PACKAGE LEAFLET: INFORMATION FOR THE USER
Budesonide/Target®
100mcg/dose, nasal spray suspension of fixed doses
Budesonide

1. IDENTIFICATIONS OF THE MEDICINAL PRODUCT

1.1. Trade name:

Budesonide/Target®

1.2. Composition

Active substance: Budesonide.
Excipients: Cellulose microcrystalline, Carmellose sodium, Dextrose anhydrous, Polysorbate 80, Disodium edetate, Potassium sorbate, Hydrochloric acid, Water purified.

1.3. Pharmaceutical form

Nasal spray suspension of fixed doses

1.4. Quantitative composition

Each dose (spraying) contains 100 mcg budesonide. Each ml contains 2 mg budesonide.

1.5. Nature and content of the container

Each carton contains a bottle of 10ml with meter-pump and a leaflet.

1.6. Pharmacotherapeutic category

Corticosteroid - Antiallergic (ATC: R01AD05).

1.7. Marketing Authorization Holder

TARGET PHARMA, 54 Menandrou st., 104 31 Athens Greece,
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

Budesonide/Target® nasal spray suspension belongs to a group of medicines called corticosteroids, which are used for the reduction of inflammation. **Budesonide/Target®** nasal spray suspension reduces and prevents inflammation or edema of nasal mucosa.

2.2. Indications

Treatment of the symptoms of seasonal or perennial allergic rhinitis in adults and children (6 years and older) and the treatment of perennial non allergic rhinitis only in adults.
Treatment of the symptoms of nasal congestion related to nasal polyps in adults.

2.3. Contraindications

All medicines can help patients, but they can also cause problems when not taken according to instructions. Before you take this medicine, you should inform your doctor if you have any unusual reaction of hypersensitivity to budesonide or any of the excipients of this medicine or to any other medicine.

2.4. Special warnings and precautions for use

2.4.1. General:

This medicine has been prescribed for your medical condition. Do not use it for any other health issue unless your doctor tells you to do it. Do not give your medicines to anybody else.
Excessive dosing or long-term treatment may lead to signs or symptoms of hypercorticoemia, suppression of HPA axis καταστολή της λειτουργίας του άξονα YYE (Hypothalamic-Pituitary-Adrenal axis) and/or delay in children's growth.
The doctor will monitor the growth rate of the children that will receive long-term treatment with corticosteroids, regardless the route of administration, to evaluate the benefits of the treatment versus the risk of delays in the growth.

Impaired liver function will affect the exertion of corticosteroids. Inform your doctor if you have issues with your liver function.
Caution is needed to patients that have pulmonary tuberculosis.
Also special care is needed to patients that have nasal infections of fungal or virus etiology and bacterial sinusitis, receiving suitable co-administered treatment.
Immunosuppressed children are more susceptible to infections than healthy children. For example, chickenpox or measles may have more pronounced course in immunosuppressed children under treatment with corticosteroids. Immunosuppressed children and non-immune adults should avoid the exposure to such diseases and if exposed the doctor should be immediately informed.

Caution is needed to the patient that will be shifted from systemic to nasal administration of **Budesonide/Target®** nasal spray suspension. In cases that another steroid is co-administered for inhalation, the sum of dosages should be adjusted so as to avoid steroidal adverse reactions, especially in children
During long-term treatment nasal mucosa should be checked for lesions at least every 6 months.
Until more clinical experience is available the use in children is not recommended.

<u>Below warnings are for corticosteroids in general:</u>
As previously mentioned, long-term treatment may cause suppression of HPA axis, i.e. suppression of adrenocortical function. The severity of this depends on the dosage and the potency of administrated corticosteroid, the duration and the frequency of administration within the day, half-life and the longevity of the treatment. The dose should be adjusted according to exacerbation or recession of the disease, personalized patient response and exposure to emotional or physical stress (infections, surgery, injuries, etc.).

2.4.2. Elderly

There are no specific instructions. Dosage should be adjusted accordingly.

2.4.3. Pregnancy

Το ρινικό εκνέφωμα **Budesonide/Target®** μπορεί να χορηγηθεί κατά τη διάρκεια της κύησης μόνο όταν, κατά την κρίση του γιατρού, τα οφέλη για τη μητέρα υπερτερούν των κινδύνων για το έμβρυο.
Εάν μείνετε έγκυος ενόσω χρησιμοποιείτε το φάρμακο, θα πρέπει να επικοινωνήσετε με το γιατρό σας, όσο το δυνατόν ταχύτερα.

2.4.4. Lactation

Budesonide/Target® nasal spray suspension may be used during lactation only if the doctor believe that the expected benefit outweighs possible risks for mother and infant.

2.4.5. Children

Long term treatment of pediatric patient with nasal corticosteroids is not yet established. See section Posology for children.

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

Budesonide/Target® nasal spray suspension does not affect the ability to drive and use machines.

2.4.7. Special warnings about the excipients

None.

2.5. Interactions with other medicines or substances

Before you use **Budesonide/Target®** nasal spray suspension, you should inform your doctor about any other medication that you are using, especially if you use medicines against anti-fungal infections (ketoconazole) and even about medicines that you buy from the pharmacy without prescription.

Bellow mentioned are interactions of corticosteroids group in general:
Caution is needed in co-administration with phenytoin, fhenovarvital, ephedrine, rifabicin, alcohol, non-steroidal anti-inflammatory drugs, potassium depleting diuretics, digitalis, coumarin anti-coagulants, insulin and oral antidiabetics.

2.6. Posology

Dosage should be personalized. Follow exactly your doctor's directions.
Before you use **Budesonide/Target®** nasal spray suspension for the first time, you should read the instruction of use and follow them carefully.

Symptomatic treatment of seasonal or perennial allergic rhinitis
Adults, elderly and children older than 6 years of age: Recommended initial dosage is 200-400 daily. This dosage may be administered once daily in the morning or divided to two doses, in the morning and evening:
200 mcg (2 sprayings x 100 mcg) in each nostril in the morning
or
100 mcg (1 spraying x 100 mcg) in each nostril twice daily in the morning and in the evening.
It should not be administered more than twice daily.

There are no data for the use of this medicine in children younger than 6 years of age for this indication, so it should not be used in this age group.

Symptomatic treatment of perennial non allergic rhinitis only in adults:
Recommended dosage is as described above. It is not indicated for children in this indication as in the clinical studies performed the number of pediatric patients was not sufficient.

Symptomatic treatment of nasal obstruction related to nasal polyps in adults
Recommended dosage is 200 mcg twice daily (1 spraying x 100 mcg) in each nostril in the morning and in the evening for an interval of up to 3 months.
There no data available for the use of the medicines in children for this indication, therefore it is indicated only to adults.

Note: Strting the treatment with **Budesonide/Target®** nasal spray suspension, you may not have immediate elimination of the symptoms. You may need to continue the treatment for some days (sometimes up to two weeks) until you experience improvement of the condition.
As soon as the therapeutic result is reached, the maintenance dose should be limited to the minimum needed to control the symptoms.
For the treatment of seasonal allergic rhinitis it is recommended to start the treatment with **Budesonide/Target®** nasal spray suspension, a few days prior the first allergic symptoms.
Budesonide/Target® nasal spray suspension is not recommended for the relief of allergic rhinitis' symptoms in the eyes. If you have eyes irritation, your doctor may prescribe to you another medicine for the relief of these symptoms.
Children should only use the nasal spray suspension under adult supervision to ensure that the correct dose is administered according to the prescribed doctor's indications.

2.7. Overdose - Management:

If you use excess quantity of this medicine only once, no significant medical conditions are expected. If you use high dosage of this medicine for extended intervals (months) it is possible to experience adverse reactions. If you feel that you experience any such reactions, talk to your doctor.
Poison Center Athens, Tel: +30 210 7793777.

2.8. Possible side effects

Along with the desired effects, all medicines may cause some side effects. Inform your doctor immediately if you experience any persisting of the below listed side effects:

Very Common: Nasal irritation, epistaxis.

Rare: immediate or belated hypersensitivity reactions, like skin rash etc. In such cases you should inform your doctor immediately.

Very Rare: ulcerations, mycoses and nasal mucosa atrophy.

Local symptoms such as stylostixis, dryness and sneezing may be experienced immediately after the application.

Below are mentioned side effects of the corticosteroid group in general:
Long term treatment may lead to severe side effects.

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 take a dose of your nasal spray, it is not necessary to try replacing it. Simply take the next dose as planned according to your doctor's prescription.
Do not double doses.

2.10. What should the patient know about the expiration date

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

2.11. Special warnings about the storage of the product

Replace the protective cap after the use.
Store at temperature below 25˚C. Do not freeze.

2.12. Date of last revision of this leaflet

14-12-2012

3. INFORMATION FOR THE RATIONAL USE OF MEDICINES

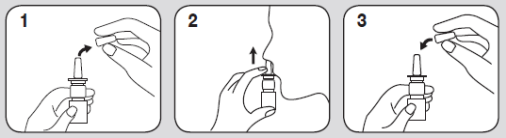
- This pharmaceutical product was prescribed by your doctor to you, according to your medical history and condition. Do not pass the product to others or use it in any other condition even if the symptoms may appear the same and without receiving your doctor's or pharmacist's advice.
- If during treatment 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.

5. INSTRUCTIONS OF USE

Read carefully the instructions before you use **Budesonide/Target®** nasal spray suspension and follow them carefully.
Children should use **Budesonide/Target®** nasal spray suspension only under parental supervision so as to ensure the proper use.
Before you use **Budesonide/Target®** nasal spray suspension for the first time, shake the bottle gently and then spray in the air (5-10 times), so as to receive a fine homogenous spray. For any next use and in case the medicine is not used on a daily basis, you spray once in the air so as to ensure that the pump is capable and releases the correct amount of the product.



1. Blow your nose. Shake the bottle gently. Remove the cap.
2. Holding the bottle to upright position, insert the applicator in your nostril. Spray the prescribed doses. Repeat for the other nostril in the same way.
3. Replace the protective cap when you finish. Do not apply more sprayings than your doctor prescribed.

Cleaning: You should often clean the plastic parts of the bottle. Remove the protective cap and pull gently the white nasal applicator. 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.