



PACKAGE LEAFLET: INFORMATION FOR THE USER

THORDEL[®] 4 mg chewable tablets
montelukast

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THORDEL[®] 4 mg chewable tablets
montelukast

Read all of this leaflet carefully before you give this medicine to your child because it contains important information.

- 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 only for your child. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.
- If you see any side effect on your child, talk to your doctor or pharmacist. 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
2. What you need to know before your child takes **THORDEL[®]**
3. How to take **THORDEL[®]**
4. Possible side effects
5. How to store **THORDEL[®]**
6. Contents of the pack and other information

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 for your child, preventing asthma symptoms during the day and night.

- **THORDEL[®]** is used for the treatment of patients 2 to 5 years of age who are not adequately controlled on their medication and need additional therapy.
- **THORDEL[®]** may also be used as an alternative treatment to inhaled corticosteroids for 2 to 5 year old patients who have not recently taken oral corticosteroids for their asthma and have shown that they are unable to use inhaled corticosteroids.
- **THORDEL[®]** also helps prevent the narrowing of airways triggered by exercise for patients 2 years of age and older.

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

What is asthma?

Asthma is a long-term disease.

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.

2. WHAT YOU NEED TO KNOW BEFORE YOUR CHILD TAKES THORDEL[®]

Tell your doctor about any medical problems or allergies your child has or have had.

Do not give THORDEL[®] to your child

- if he/she is allergic to montelukast or any other ingredient of this medicine (see section 6).

Warnings and precautions

Talk to your doctor or pharmacist before you give THORDEL[®] to your child.

- If your child's 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 for the child. Always have with you the inhaled rescue medicine for asthma attacks for your child.
- It is important that your child takes all asthma medications prescribed by the doctor. THORDEL[®] should not be substituted by other asthma medications your doctor has prescribed for your child.
- You should be aware that if a child on anti-asthma medication develops a combination of symptoms such as flu-like illness, pins and needles or numbness of arms or legs, worsening of pulmonary symptoms, and/or rash, you should consult your doctor.
- Your child should not take acetyl-salicylic acid (aspirin) or anti-inflammatory medicines (also known as non-steroidal anti-inflammatory drugs or NSAIDs) if they make his/hers asthma worse.

Children and adolescents

Do not administer to children younger than 2 years of age.

There are available other pharmaceutical forms for pediatric patients based on the age range.

Other medications and THORDEL[®]

Tell your doctor or pharmacist if your child has been taking, have recently taken or might take any other medicine, including those taken without prescription.

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

Tell your doctor if your child is taking any of the following medicines before starting taking THORDEL[®] chewable tablets:

- phenobarbital (used for treatment of epilepsy)
- phenytoin (used for treatment of epilepsy)
- rifampicin (used to treat tuberculosis and some other infections)

Taking THORDEL[®] with food and drink

THORDEL[®] 4 mg chewable tablets should not be taken at the same time with food; they should be taken at least one hour before or two hours after food.

Pregnancy and breast-feeding

This section is not applicable as THORDEL[®] 4 mg chewable tablets will be used by children aged 2 to 5 years old.

Driving and using machines

This section is not applicable to THORDEL[®] 4mg chewable tablets, as it will be taken by children aged 2 to 5 years old, however the information affects the active substance, montelukast.

THORDEL[®] is not expected to affect 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[®] 4 mg chewable tablets contain aspartame, a source of phenylalanine. It may be harmful for you or your children if you suffer of phenylketonuria (a rare, hereditary disorder for the metabolism).

3. HOW TO TAKE THORDEL[®]

You or your child should always take this medicine according to the doctor's or pharmacist's instructions. If you are not sure, ask your child's doctor or pharmacist.

- This medicine should be administered to a child under the supervision of an adult. For children with difficulties to take chewable tablets there is a pharmaceutical form of granules.
- Your child should take one **THORDEL**[®] 4 mg chewable tablet once daily as your doctor prescribed.
- It should be taken even when your child has no symptoms or if your child has an acute asthma attack.

For children 2 to 5 years old:

The recommended dose is one chewable tablet of 4 mg daily, to be taken in the evening.

If your child takes **THORDEL**[®] 4mg chewable tablets, be sure that he/she does not take any other medicine that contains the same active ingredient, montelukast.

This medicine should be taken orally.

These tablets should be chewed before swallowed.

THORDEL[®] 4mg chewable tablets should not be taken at the same time with food; they should be taken at least one hour before or two hours after food.

If your child takes more THORDEL[®] than he/she should

Contact your child's doctor immediately for advice.

There are no side effects in the majority of overdose cases.

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 give to your child THORDEL[®]

Try to give **THORDEL**[®] as prescribed. However, if your child misses a dose, just resume the usual schedule of one chewable tablet once daily.

Do not give a double dose to make up for the forgotten dose.

If your child stops taking THORDEL[®]

THORDEL[®] 4mg chewable tablets can treat your child's asthma only if your child continues taking it.

It is important for your child to continue taking **THORDEL**[®] for as long as your doctor prescribes, as it will help control your child's asthma.

If you have any further questions on the use of this medicine, 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 4mg chewable tablets, the most commonly reported side effects (occurring in at least 1 out of 100 patients and less than 1 of 10 pediatric patients treated) thought to be related with montelukast chewable tablets were:

- abdominal pain
- thirst

Additionally, the following side effect was reported in clinical studies with montelukast 10 mg film-coated tablets and 5mg chewable tablets:

- headache

These were usually mild and occurred at a greater frequency in patients treated with montelukast than placebo (a pill 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 impairment (*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 occurring 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. HOE 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 chewable tablet contains sodium montelukast equivalent to 4mg montelukast.
- The other ingredients are:
Mannitol, Cellulose microcrystalline, Hydroxypropylcellulose, Iron oxide red (E172), Carmellose sodium, Cherry flavor, Aspartame and Magnesium stearate.

What **THORDEL**® looks like and contents of the pack

THORDEL® 4mg chewable tablets are pink colored, round, biconvex shape.
Packed in blisters containing 14 or 28 chewable tablet.

Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer

Marketing Authorization Holdr

TARGET PHARMA Ltd.
54 Menandrou st., 10431 Athens Greece
Tel.: +30 210 52 24 830, Fax: +30 210 52 24 838
E-mail info@targetpharma.gr, www.targetpharma.gr

Manufacturer

PHARMATHEN PHARMACEUTICALS ABEE
6 Dervenakion st. 153 31 Pallini, Attikis, Greece

This leaflet was last revised on November 2017.



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1. WHAT THORDEL[®] IS AND WHAT IS USED FOR**What is THORDEL[®]**

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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 for your child, preventing asthma symptoms during the day and night.

- **THORDEL[®]** is used for the treatment of pediatric patients 6 to 14 years of age who are not adequately controlled on their medication and need additional therapy.
- **THORDEL[®]** may also be used as an alternative treatment to inhaled corticosteroids for 6 to 14 year old patients who have not recently taken oral corticosteroids for their asthma and have shown that they are unable to use inhaled corticosteroids.
- **THORDEL[®]** also helps prevent the narrowing of airways triggered by exercise.

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

What is asthma?

Asthma is a long-term disease.

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.

2. WHAT YOU NEED TO KNOW BEFORE YOUR CHILD TAKES THORDEL®

Tell your doctor about any medical problems or allergies your child has or have had.

Do not give THORDEL® to your child

- if he/she is allergic to montelukast or any other ingredient of this medicine (see section 6).

Warnings and precautions

Talk to your doctor or pharmacist before you give THORDEL® to your child.

- If your child's 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 for the child. Always have with you the inhaled rescue medicine for asthma attacks for your child.
- It is important that your child takes all asthma medications prescribed by the doctor. THORDEL® should not be substituted by other asthma medications your doctor has prescribed for your child.
- You should be aware that if a child on anti-asthma medication develops a combination of symptoms such as flu-like illness, pins and needles or numbness of arms or legs, worsening of pulmonary symptoms, and/or rash, you should consult your doctor.
- Your child should not take acetyl-salicylic acid (aspirin) or anti-inflammatory medicines (also known as non-steroidal anti-inflammatory drugs or NSAIDs) if they make his/hers asthma worse.

Children and adolescents

Do not administer to children younger than 6 years of age.

There are available other pharmaceutical forms for pediatric patients based on the age range.

Other medications and THORDEL®

Tell your doctor or pharmacist if your child has been taking, have recently taken or might take any other medicine, including those taken without prescription.

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

Tell your doctor if your child is taking any of the following medicines before starting taking THORDEL® chewable tablets:

- phenobarbital (used for treatment of epilepsy)
- phenytoin (used for treatment of epilepsy)
- rifampicin (used to treat tuberculosis and some other infections)

Taking THORDEL® with food and drink

THORDEL® 5 mg chewable tablets should not be taken at the same time with food; they should be taken at least one hour before or two hours after 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®.

Pregnancy

Your doctor will assess whether you can take THORDEL® during this time.

Breast-feeding

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[®] 5mg chewable tablets contain aspartame, a source of phenylalanine. It may be harmful for you or your children if you suffer of phenylketonuria (a rare, hereditary disorder for the metabolism).

3. HOW TO TAKE THORDEL[®]

You or your child should always take this medicine according to the doctor's or pharmacist's instructions. If you are not sure, ask your doctor or pharmacist.

- You or your child should take one **THORDEL[®] 5 mg chewable tablet** once daily as your doctor prescribed.
- It should be taken even when your child has no symptoms or if your child has an acute asthma attack.

For children 6 to 14 years old:

The recommended dose is one chewable tablet of 5mg daily, to be taken in the evening.

If you or your child takes **THORDEL[®] 5mg chewable tablets**, be sure that you or your child does not take any other medicine that contains montelukast.

This medicine should be taken orally.

These tablets should be chewed before swallowed.

THORDEL[®] 5mg chewable tablets should not be taken at the same time with food; they should be taken at least one hour before or two hours after food.

If you or your child takes more THORDEL[®] than you should

Contact your doctor immediately for instructions.

There are no side effects in the majority of overdose cases.

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 or give to your child THORDEL[®]

Try to take or give to your child **THORDEL[®]** as prescribed.

However if you or your child misses a dose, just resume the usual schedule of one chewable tablet once daily.

Do not take or give to your child double dose to make up for the forgotten dose.

If you or child stops taking THORDEL[®]

THORDEL[®] 5mg chewable tablets can treat yours or your child's asthma only if you or your child continues to taking it.

It is important for you or your child to continue taking **THORDEL[®]** for as long as your doctor prescribes, as it will help control yours or your child's asthma.

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

4. ΠΙΘΑΝΕΣ ΑΝΕΠΙΘΥΜΗΤΕΣ ΕΝΕΡΓΕΙΕΣ

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

In clinical studies with montelukast 5mg chewable tablets, the most commonly reported side effects (occurring in at least 1 out of 100 patients and less than 1 of 10 pediatric patients treated) thought to be related with montelukast chewable tablets were:

- headache

Additionally, the following side effect was reported in clinical studies with montelukast 10mg film-coated tablets:

- abdominal pain

These were usually mild and occurred at a greater frequency in patients treated with montelukast than placebo (a pill 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

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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 impairment (*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

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By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE THORDEL[®]

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6. CONTENTS OF THE PACK AND OTHER INFORMATION

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- The other ingredients are:
Mannitol, Cellulose microcrystalline, Hydroxypropylcellulose, Iron oxide red (E172), Carmellose sodium, Cherry flavor, Aspartame and Magnesium stearate.

What **THORDEL[®]** looks like and contents of the pack

THORDEL[®] 5mg chewable tablets are pink colored, round, biconvex shape.
Packed in blisters containing 14 or 28 tablets.

Not all pack sizes may be marketed

Marketing Authorization Holder and Manufacturer

Marketing Authorization Holdr

TARGET PHARMA Ltd.

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Manufacturer

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This leaflet was last revised on November 2017.