PACKAGE LEAFLET: INFORMATION FOR THE USER

Mometasone/Target®
50 mcg/dose nasal spray suspension
Mometasone furoate monohydrate

Please read this leaflet carefully before you start taking your medicine. If you have any questions ask your doctor or pharmacist.

1. IDENTIFICATIONS OF THE MEDICINAL PRODUCT

1.1. Trade name

Mometasone/Target® nasal spray suspension.

1.2. Composition

Active substance: Mometasone furoate monohydrate.
Excipients: Dispersable cellulose, Glycerol, Sodium citrate dihydrate, Citric acid monohydrate, Polysorbate 80, Benzalkonium chloride, Phenethyl alcohol, Water purified.

1.3. Pharmaceutical form

Nasal spray suspension.

1.4. Quantitative composition

Mometasone/Target® nasal spray suspension contains mometasone furoate monohydrate 0.05% w/w.
Mometasone/Target® nasal spray suspension contains 50 mcg Mometasone furoate in each dose.

1.5. Nature and content of the container

Each carton contains a plastic bottle containing 18g of nasal spray suspension, delivering 140 doses and a leaflet.
Plastic bottle is fitted with a spray dosing pump that releases 50 mcg of active substance per actuation.

1.6. Pharmacotherapeutic category

Medicines for the relief of nasal congestion and other nasal formulations for topical use - Corticosteroids.

1.7. Marketing Authorization Holder

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Tel.: +30 210 5224830, Fax: +30 210 5224838, E-mail: info@targetpharma.gr, www.targetpharma.gr

1.8. Manufacturer

Pharmaceutical Industry PROEL Epam. G. Koronis S.A.

2. WHAT SHOULD THE PATIENT KNOW ABOUT THIS MEDICINE

2.1. General information

Mometasone/Target® nasal spray suspension contains mometasone furoate monohydrate a medicine that belongs to the group of drugs called corticosteroids. Mometasone furoate monohydrate should not

be confused the anabolic steroids which are misused by athletes, administered as tablets or injections. Intranasal spraying of low doses mometasone furoate relieves symptoms of inflammation, sneezing, itching, nasal congestion and rhinorrhea.

Mometasone/Target® nasal spray suspension is used in adult patient and children older than 6 years of age for the treatment of seasonal allergic rhinitis and perennial allergic rhinitis.
Mometasone/Target® nasal spray suspension is also used in adult patients older than 18 years, for the treatment of nasal polyps.

Seasonal allergic rhinitis occurs during certain times of the year and it is an allergic reaction caused by inhalation of pollen from trees, grass, weeds, fungus and some fungal spores. Perennial rhinitis occur throughout the year and the symptoms may be caused due to sensitivity to several antigens such as dust mites, animal hair, feathers and certain foods. These allergic reactions occur as rhinorrhea, sneezing and swelling of nasal mucosa, resulting to nasal congestion sensation. **Mometasone/Target®** nasal spray suspension reduces edema and irritation of the nose and in this way relieves from symptoms like sneezing, itching, nasal congestion and rhinorrhea.

Nasal polyps are projections of edematous nasal mucosa and usually affect both nostrils. It is considered as a chronic nasal inflammation as it causes abnormal proliferation of mucosa, leading to polyps. The main symptom is the sensation of obstructed nose. Breathing may be difficult if the polyps is grown at size. Rhinorrhea, leaking sensation at the back of larynx, loss of appetite and smell sensations may be reported. **Mometasone/Target®** nasal spray suspension reduces nasal inflammation inducing gradual shrinkage of polyps.

2.2. Indications

Mometasone/Target® nasal spray suspension is indicated for the treatment of seasonal allergic rhinitis and perennial allergic rhinitis, in adults and children older than 6 years of age.

Patients with medical history that includes moderate to severe symptoms of seasonal allergic rhinitis may begin prophylactic treatment with **Mometasone/Target®** nasal spray suspension, up to four weeks before the pollen season.

Mometasone/Target® nasal spray suspension is also indicated for the treatment of nasal polyps in patients older than 18 years of age.

2.3. Contraindications

You should not use **Mometasone/Target®** nasal spray suspension:

- If you had in the past allergic reaction to **Mometasone/Target®** nasal spray or any of the excipients. You should ask your doctor to recommend you another medicine.
- If you have any nasal infection.
- If you had surgical operation in the nose or you have any nasal trauma. You should wait until your nose recovers before you start treatment with nasal spray.

Before you start treatment with **Mometasone/Target®** nasal spray suspension, inform your doctor if:

- You are pregnant, it is possible to get pregnant or if you are breast-feeding.
- If you have or ever had tuberculosis.
- If you have ocular herpes simplex.
- If you have any kind of infection.
- If you receive any other corticosteroid orally or injectable.

During treatment with **Mometasone/Target®** nasal spray suspension, avoid contact with patients suffering of measles or chickenpox. You should inform your doctor if you get exposed to any of these infections.

2.4. Special warnings and precautions for use

If you receive other corticosteroid allergy treatment, oral or injectable, you doctor may recommend you to discontinue when you use **Mometasone/Target®** nasal spray suspension. Discontinuation of systemic corticosteroid treatment may result to some patients adverse reactions like arthralgia, myalgia, weakness and depression. However, treatment with **Mometasone/Target®** nasal spray suspension should be continued. You may also experience other allergic reactions like itching, lacrimation or eye irritation and itching on the skin. You should consult with your doctor if you experience any of these symptoms.

2.4.1. General

Mometasone/Target® nasal spray suspension should be used with caution and only if the use is necessary, in patients with active or non-active tuberculosis infection of respiratory tract or fungal, bacterial and systemic viral infections that are not treated or ocular herpes simplex.

Like with other long-term treatments, patients that are using **Mometasone/Target®** nasal spray suspension for several months or longer should be examined occasionally for possible lesions in nasal mucosa. If fungal infection appears in the nose or pharynx, **Mometasone/Target®** nasal spray treatment should be discontinued and the patient should receive proper anti-fungal treatment. Persistent symptoms in nose and pharynx are also criteria for treatment discontinuation.
Although **Mometasone/Target®** nasal spray suspension will manage the nasal symptoms in the majority of the patients; concomitant use of complementary treatment may offer additional relief to other symptoms, especially ocular.

2.4.2. Pregnancy and lactation

Like with other nasal corticosteroids, **Mometasone/Target®** nasal spray, suspension should not be used during pregnancy or lactation, unless the expected benefit for the mother, overweigh the possible risks for mother, fetus or infant. Infants delivered by mothers under treatment with corticosteroids during pregnancy, should be carefully monitored for hypoadrenalism.

2.4.3. Effect on the ability to drive and use of machines

None known.

2.4.4. Special warnings about the excipients

See section 2.3. Contraindications.

2.5. Interactions with other medicines or substances

No interaction with loratidine was reported.

2.6. Posology

For seasonal and perennial allergic rhinitis:
The usual recommended dose is two sprayings in each nostril once daily for adults and children older than 12 years of age. As soon as your symptoms are managed, your doctor may recommend you to use one spraying in each nostril daily. However, if there is no improvement, you should consult your doctor as he may advise you to increase to maximum daily dose of 4 sprayings in each nostril once daily. As soon as your symptoms are managed, your doctor may recommend you to use two sprayings in each nostril daily.
For children between 6 and 11 years of age, the usual dose is one spraying in each nostril once daily.

In some patients **Mometasone/Target®** nasal spray suspension will relieve the symptoms in 12 hours after initial dose. Maximum benefit from the treatment may occur in two or more days.

It is important to receive your nasal spray regularly. Do not discontinue the treatment even if you feel better unless your doctor asks you to stop.

In cases of severe seasonal rhinitis, your doctor may recommend you to start the use of **Mometasone/Target®** nasal spray suspension two or four week prior pollen season, as this will prevent allergic rhinitis symptoms. Your doctor may also recommend you to use additional treatmens with **Mometasone/Target®** nasal spray suspension, especially if you suffer itching in the eyes and irritation. By the end of pollen season, your allergic rhinitis symptoms will improve and you may not need more treatment..

For nasal polyps:
For adults, older than 18 years of age, the recommended dose is two sprayings in each nostril once daily. If your symptoms are not managed after 5 to 6 weeks, the dose may be increased to two sprayings in each nostril twice daily. As soon as your symptoms retreat, your doctor will ask you to decrease the dose. If there is no improvement after 5 to 6 weeks of twice daily treatment, your doctor may evaluate alternative treatments.

Always follow your doctor's instruction. Do not use increased doses or use the nasal spray more often than recommended.

Long-term treatment of nasal steroids in high dosages, may delay growth in children. Your doctor may monitor your child's height during treatment and decrease the dose if needed.

About your nasal spray
Mometasone/Target® nasal spray has a cap that protects and keeps clean the applicator. Remember to remove the cap before the use of the nasal spray and replace it after use.

If you are using the nasal spray for the first time or you have not use it for the last 14 or more days, the pump should be primed by actuating 6-7 times or until a fine spray appears.
First shake the bottle gently and then hold it as follows: Using your index and middle fingers on the sides of the applicator and the thumb to the bottom of the bottle. Press the applicator away from your body until the spray is pumped.

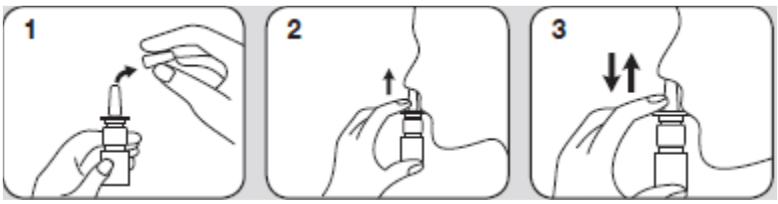
It is important to clean the nasal spray applicator regularly in order to work properly. Remove the cap and the nasal applicator gently. Soak the nasal applicator and the cap in hot water and rinse both ends of the nasal applicator under tap water. Set them dry in a warm place. Put the nasal applicator back together and replace the cap. Reprime the pump the first time after cleaning, if necessary.

For common treatment with two spraying in each nostril daily for the treatment of seasonal and perennial allergic rhinitis, this product will deliver enough doses for 35 days.

For the treatment of nasal polyps this product will deliver enough doses for 35 days.

Instructions of use of your nasal spray

1. Shake gently the bottle and remove the cap (Figure 1).
2. Gently blow to clean your nose.
3. Close one nostril and insert the applicator to the open nostril as seen in Figure 2. Tilt your head slightly front keeping the bottle in upright position.
4. Inhale gently and slowly through the nostril and while you inhale depress firmly downwards the applicator with your fingers (Figure 3)
5. Exhale through the mouth. Repeat step 4 to inhale a second dose in the same nostril.
6. Remove the applicator form the nostril and exhale out through the mouth.
7. Repeat steps 3 and 6 for the other nostril.



After the use, wipe the nasal applicator with a clean tissue and replace the cap.

2.7. Overdose – Management

Tell your doctor if you accidentally take a dose higher than the recommended.
Long-term or excessive use of corticosteroids can rarely affect your hormones and the growth in children.

Poison Center Athens, Tel: +30 210 7793777.

2.8. Possible side effects

Adverse events reported during clinical trials in adult and adolescent patients with allergic rhinitis are listed below (Table 1).

Table 1: *Allergic rhinitis* - Adverse events ≥1% related to the treatment with Mometasone/Target®nasal spray suspension Very common (>1/10), Common (>1/100, <1/10), Uncommon (>1/1.000, <1/100), Rare (>1/10.000, <1/1.000), Very rare (<1/10.000)	
Respiratory, thoracic and mediastina disorders Common:	Nose bleeding, pharyngitis, nasal burning, nostril irritation, nostril ulceration
General disorders and reactions at the site of administration. Common:	Headache

Nose bleeding was generally eliminated and of moderate severity and occurred more frequently than with placebo (5%), but comparable or less frequently than with control nasal corticosteroids (up to 15%). The incidence of all other adverse effects was comparable to that of the placebo.

In pediatric patients, the incidence of adverse events e.g. nose bleeding (6%), headache (3%), nose irritation (2%) and sneezing (2%) was comparable to that of the placebo.

In patients under treatment for nasal polyps, the overall incidence of adverse effects was comparable to that of the placebo and to that reported in patients with allergic rhinitis. Adverse events reported during clinical trials in ≥1% of patients with nasal polyps are listed below (Table 2).

Table 2: *Polyps* – Adverse events ≥1% related to the treatment with Mometasone/Target® nasal spray suspension πολύ συχνές (>1/10), συχνές (>1/100, <1/10), ασυνήθεις (>1/1.000, <1/100), σπάνιες (>1/10.000, <1/1.000), Very rare (<1/10.000)		
	(200 mcg once daily)	(200 mcg twice daily)
Respiratory, thoracic and mediastina disorders		
Upper respiratory tract infection	Common	Uncommon
Nose bleeding	Common	Very common
Gastrointestinal disorders		
Pharynx irritation		Common
General disorders and reactions at the site of administration		
Headache	Common	Common

Hypersensitivity reactions, including bronchospasm and dyspnea, were reported rarely after nasal administration of mometasone furoate monohydrate. Very rarely were reported anaphylaxis and angioedema.
Disturbances in taste and smell have been very rarely reported.
Systemic reactions to nasal corticosteroids may occur, when high doses are administered for long periods.
If you have questions about the mentioned or any other side effect you should inform your doctor or pharmacist.

If you get any side effects, please talk to your doctor or pharmacist or any other health care provider or directly to the National Medicines Agency (284 Mesogion Av., 15562, Cholargos, Athens, Greece www.eof.gr).

2.9. What you should know in case you forget to take one dose

If you forget to use your nasal spray, apply the next dose as soon as you remember and continue your treatment as planned. Do not double dosages.

2.10. What should the patient know about the expiration date

Do not use this medicine after the expiration date mentioned in the container.

2.11. Special warnings about the storage of the product

Mometasone/Target® nasal spray suspension should be stored at temperature below 25ºC.
As with all medicines, keep out of reach of children.

2.12. Date of last revision of this leaflet:

14-12-2012

3. INFORMATION FOR THE RATIONAL USE OF MEDICINES

- This pharmaceutical product was prescribed by your doctor to you, according to your medical history and condition. Do not pass the product to others or use it in any other condition even if the symptoms may appear the same and without receiving your doctor's or pharmacist's advice.
- If during treatment with this medicine you experience any problem or issue, contact immediately your doctor or pharmacist.
- If you have any questions regarding the information for this product, its use or about the medical condition that you suffer, you should ask your doctor or pharmacist.
- This product will be safe and effective if it is used exactly according to instructions provided.
- For your own safety it is highly recommended that you read carefully all information provided for the prescribed medicine.
- Do not store medicines in bathroom lockers, as the high temperature and the humidity may degrade the product which may be harmful to your health.
- Store the product in the original packaging.
- If your doctor instructed you to stop the use of this product, dispose the remaining product and do not use it.
- Do not keep the medicine you do not need any more or those that are expired.
- Keep all medicines in safe place out of reach and sight of children.

4. PRESCRIBING INFORMATION

This medicine is subjected to medicinal prescription.