PACKAGE LEAFLET: INFORMATION FOR THE USER

THORDEL® 10 mg film-coated tablets
montelukast

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you..
- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. WHAT THORDEL® IS AND WHAT IS USED FOR

What is THORDEL®
THORDEL® leukotriene receptor antagonist that blocks substances called leukotrienes.

How THORDEL® works
Leukotrienes cause narrowing and swelling of airways in the lungs and also cause allergy symptoms. By blocking leukotrienes **THORDEL®** improves asthma symptoms, helps control asthma and improves seasonal allergy symptoms (also known as hay fever or seasonal allergic rhinitis).

When THORDEL® should be used
Your doctor has prescribed **THORDEL®** to treat asthma, preventing your asthma symptoms during the day and night.
- **THORDEL®** is used for the treatment of patients who are not adequately controlled on their medication and need additional therapy.
- **THORDEL®** also helps prevent the narrowing of airways triggered by exercise.
- In those asthmatic patients in whom **THORDEL®** is indicated in asthma, **THORDEL®** can also procide symptomatic relief of seasonal allergic rhinitis.

Your doctor will determine how **THORDEL®** should be used depending on the symptoms and severity of your asthma.

What is asthma?
Asthma is a long-term desease.
Asthma includes:
- difficulty breathing because of narrowed airways. This narrowing of airways worsens and improves in response to various conditions.
- sensitive airways that react to many things, such as cigarette, smoke, pollen, cold air or exercise.
- swelling (inflammation) in the lining of the airways.

Symptoms of asthma include Coughing, wheezing and chest tightness.

What are seasonal allergies?
Seasonal allergies (also known as hay fever or seasonal allergic rhinitis) are an allergic response often caused by airborne pollens from trees, grasses and weeds. The symptoms of seasonal allergies typically may include: stuffy, runny, itchy nose; sneezing; watery, swollen, red, itchy eyes.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE THORDEL®

Tell your doctor about any medical problems or allergies you have now or have had.

Do not take THORDEL®
- if you are allergic to montelukast or any other ingredient of this medicine (see section 6).

Warnings and precautions
Talk to your doctor or pharmacist before taking **THORDEL®**:
- If your asthma or breathing gets worse, tell your doctor immediately.
- **THORDEL®** is not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor has given you. Always have your inhaled rescue medicine for asthma attacks with you.
- It is important that you take all asthma medications prescribed by your doctor. **THORDEL®** should not be substituted by other asthma medications your doctor has prescribed for you.
- Any patient on anti-asthma medicines should be aware that if you develop a combination of symptoms such as a flu-like illness, pins and needles or numbness of arms or legs, worsening of pulmonary symptoms, and/or rash, you should consult your doctor.
- You should not take acetyl-salicylic acid (aspirin) or anti-inflammatory medicines (also known as non-steroidal anti-inflammatory drugs or NSAIDs) if they make your asthma worse.

Children and adolescents
THORDEL® 10mg film-coated tablets are not recommended for use in children and adolescents under the age of 15.
There are available other pharmaceutical forms for pediatric patients based on the age range.

Other medicines and THORDEL®
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those you take without prescription.

Some medicines may affect how **THORDEL®** works or **THORDEL®** may affect how other medicines work.

Tell your doctor if you are taking any of the following medicines before starting **THORDEL®**:
- phenobarbital (used for treatment of epilepsy)
- phenytoin (used for treatment of epilepsy)
- rifampicin (used to treat tuberculosis and some other infections)
- gemfibrozil (used for treatment of high lipid levels in plasma)

THORDEL® with food and drink
THORDEL® 10 mg film-coated tablets may be taken with or without food.

Pregnancy and breast-feeding
If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking **THORDEL®**.

<u>Pregnancy</u>
Your doctor will assess whether you can take **THORDEL®** during this time.

Breast-feading
It is unknown whether montelukast is excreted in human milk. You should consult your doctor before taking **THORDEL®** if you are breast-feeding or intend to breast-feed.

Driving and using machines
THORDEL® is not expected to influence your ability to drive and use machines. However, individual responses to medication may vary. Certain side effects (such as dizziness and drowsiness) that have been reported very rarely with montelukast may affect some patients' ability to drive or operate machinery.

THORDEL® 10mg film-coated tablets contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE THORDEL®

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- You should take only one tablet of **THORDEL®** once a day as prescribed by your doctor.
- It should be taken even when you have no symptoms or have an acute asthma attack.

For adults and adolescents 15 years of age and older:
The recommended dose is one 10 mg tablet to be taken daily in the evening.
If you are taking **THORDEL®**, be sure that you do not take any other products that contain the same active ingredient, montelukast.

This medicine is for oral use.
THORDEL® 10 mg film-coated tablets may be taken with or without food.

If you take more THORDEL® than you should
Contact your doctor immediately for advice.
There were no side effects reported in the majority of overdose reports. The most frequently occurring symptoms reported with overdose in adults and children included abdominal pain, sleepiness, thirst, headache, vomiting, and hyperactivity.

If you forget to take THORDEL®
Try to take **THORDEL®** as prescribed. However, if you miss a dose, just resume th usual schedule of one tablet once daily.
Do not take a double dose to make up for a forgotten dose.

If you stop taking THORDEL®

THORDEL® can treat your asthma only if you continue to take it.

It is important to continue taking **THORDEL®** for as long as your doctor prescribes. It will help control your asthma.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

In clinical studies with montelukast 10mg film-coated tablets, the most commonly reported side effects (occurring in at least 1 of 100 patients and less than 1 of 10 patients treated) thought to be related to montelukast 10mg film-coated tablets were:
- abdominal pain
- headache

These were usually mild and occurred at a greater frequency in patients treated with montelukast than placebo (a containing no medication).

The frequency of possible side effects presented below is characterized as:
Very common: may occur in more than 1 of 10 patients
Common: may occur in up to 1 of 10 patients
Uncommon: may occur in up to 1 of 100 patients
Rare: may occur in up to 1 of 1.000 patients
Very rare: may occur in up to 1 of 10.000 patients
Not known: frequency cannot be evaluated based on the available data.

In addition, while the medicine has been marketed, the following have been reported:
- upper respiratory infection *(Very common)*
- increased bleeding tendency *(Rare)*
- allergic reactions including swelling of the face, lips, tongue and/or throat which may cause difficulty in breathing or swallowing *(Uncommon)*
- behavior and mood related changes [abnormal dreams, including nightmares , trouble sleeping, sleep walking, irritability, feeling anxious, restlessness, agitation including aggressive behavior or hostility, depression *(Uncommon)*, tremor, disturbance in attention, memory impairement *(Rare)*, hallucinations, disorientation, suicidal thoughts and actions (*Very Rare*)]
- dizziness, drowsiness, pins and needles/numbness, seizure *(Uncommon)*
- palpitations *(Rare)*
- nosebleed *(Uncommon)*, swelling (inflammation) of the lungs *(Very Rare)*
- diarrhea, nausea, vomiting *(Common)*, dry mouth, indigestion *(Uncommon)*
- hepatitis (inflammation of the liver) *(Very rare)*
- rash (*Common)*, bruising, itching, hives *(Uncommon)*, tender red lumps under the skin most commonly on your shins (erythema nodosum), severe skin reactions (erythema multiforme) that may occur without warning *(Very rare)*
- joint or muscle pain, muscle cramps *(Uncommon)*
- fever *(Common)*, weakness/tiredness, feeling unwell, swelling *(Uncommon)*

In asthmatic patients treated with montelukast, very rare cases of a combination of symptoms such as flu-like illness, pins and needles or numbness of arms and legs, worsening of pulmonary symptoms and/or rash (Churg-Strauss syndrome) have been reported. You must tell your doctor right away if you get one or more of these symptoms (see section 2).

Reporting of side effects
If you get any side effect, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You should report any side effect occuring through the national reporting system:

Greece
National Drug Organisation
284 Mesogeion Av. GR-15562 Cholargos, Athens Tel.: + 30 21 32040380/337, Fax: + 30 21 06549585 webpage: http://www.eof.gr
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE THORDEL®

- Keep this medicine out of the sight and reach of children.
- Do not use **THORDEL®** after the expiry date which is stated on the label or carton after EXP. the first two digits refers to month and the four last digits indicate the year. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What THORDEL® contains

- The active substance is montelukast. Each film-coated tablet contains sodium montelukast equivalent to 10mg montelukast.
- The other ingredients are:
  Core: Cellulose microcrystalline, Lactose monohydrate (89.3mg), croscarmellose sodium, hydroxypropylcellulose και magnesium stearate
  Coating: Opadry AMB TAN 80W27179: Polyvinyl alcohol, Talc, Titanium dioxide (E 171) Iron oxide red, yellow and black (E 172), Lecithin, Xanthan gum.

What THORDEL® looks like and contents of the pack

THORDEL® 10mg film-coated tablets are pink beige colored, round, biconvex shape.
Packed in blisters containing 14 or 28 film-coated tablets.
Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer

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