

 **27 September 2024**

**SUMMARY OF PRODUCT CHARACTERISTICS**

**for**

**Triamcinolone acetonide "Medipha", nasal spray, suspension**

**0. D.SP.NO.**

32966

**1. NAME OF THE MEDICINAL PRODUCT**

Triamcinolone acetonide Medipha

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

One spray bottle of Triamcinolone acetonide "Medipha"[[1]](#footnote-1)\* provides 120 actuations. One actuation of 100 milligrams delivers a dose of 55 micrograms of triamcinolone acetonide.

Excipient(s) with known effect: 15 micrograms of benzalkonium chloride per delivered dose.

For the full list of excipients, see section 6.1.

**3. PHARMACEUTICAL FORM**

Nasal spray, suspension

Greyish-white, thixotropic aqueous suspension.

**4. CLINICAL PARTICULARS**

**4.1 Therapeutic indications**

Triamcinolone acetonide "Medipha" is indicated for the treatment of symptoms of seasonal and perennial allergic rhinitis in adults and children aged 2 years and older.

**4.2 Posology and method of administration**

Posology

*Adults and children (over 12 years)*

The recommended daily starting dose is 220 micrograms, equivalent to 2 actuations in each nostril once daily. As soon as symptoms are under control, the dose can be reduced to 110 micrograms, equivalent to 1 actuation in each nostril once daily.

*Paediatric population*

Children aged 6 to 12 years

The recommended daily dose is 110 micrograms, equivalent to 1 actuation in each nostril once daily. For more severe symptoms, the dose can be doubled to 220 micrograms. However, as soon as symptoms are under control, the lowest effective dose should be maintained (see sections 4.4 and 5.1).

Children aged 2 to 5 years

The recommended and maximum daily dose is 110 micrograms, equivalent to 1 actuation in each nostril once daily (see sections 4.4 and 5.1).

In children under 12 years, long-term use of more than 3 months is not recommended.

Method of administration

For nasal use.

It is important to shake the bottle gently before each use.

After releasing 5 actuations prior to initial use (until a fine mist is produced), a dosage of 55 micrograms of triamcinolone acetonide per actuation is ensured (*in vitro* test results). This is also sufficient if the product is not used for more than 2 weeks.

If Triamcinolone acetonide "Medipha" has not been used for more than 2 weeks, the release of one actuation is sufficient to ensure exact dosage. The nozzle should be pointed away while the patient is doing this.

After use of the nasal spray the nozzle should be wiped carefully with a clean tissue or handkerchief and the cap should be replaced.

If the nasal spray does not work, it may be blocked. The patient must clean it. The patient should be instructed, NEVER to try to unblock it or enlarge the tiny spray hole with a pin or other sharp object because this will destroy the spray mechanism.

The nasal spray must be cleaned at least once a week or more often if it gets blocked.

The nasal spray must be cleaned as follows:

1. Only the cap and spray nozzle to be removed.
2. Cap and spray nozzle to be soaked in warm water for a few minutes and then both parts rinsed under cold running water.
3. Excess water shaked or tapped off. Cap and spray nozzle left to air-dry.
4. Spray nozzle re-fitted.
5. Safety clip removed.
6. The nasal spray must be primed until a fine mist is produced
7. Then the nasal spray is used as usual.

The Triamcinolone acetonide "Medipha" spray bottle should no longer be used than 2 months after first opening. Any remaining fluid should not discarded.

**4.3 Contraindications**

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

**4.4 Special warnings and precautions for use**

If there is any reason to suppose that adrenocortical function is impaired, appropriate precautions must be observed when switching from systemic steroid treatment to Triamcinolone acetonide "Medipha".

For nasopharyngeal infections with *Candida albicans*, which occurred in rare cases in clinical studies with triamcinolone acetonide nasal spray, suspension, appropriate topical therapy and, if necessary, temporary discontinuation of Triamcinolone acetonide "Medipha" therapy may be required.

Due to the inhibitory effect of corticosteroids on wound healing, Triamcinolone acetonide "Medipha" should be used with caution in patients with nasal septal ulcers or after surgery and injuries in the nasal region, until complete healing has occurred.

Especially at high doses and with prolonged use, systemic effects cannot be excluded even with nasally administered corticosteroids. Compared to oral corticosteroids, these systemic effects are much less likely to occur and may vary depending on the patient and corticosteroid preparation. Possible systemic effects include Cushing’s syndrome, cushingoid facies, adrenal suppression, growth retardation in children and adolescents, cataract, glaucoma and, in even rarer cases, a range of different psychological effects or behavioural abnormalities including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children).

If the recommended dosage is exceeded, there is a possibility of a clinically relevant decrease in adrenocortical function.

If there is evidence of patients significantly exceeding the recommended dosages, systemic corticosteroid administration should be considered in stress situations (e.g. prior to surgery).

Glaucoma and/or cataracts have been described in patients receiving nasal corticosteroids. Therefore, close monitoring is required in patients with visual changes or with a history of increased intraocular pressure, glaucoma and/or cataracts.

Visual disturbance

Visual disturbances may occur with systemic and topical use of corticosteroids. If a patient presents with symptoms such as blurred vision or other visual disturbances, consideration should be given to referring the patient to an ophthalmologist for assessment of possible causes; these may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSR), which has been reported after the use of systemic or topical corticosteroids.

**Triamcinolone acetonide "Medipha" contains benzalkonium chloride**

Long term use may cause oedema of the nasal mucosa.

If such a reaction is suspected (persistent nasal congestion), a nasal preparation containing no preservatives should be used wherever possible. If no such preservative-free nasal preparations are available, a different pharmaceutical form should be considered.

Paediatric population

Triamcinolone acetonide "Medipha" is not recommended for use in children under 2 years of age.

Growth retardation has been reported in children receiving nasal corticosteroid therapy, including triamcinolone acetonide nasal spray suspension, at the prescribed dosage (see section 5.1).

Therefore, regular monitoring of height gain is advisable for children on therapy with nasal corticosteroids.

The dose should be reduced over the course of treatment to the minimum required for maintaining symptomatic control. The long-term effects of growth retardation associated with nasal corticosteroids, including the effect on final height in adults, are not known. Furthermore, the patient should be referred as necessary to a paediatrician; this is strongly recommended for children under 6 years of age.

**4.5 Interaction with other medicinal products and other forms of interaction**

During concomitant treatment with CYP3A inhibitors, including medicinal products containing cobicistat, an increased risk of systemic adverse reactions can be expected. The combination should be avoided, unless the benefit outweighs the increased risk of systemic adverse reactions to corticosteroids, in which case patients should be monitored for systemic corticosteroid adverse reactions.

**4.6 Fertility, pregnancy and lactation**

Only limited clinical experience is available with regard to use during pregnancy. Experimental studies in animals showed that corticosteroids induce teratogenic effects. It cannot be ruled out that triamcinolone acetonide is excreted in human milk. Hence, triamcinolone acetonide should only be used during pregnancy and breast-feeding when the potential benefit to the mother outweighs the risk to the child.

**4.7 Effects on ability to drive and use machines**

No traffic warning.

Triamcinolone acetonide "Medipha" has no or negligible influence on the ability to drive and use machines.

**4.8 Undesirable effects**

The most commonly reported adverse events in clinical studies with Triamcinolone acetonide "Medipha" involved the nasopharyngeal mucosa.

The following categories are used for expressing the frequency of adverse reactions:

Very common (≥1/10)

Common (≥1/100 to <1/10)

Uncommon (≥1/1,000 to <1/100)

Rare (≥1/10,000 to <1/1,000)

Very rare (<1/10,000)

Not known (cannot be estimated from the available data).

Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

The most frequent adverse reactions in adults and children aged 2 years and older were:

* Infections and infestations

Common: influenza, pharyngitis, rhinitis.

* Immune system disorders

Not known (cannot be estimated from the available data): hypersensitivity reactions (including skin rash, urticaria, pruritus and facial oedema).

* Psychiatric disorders

Not known (cannot be estimated from the available data): insomnia.

* Nervous system disorders

Common: headache.

Not known (cannot be estimated from the available data): light-headedness, dysgeusia and parosmia.

* Eye disorders

Not known (cannot be estimated from the available data): chorioretinopathy, cataract, glaucoma, increased intraocular pressure, blurred vision (see also section 4.4).

* Respiratory, thoracic and mediastinal disorders

Common: bronchitis, epistaxis, cough.

Rare: septum perforation.

Not known (cannot be estimated from the available data): irritation and dryness of the nasal mucosa, nasal congestion, sneezing, dyspnoea.

* Gastrointestinal disorders

Common: dyspepsia, tooth problems.

Not known (cannot be estimated from the available data): nausea.

* General disorders and administration site conditions

Not known (cannot be estimated from the available data): fatigue.

* Investigations

Not known (cannot be estimated from the available data): decreased blood cortisol levels.

In a post-marketing clinical study in children, growth retardation has been reported during therapy with triamcinolone acetonide nasal spray, suspension (see section 5.1).

Especially at high doses and with prolonged use, systemic effects cannot be excluded even with nasally administered corticosteroids. Growth retardation has been reported in children receiving nasal corticosteroid therapy.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via:

Lægemiddelstyrelsen

Axel Heides Gade 1

DK-2300 København S

Website: www.meldenbivirkning.dk

**4.9 Overdose**

Acute cases of overdose are unlikely in view of the total amount of active substance contained in the nasal spray bottle. No clinically relevant systemic adverse reactions are to be expected even after single nasal or oral administration of the entire bottle contents. Mild gastrointestinal complaints are possible in the event of accidental oral ingestion.

**4.10 Legal status**

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**5. PHARMACOLOGICAL PROPERTIES**

**5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Decongestants and other nasal preparations for topical use, Corticosteroids, ATC code: R 01 AD11.

Mechanism of action

Triamcinolone acetonide is a more potent derivative of triamcinolone and is approximately 8 times more potent than prednisone. Although the precise mechanism of action is not yet fully known, corticosteroids are highly effective substances for the treatment of allergic diseases.

Pharmacodynamic effects

Triamcinolone acetonide "Medipha" has no immediate effect on allergic symptoms. In some patients, an improvement in symptoms starts as early as during the first day of treatment. Full efficacy can be expected after 3 to 4 days. If Triamcinolone acetonide "Medipha" is prematurely discontinued, it takes a few days before symptoms may recur. In clinical studies after nasal administration of dosages up to 440 micrograms daily in adults and children aged 6 years or older, or 110 micrograms daily in children aged 2 to 5 years, no functional suppression of the hypothalamus, anterior pituitary gland and adrenal cortex has been identified.

A double-blind, placebo-controlled, parallel-group study over a period of one year in 289 treated paediatric patients (aged 3 to 9 years) was conducted to assess the effect of triamcinolone acetonide nasal spray, suspension (once-daily dose of 110 μg) on growth velocity using measurements of height. From the primary analysis of evaluable patients (134 on triamcinolone acetonide nasal spray, suspension and 133 on placebo), the estimated growth velocity in the triamcinolone acetonide nasal spray, suspension group was 0.45 cm/year lower than in the placebo group; for a confidence interval of 95%, values were between 0.11 and 0.78 cm/year lower than in the placebo group. This difference between treatment groups developed within 2 months after initiation of treatment. After cessation of treatment during the 2-month follow-up period, it was observed that mean growth velocity in the treatment group returned to baseline values (prior to initiation of treatment).

**5.2 Pharmacokinetic properties**

Studies with a single intranasal dose of 220 micrograms in adult subjects and patients revealed that the absorption of triamcinolone acetonide is low. The mean peak plasma concentration 1.5 hours after nasal administration is 0.5 ng/mL (0.1‑1 ng/ml). After 12 hours, the plasma active substance concentration falls to less than 0.06 ng/mL and is below the limit of detection after 24 hours. The mean plasma elimination half-life is 3.1 hours. Dose proportionality was demonstrated both in subjects and patients between 110 micrograms and 220 micrograms of a single intranasal dose.

Paediatric population

After repeated nasal administration of triamcinolone acetonide in children aged 6 to 12 years, similar systemic exposure as in adults was observed.

Nasal administration of 110 micrograms of triamcinolone acetonide once daily in children aged 2 to 5 years resulted in systemic exposure similar to that of 220 micrograms of triamcinolone acetonide once daily in adults.

The apparent clearance and apparent volume of distribution in children aged 2 to 5 years were approximately half those in adults.

**5.3 Preclinical safety data**

In preclinical studies, only effects typical of glucocorticoids were observed.

As with other corticosteroids, teratogenic effects were shown in rats and rabbits following administration of triamcinolone acetonide by inhalation or other routes, resulting in cleft palate and/or internal hydrocephalus and axial skeletal defects. Teratogenic effects (CNS and cranial malformations) have also been observed in primates.

*In vitro* tests showed no indications of mutagenicity.

Carcinogenicity tests in rodents showed no increased incidence of individual tumour types.

There are indications from preclinical studies that benzalkonium chloride may time- and dose‑dependently induce an inhibitory effect on ciliary motility to the point of irreversible arrest, as well as histopathological changes to the nasal mucosa.

**6. PHARMACEUTICAL PARTICULARS**

**6.1 List of excipients**

- Disodium edetate

- Anhydrous glucose

- Microcrystalline cellulose and carmellose sodium

- Polysorbate 80

- Benzalkonium chloride

- Dilute hydrochloric acid (for pH adjustment)

- Purified water

**6.2 Incompatibilities**

Not applicable.

**6.3 Shelf life**

3 years.

After first opening of the container: 2 months.

**6.4 Special precautions for storage**

Do not store above 25 °C.

**6.5 Nature and contents of container**

Triamcinolone acetonide "Medipha" is available in a 20 mL high-density polyethylene (HDPE) bottle fitted with a metered‑dose spray pump unit.

Each Triamcinolone acetonide "Medipha" bottle contains 16.5 g suspension (equivalent to at least 120 actuations).

**6.6 Special precautions for disposal and other handling**

No special requirements.

**7. MARKETING AUTHORISATION HOLDER**

MEDIPHA SANTE

Les Ferreries

Saint-Denis d’Authou

28480 Saintigny

France

**8. MARKETING AUTHORISATION NUMBER(S)**

67673

**9. DATE OF FIRST AUTHORISATION**

27 September 2024

**10. DATE OF REVISION OF THE TEXT**

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1. \* Triamcinolone acetonide "Medipha" stands for Triamcinolone acetonide "Medipha"® 55 micrograms/dose. [↑](#footnote-ref-1)