่นยาครั้งที่สองให้ครบทั้งสองข้าง
- ใช้ยาอย่างต่อเนื่อง สม่ำเสมอตามที่แพทย์สั่ง
- พบแพทย์ตามนัดเพื่อติดตามผลการรักษา
- ห้ามหยุดยาเอง ยกเว้นได้รับคำแนะนำจากแพทย์

5. อันตรายที่อาจเกิดจากยา

5.1 อาการที่ต้อง<u>หยุดยา</u>แล้ว<u>รีบไปพบแพทย์ทันที</u>

- ลมพิษ บวมที่ใบหน้า เปลือกตา ริมฝีปาก
- หน้ามืด เป็นลม แน่นหน้าอก หายใจลำบาก
- ผื่นแดง ตุ่มผอง ผิวหนังหลุดลอก มีจ้ำตามผิวหนัง

5.2 อาการที่<u>ไม่จำเป็นต้องหยุดยา</u> แต่ถ้ามีอาการรุนแรงให้ไปพบแพทย์

- ปวดหัว
- จาม
- เลือดกำเดาไหล
- เจ็บคอ หรือเจ็บโพรงจมูก
- มีแผลในจมูก
- ติดเชื้อในทางเดินหายใจ

"ไม่<u>จำเป็น</u>ต้องหยุดยา แต่ถ้ามีอาการ<u>รุนแรง</u>ให้ไป<u>พบแพทย์</u>"

6. ควรเก็บยานี้อย่างไร

- เก็บยาในบรรจุภัณฑ์เดิมตามที่ได้รับมา
- เก็บยาในที่แห้ง อย่าให้โดนแสงโดยตรง หรือในที่ชื้น ควรเก็บที่อุณหภูมิไม่เกิน 30 องศาเซลเซียส
- ห้ามเก็บยาในช่องแช่แข็ง
- เก็บยาให้พ้นมือเด็ก
- ยามีอายุ 2 เดือนนับจากเปิดใช้ครั้งแรก

7. ลักษณะและส่วนประกอบของยา

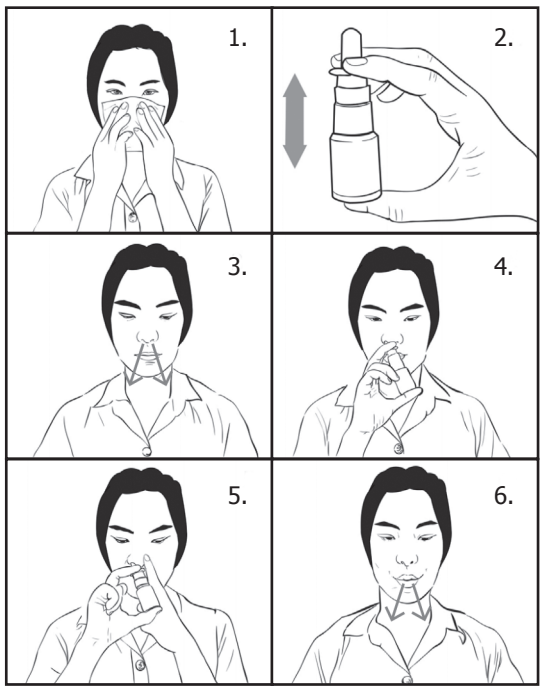
- **ลักษณะยา** น้ำแขวนตะกอนสีขาวถึงสีขาวออกเหลือง สำหรับพ่นจมูก
- **ตัวยาสำคัญ** โมเมทาโซนฟูโรเอต (Mometasone Furoate)
- **ส่วนประกอบอื่น ๆ** ได้แก่ เบนซาลโคเนียม คลอไรด์ (benzalkonium chloride) กลีเซอรอล (glycerol) โพลีซอร์เบต 80 (polysorbate 80) ไมโครคริสทัลลีนเซลลูโลส (microcrystalline cellulose) คาร์เมลโลสโซเดียม (carmellose) ซิตริกแอซิดโมโนไฮเดรต (citric acid monohydrate) โซเดียมซิเตรท (sodium citrate) น้ำ (purified water)

ผู้ผลิต Farmea ประเทศฝรั่งเศส
ผู้นำเข้าและผู้แทนจำหน่าย
บริษัท อัลโวเจน (ประเทศไทย) จำกัด
เอกสารนี้ปรับปรุงครั้งล่าสุดเมื่อ 23 ธันวาคม 2563
<u>ศึกษาข้อมูลยาเพิ่มเติมทางเว็บไซต์ของ อย.</u>
http://www.fda.moph.go.th/sites/oss/Pages/Main.aspx
http://ndi.fda.moph.go.th

เอกสารนี้เป็นข้อมูลโดยย่อ หากมีข้อสงสัยให้ปรึกษาแพทย์หรือเภสัชกร

ข้อแนะนำวิธีการใช้ยาพ่นจมูก

1. กำจัดน้ำมูกออกจากจมูกให้หมด (ถ้ามี) แล้วล้างมือให้สะอาด
2. เขย่าขวดยา เปิดฝาครอบขวดยา และถอดปลอกพลาสติกที่ครอบขวดยาออก
3. นั่งตัวตรง ตั้งศีรษะตรง กัมศีรษะเล็กน้อย หายใจออกช้า ๆ
4. ใช้มือข้างที่ถนัดจับขวดยา สอดปลายที่พ่นยาเข้าไปในรูจมูกข้างใดข้าง หนึ่งลึกประมาณ 1 เซนติเมตร โดยให้ปลายหลอดชี้ไปทางผนังด้านข้างจมูก และห้าม ออกจากผนังกั้นช่องจมูก
5. ปิดรูจมูกข้างที่เหลือโดยกดเบา ๆ บนปีกจมูกด้วยนิ้วมืออีกข้าง สูดหายใจเข้าช้า ๆ พร้อมกับกดที่พ่นยาเข้าจมูก
6. จากนั้นกลั้นหายใจประมาณ 2-3 วินาทีและหายใจออกทางปาก
7. พ่นยาในรูจมูกอีกข้างโดยปฏิบัติตามขั้นตอนข้อ 4-6 (ถ้าต้องพ่นยา เข้าจมูกทั้งสองข้าง)
8. เช็ดทำความสะอาดปลายที่พ่นยา ปิดฝาเก็บให้เรียบร้อย



ที่มา คู่มือทักษะตามเกณฑ์ความรู้ความสามารถทางวิชาชีพของผู้ประกอบวิชาชีพเภสัชกรรม (สมรรถนะร่วม) พ.ศ. 2562

MOMENSA 50 µg/actuation nasal spray, suspension
MOMETASONE FUROATE

Alvogen

1. NAME OF THE MEDICINAL PRODUCT

MOMENSA (50 µg/actuation nasal spray, suspension)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each delivered dose contains mometasone furoate monohydrate equivalent to 50 micrograms of mometasone furoate anhydrous.

<u>Excipient with known effect:</u>
This medicinal product contains 20 micrograms of benzalkonium chloride per actuation.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Nasal spray, suspension.
White to off-white viscous suspension with pH between 4.3 and 4.9.

4. Clinical particulars

4.1 Therapeutic indications

MOMENSA nasal spray is indicated for use in adults and children 3 years of age and older to treat the symptoms of seasonal allergic or perennial rhinitis.

MOMENSA nasal spray is indicated for the treatment of nasal polyps in adults 18 years of age and older.

4.2 Posology and method of administration

After initial priming of the MOMENSA nasal spray pump, each actuation delivers approximately 100 mg of mometasone furoate suspension, containing mometasone furoate monohydrate equivalent to 50 micrograms mometasone furoate.

<u>Posology</u>

<u>Seasonal Allergic or Perennial Rhinitis</u>
Adults (including older patients) and children 12 years of age and older: The usual recommended dose is two actuations (50 micrograms/actuation) in each nostril once daily (total dose 200 micrograms). Once symptoms are controlled, dose reduction to one actuation 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 actuations in each nostril once daily (total dose 400 micrograms). Dose reduction is recommended following control of symptoms.

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

Mometasone furoate demonstrated a clinically significant onset of action within 12 hours after the first dose in some patients with seasonal allergic rhinitis; however, full benefit of treatment may not be achieved in the first 48 hours. Therefore, the patient should continue regular use to achieve full therapeutic benefit.
Treatment with MOMENSA nasal spray may need to be initiated some days before the expected start of the pollen season in patients who have a history of moderate to severe symptoms of seasonal allergic rhinitis.

<u>Nasal Polyposis</u>
The usual recommended starting dose for polyposis is two actuations (50 micrograms/actuation) in each nostril once daily (total daily dose of 200 micrograms). If after 5 to 6 weeks symptoms are inadequately controlled, the dose may be increased to a daily dose of two sprays in each nostril twice daily (total daily dose of 400 micrograms). The dose should be titrated to the lowest dose at which effective control of symptoms is maintained. If no improvement in symptoms is seen after 5 to 6 weeks of twice daily administration, the patient should be re-evaluated and treatment strategy reconsidered.

Efficacy and Safety studies of mometasone furoate for the treatment of nasal polyposis were four months in duration.

<u>Paediatric population</u>

Seasonal Allergic Rhinitis and Perennial Rhinitis
The safety and efficacy of mometasone furoate in children under 3 years of age have not been established.

Nasal Polyposis
The safety and efficacy of mometasone furoate in children and adolescents under 18 years of age have not been established.

<u>Method of administration</u>

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

Shake container well before each use. The bottle should be discarded after the labelled number of actuations or within 2 months of first use.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

MOMENSA nasal spray should not be used in the presence of untreated localised infection involving the nasal mucosa, such as herpes simplex.

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.

4.4 Special warnings and precautions for use

<u>Immunosuppression</u>
Mometasone furoate 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, or systemic viral infections.

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.

<u>Local Nasal Effects</u>
Following 12 months of treatment with mometasone furoate in a study of patients with perennial rhinitis, 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. Nevertheless, patients using mometasone furoate over several months or longer should be examined periodically for possible changes in the nasal mucosa. If localised fungal infection of the nose or pharynx develops, discontinuance of mometasone furoate nasal spray therapy or appropriate treatment may be required. Persistence of nasopharyngeal irritation may be an indication for discontinuing mometasone furoate nasal spray.

MOMENSA nasal spray is not recommended in case of nasal septum perforation (see section 4.8).

In clinical studies, epistaxis occurred at a higher incidence compared to placebo. Epistaxis was generally self-limiting and mild in severity (see section 4.8).

MOMENSA nasal spray contains benzalkonium chloride which may cause nasal irritation.

<u>Systemic Effects of Corticosteroids</u>
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).

Following the use of intranasal corticosteroids, instances of increased intraocular pressure have been reported (see section 4.8).

<u>Visual disturbance</u>
Visual disturbance may be reported with systemic and topical 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.

Patients who are transferred from long-term administration of systemically active corticosteroids to mometasone furoate 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, or symptoms of withdrawal (e.g., joint and/or muscular pain, lassitude, and depression initially) despite relief from nasal symptoms, systemic corticosteroid administration should be resumed and other modes of therapy and appropriate measures instituted. Such transfer may also unmask pre-existing allergic conditions, such as allergic conjunctivitis and eczema, previously suppressed by systemic corticosteroid therapy.

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.

Nasal Polyps
The safety and efficacy of mometasone furoate nasal spray has not been studied for use in the treatment of unilateral polyps, polyps associated with cystic fibrosis, or polyps that completely obstruct the nasal cavities.

Unilateral polyps that are unusual or irregular in appearance, especially if ulcerating or bleeding, should be further evaluated.

Effect on Growth in Paediatric Population
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 the patient to a paediatric specialist.

Non-nasal Symptoms
Although MOMENSA nasal spray 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.

4.5 Interaction with other medicinal products and other forms of interaction

(See section 4.4 Special warnings and special precautions for use with systemic corticosteroids.)

A clinical interaction study was conducted with loratadine. No interactions were observed.

Co-treatment with CYP3A inhibitors, including cobicistat-containing products, is expected to increase the risk of systemic side-effects. The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects.

4.6 Fertility, pregnancy and lactation

Pregnancy
There is no or limited amount of data from the use of mometasone furoate in pregnant women.

Studies in animals have shown reproductive toxicity (see section 5.3). As with other nasal corticosteroid preparations, MOMENSA nasal spray should not be used in pregnancy unless the potential benefit to the mother justifies any potential risk to the mother, foetus or infant. Infants born of mothers who received corticosteroids during pregnancy should be observed carefully for hypoadrenalism.

Breastfeeding
It is unknown whether mometasone furoate is excreted in human milk. As with other nasal corticosteroid preparations, a decision must be made whether to discontinue breast-feeding or to discontinue/abstain from MOMENSA nasal spray therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

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 (see section 5.3).

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Summary of the safety profile
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 when compared to the active control nasal corticosteroids studied (up to 15%) as reported in clinical studies for allergic rhinitis. The incidence of all other adverse events was comparable with that of placebo. In patients treated for nasal polyposis, the overall incidence of adverse events was similar to that observed for patients with allergic rhinitis.

Systemic effects of nasal corticosteroids may occur, particularly when prescribed at high doses for prolonged periods.

Tabulated list of adverse reactions
Treatment related adverse reactions (≥1%) reported in clinical trials in patients with allergic rhinitis or nasal polyposis and post-marketing regardless of indication are presented in Table 1. Adverse reactions are listed according to MedDRA primary system organ class. Within each system organ class, adverse reactions are ranked by frequency. Frequencies were defined as follows: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100). The frequency of post-marketing adverse events is considered as "not known (cannot be estimated from the available data).

Table 1: Treatment-related adverse reactions reported by system organ class and frequency

	Very common	Common	Not known
Infections and infestations		Pharyngitis Upper respiratory tract infection†	
Immune system disorders			Hypersensitivity including anaphylactic reactions, angioedema, bronchospasm, and dyspnoea
Nervous system disorders		Headache	
Eye disorders			Glaucoma Increased intraocular pressure Cataracts Vision, blurred (see also section 4.4)
Respiratory, thoracic and mediastinal disorders	Epistaxis*	Epistaxis Nasal burning Nasal irritation Nasal ulceration	Nasal septum perforation
Gastrointestinal disorders		Throat irritation*	Disturbances of taste and smell

*recorded for twice daily dosing for nasal polyposis
†recorded at uncommon frequency for twice daily dosing for nasal polyposis

Paediatric population
In the paediatric population, the incidence of recorded adverse events in clinical studies, e.g., epistaxis (6%), headache (3%), nasal irritation (2%) and sneezing (2%) was comparable to placebo.

4.9 Overdose

Symptoms
Inhalation or oral administration of excessive doses of corticosteroids may lead to suppression of HPA axis function.

Management
Because the systemic bioavailability of mometasone furoate nasal spray is <1%, 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

Pharmacotherapeutic group: Decongestants and Other Nasal Preparations for Topical Use-Corticosteroids, ATC code: R01A D09

Mechanism of action
Mometasone furoate is a topical glucocorticosteroid with local anti-inflammatory properties at doses that are not systemically active.

It is likely that much of the mechanism for the anti-allergic and anti-inflammatory effects of mometasone furoate lies in its ability to inhibit the release of mediators of allergic reactions. Mometasone furoate significantly inhibits the release of leukotrienes from leucocytes of allergic patients.
In cell culture, mometasone furoate demonstrated high potency in inhibition of synthesis and release of IL-1, IL-5, IL-6 and TNFα; it is also a potent inhibitor of leukotriene production. In addition, it is an extremely potent inhibitor of the production of the Th2 cytokines, IL-4 and IL-5, from human CD4+ T-cells.

Pharmacodynamic effects
In studies utilising nasal antigen challenge, mometasone furoate 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 28% of the patients with seasonal allergic rhinitis, mometasone furoate nasal spray demonstrated a clinically significant onset of action within 12 hours after the first dose. The median (50%) onset time of relief was 35.9 hours.

Paediatric population
In a placebo-controlled clinical trial in which paediatric patients (n=49/group) were administered mometaone furoate 100 micrograms daily for one year, no reduction in growth velocity was observed.

There are limited data available on the safety and efficacy of mometasone furoate in the paediatric population aged 3 to 5 years, and an appropriate dosage range cannot be established. In a study involving 48 children aged 3 to 5 years treated with intranasal mometasone furoate 50, 100 or 200 µg/day for 14 days, there was no significant differences from placebo in the mean change in plasma cortisol level in response to the tetracosactrin stimulation test.

The European Medicines Agency has waived the obligation to submit the results of studies with the reference medicinal product containing mometasone furoate in all subsets of the paediatric population in seasonal and perennial allergic rhinitis (see section 4.2 for information on paediatric use).

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
Absorbed mometasone furoate is extensively metabolized and the metabolites are excreted in urine and bile.

5.3 Preclinical safety data

No toxicological effects unique to mometasone furoate exposure were demonstrated. All observed effects are typical of this class of compounds and are related to exaggerated pharmacologic effects of glucocorticoids.

Preclinical studies demonstrate that mometasone furoate is devoid of androgenic, antiandrogenic, estrogenic or antiestrogenic activity but, like other glucocorticoids, it exhibits some antiuterotrophic activity and delays vaginal opening in animal models at high oral doses of 56 mg/kg/day and 280 mg/kg/day.

Like other glucocorticoids, mometasone furoate showed a clastogenic potential in-vitro at high concentrations. However, no mutagenic effects can be expected at therapeutically relevant doses.

In studies of reproductive function, subcutaneous mometasone furoate, at 15 micrograms/kg prolonged gestation and prolonged and difficult labour occurred with a reduction in offspring survival and body weight or body weight gain. There was no effect on fertility.

Like other glucocorticoids, mometasone furoate is a teratogen in rodents and rabbits. Effects noted were umbilical hernia in rats, cleft palate in mice and gallbladder agenesis, umbilical hernia, and flexed front paws in rabbits. There were also reductions in maternal body weight gains, effects on foetal growth (lower foetal body weight and/or delayed ossification) in rats, rabbits and mice, and reduced offspring survival in mice.

The carcinogenicity potential of inhaled mometasone furoate (aerosol with CFC propellant and surfactant) at concentrations of 0.25 to 2.0 micrograms/l was investigated in 24-month studies in mice and rats. Typical glucocorticoid-related effects, including several non-neoplastic lesions, were observed. No statistically significant dose-response relationship was detected for any of the tumour types.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride
Glycerol (E422)
Polysorbate 80 (E433)
Microcrystalline cellulose (E460) and carmellose sodium (E468)
Citric acid monohydrate (E330)
Sodium citrate (E331)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life
2 years
Use within 2 months of first use.

6.4 Special precautions for storage

Do not store above 30ºC.

6.5 Nature and contents of container

MOMENSA nasal spray is contained in a white, high density polyethylene bottle, that contains 140 actuations (18 g) of product formulation, supplied with a metering pump and on which a nasal applicator with cap is fitted.

Pack size: 1 bottle of 18 g of suspension

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Alvogen (Thailand) Ltd.
Bangkok, Thailand

8. MARKETING AUTHORISATION NUMBER(S)

Registration Number: 1C 15067/63 (NG)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19/03/2020

10. DATE OF REVISION OF THE TEXT

March 2019