

PACKAGE LEAFLET: INFORMATION FOR THE USER

Montelukast 4 mg chewable tablets

For children from 2 to 5 years

Montelukast

Read all of this leaflet carefully before your child starts taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for your child. Do not pass it on to others. It may harm them, even if their symptoms are the same as your child's.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Montelukast chewable tablets are and what they are used for
2. Before Montelukast chewable tablets are taken
3. How to take Montelukast chewable tablets
4. Possible side effects
5. How to store Montelukast chewable tablets
6. Further information

1. WHAT MONTELUKAST CHEWABLE TABLETS ARE AND WHAT THEY ARE USED FOR

Montelukast chewable tablets are a leukotriene receptor antagonist that blocks substances called leukotrienes.

Leukotrienes cause narrowing and swelling of airways in the lungs. By blocking leukotrienes, Montelukast chewable tablets improve asthma symptoms and help control asthma.

Your doctor has prescribed Montelukast chewable tablets to treat your child's asthma, preventing asthma symptoms during the day and night.

- Montelukast chewable tablets are used for the treatment of 2 to 5 year old patients who are not adequately controlled on their medication and need additional therapy.
- Montelukast chewable tablets 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.
- Montelukast chewable tablets also help prevent the narrowing of airways triggered by exercise for patients 2 years of age and older.

Your doctor will determine how Montelukast chewable tablets 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. BEFORE MONTELUKAST CHEWABLE TABLETS ARE TAKEN

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

Do not give Montelukast chewable tablets to your child if he/she is

- allergic (hypersensitive) to montelukast or any of the other ingredients of Montelukast chewable tablets (see section 6. Further information).

Take special care with Montelukast chewable tablets

- If your child's asthma or breathing gets worse, tell your doctor immediately.
- Montelukast chewable tablets are not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor has given you for your child. Always have your

child's inhaled rescue medicine for asthma attacks with you.

- It is important that your child takes all asthma medications prescribed by your doctor. Montelukast chewable tablets should not be used instead of other asthma medications your doctor has prescribed for your child.
- If your child is on anti-asthma medicines, be aware that if he/she develops a combination of symptoms such as flu-like illness, pins and needles or numbness of arms or legs, worsening of pulmonary (lung) 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/her asthma worse.

Taking other medicines

Some medicines may affect how Montelukast chewable tablets work, or Montelukast chewable tablets may affect how your child's other medicines work.

Please tell your doctor or pharmacist if your child is taking or has recently taken other medicines, including those obtained without a prescription.

Tell your doctor if your child is taking the following medicines before starting Montelukast chewable tablets:

- 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)

Taking Montelukast chewable tablets with food and drink

Montelukast 4 mg chewable tablets should not be taken at the same time as food; they should be taken at least 1 hour before or 2 hours after food.

Pregnancy and breast-feeding

This subsection is not applicable for the Montelukast 4 mg chewable tablets, since they are intended for use in children 2 to 5 years of age, however the following information is relevant to the active ingredient, montelukast.

Use in pregnancy

Women who are pregnant or intend to become pregnant should consult their doctor before taking Montelukast chewable tablets. Your doctor will assess whether you can take Montelukast chewable tablets during this time.

Use in breast-feeding

It is not known if Montelukast appears in breast milk. You should consult your doctor before taking Montelukast chewable tablets if you are breast-feeding or intend to breast-feed.

Driving and using machines

This subsection is not applicable for the Montelukast 4 mg chewable tablets since they are intended for use in children 2 to 5 years of age, however the following information is relevant to the active ingredient, montelukast.

Montelukast chewable tablets are not expected to affect your ability to drive a car or operate machinery. 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.

Important information about some of the ingredients of Montelukast chewable tablets

Montelukast chewable tablets contain aspartame, a source of phenylalanine. May be harmful for patients with phenylketonuria. If your child has phenylketonuria (a rare, hereditary disorder of the metabolism), you should take into account that each 4 mg chewable tablet contains phenylalanine (equivalent to 0.169 mg phenylalanine per 4 mg chewable tablet).

3. HOW TO TAKE MONTELUKAST CHEWABLE TABLETS

- This medicine is to be given to a child under adult supervision.
- Your child should take only one Montelukast chewable tablet once a day as prescribed by your doctor.
- It should be taken even when your child has no symptoms or if he/she has an acute asthma attack.
- Always have your child take Montelukast chewable tablets as your doctor has told you. You should check with your child's doctor or pharmacist if you are not sure.

- To be taken by mouth.

For children 2 to 5 years of age:

One 4 mg chewable tablet daily to be taken in the evening. Montelukast 4 mg chewable tablets should not be taken at the same time as food; it should be taken at least 1 hour before or 2 hours after food.

If your child is taking Montelukast chewable tablets, be sure that he/she does not take any other medicines that contain the same active ingredient, montelukast.

For children 2 to 5 years old, Montelukast 4 mg chewable tablets are available.

For children 6 to 14 years old, Montelukast 5 mg chewable tablets are available.

The Montelukast 4 mg chewable tablet is not recommended below 2 years of age.

If your child takes more Montelukast chewable tablets than he/she should

Contact your child's 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 give Montelukast chewable tablets to your child

Try to give Montelukast chewable tablets as prescribed. However, if your child misses a dose, just resume the usual schedule of one tablet once daily.

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

If your child stops taking Montelukast chewable tablets

Montelukast chewable tablets can treat your child's asthma only if he/she continues taking them.

It is important for your child to continue taking Montelukast chewable tablets for as long as your doctor prescribes. They will help control your child's 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, Montelukast chewable tablets can cause side effects, although not everybody gets them.

If you notice any of the following serious side effects that have been reported with montelukast, stop giving Montelukast tablets to your child and contact a doctor immediately:

- rash, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing (severe allergic reaction).
- flu-like illness, pins and needles or numbness of arms and legs, worsening of pulmonary symptoms and/or rash (Churg-Strauss syndrome).
- behaviour and mood related changes such as suicidal thoughts and actions.
- severe skin reactions (erythema multiforme) that may occur without warning.

The frequency of possible side effects listed below is defined using the following convention:

Very common (affects more than 1 user in 10)

Common (affects 1 to 10 users in 100)

Uncommon (affects 1 to 10 users in 1,000)

Rare (affects 1 to 10 users 10,000)

Very rare (affects less than 1 user in 10,000)

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

Common side effects

In clinical studies the following side effects were reported:

- abdominal pain
- thirst

Additionally, the following side effect was reported in clinical studies with Montelukast 10 mg tablets and 5 mg 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).

Additionally, while montelukast has been on the market, 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*)
- behaviour and mood related changes [dream abnormalities, including nightmares, trouble sleeping, sleepwalking, irritability, feeling anxious, restlessness, agitation including aggressive behaviour or hostility, depression (*Uncommon*); tremor (*Rare*), hallucinations, disorientation, suicidal thoughts and actions (*Very rare cases*)]
- dizziness, drowsiness, pins and needles/numbness, seizure (*Uncommon*)
- palpitations (*Rare*)
- nosebleed (*Uncommon*)
- diarrhoea, 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*); tiredness, feeling unwell, swelling (*Uncommon*)
- 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) (*Very rare*)

Ask your doctor or pharmacist for more information about side effects. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your child's doctor or pharmacist.

5. HOW TO STORE MONTELUKAST CHEWABLE TABLETS

Keep out of the reach and sight of children.

Do not use Montelukast chewable tablets after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions.

Store in the original package in order to protect from light and moisture.

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. FURTHER INFORMATION

What Montelukast chewable tablets contain

- The active substance is montelukast. Each tablet contains 4.16 mg montelukast sodium which corresponds to 4 mg of montelukast.
- The other ingredients are: microcrystalline cellulose, croscarmellose sodium, magnesium stearate, aspartame (E951), iron oxide red (E172), mannitol (E421), cherry flavour (Firmenich CHERRY 501027 AP0551).

What Montelukast chewable tablets look like and contents of the pack

Montelukast 4 mg chewable tablets are pink coloured, oval biconvex shaped, uncoated tablets, with breakline on both sides. Tablets are packed into Alu/Alu blisters. The blisters are packed into cartons.

Pack sizes: 28 tablets

Marketing Authorisation Holder and Manufacturer

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PACKAGE LEAFLET: INFORMATION FOR THE USER

Montelukast 5 mg chewable tablets

For children from 6 to 14 years

Montelukast

Read all of this leaflet carefully before your child starts taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for your child. Do not pass it on to others. It may harm them, even if their symptoms are the same as your child's.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Montelukast chewable tablets are and what they are used for
2. Before Montelukast chewable tablets are taken
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1. WHAT MONTELUKAST CHEWABLE TABLETS ARE AND WHAT THEY ARE USED FOR

Montelukast chewable tablets are a leukotriene receptor antagonist that blocks substances called leukotrienes.

Leukotrienes cause narrowing and swelling of airways in the lungs. By blocking leukotrienes, Montelukast chewable tablets improve asthma symptoms and help control asthma.

Your doctor has prescribed Montelukast chewable tablets to treat your child's asthma, preventing asthma symptoms during the day and night.

- Montelukast chewable tablets are used for the treatment of patients who are not adequately controlled on their medication and need additional therapy.
- Montelukast chewable tablets 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.
- Montelukast chewable tablets also help prevent the narrowing of airways triggered by exercise.

Your doctor will determine how Montelukast chewable tablets 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. BEFORE MONTELUKAST CHEWABLE TABLETS ARE TAKEN

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

Do not give Montelukast chewable tablets to your child if he/she is

- allergic (hypersensitive) to montelukast or any of the other ingredients of Montelukast chewable tablets (see section 6. Further information).

Take special care with Montelukast chewable tablets

- If your child's asthma or breathing gets worse, tell your doctor immediately.
- Montelukast chewable tablets are not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor has given you for your child. Always have your child's inhaled rescue medicine for asthma attacks with you.
- It is important that your child takes all asthma medications prescribed by your doctor. Montelukast chewable tablets

should not be used instead of other asthma medications your doctor has prescribed for your child.

- If your child is on anti-asthma medicines, be aware that if he/she develops a combination of symptoms such as flu-like illness, pins and needles or numbness of arms or legs, worsening of pulmonary (lung) 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/her asthma worse.

Taking other medicines

Some medicines may affect how Montelukast chewable tablets work, or Montelukast chewable tablets may affect how your child's other medicines work.

Please tell your doctor or pharmacist if your child is taking or has recently taken other medicines, including those obtained without a prescription.

Tell your doctor if your child is taking the following medicines before starting Montelukast chewable tablets:

- 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)

Taking Montelukast chewable tablets with food and drink

Montelukast 5 mg chewable tablets should not be taken at the same time as food; they should be taken at least 1 hour before or 2 hours after food.

Pregnancy and breast-feeding

Use in pregnancy

Women who are pregnant or intend to become pregnant should consult their doctor before taking Montelukast chewable tablets. Your doctor will assess whether you can take Montelukast chewable tablets during this time.

Use in breast-feeding

It is not known if Montelukast appears in breast milk. You should consult your doctor before taking Montelukast chewable tablets if you are breast-feeding or intend to breast-feed.

Driving and using machines

This subsection is not applicable for the Montelukast 5 mg chewable tablets since they are intended for use in children 6 to 14 years of age, however the following information is relevant to the active ingredient, montelukast.

Montelukast chewable tablets are not expected to affect your ability to drive a car or operate machinery. 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.

Important information about some of the ingredients of Montelukast chewable tablets

Montelukast chewable tablets contain aspartame, a source of phenylalanine. May be harmful for patients with phenylketonuria. If your child has phenylketonuria (a rare, hereditary disorder of the metabolism), you should take into account that each 5 mg chewable tablet contains phenylalanine (equivalent to 0.221 mg phenylalanine per 5 mg chewable tablet).

3. HOW TO TAKE MONTELUKAST CHEWABLE TABLETS

- Your child should take only one Montelukast chewable tablet once a day as prescribed by your doctor.
- It should be taken even when your child has no symptoms or if he/she has an acute asthma attack.
- Always have your child take Montelukast chewable tablets as your doctor has told you. You should check with your child's doctor or pharmacist if you are not sure.
- To be taken by mouth. The tablet can be chewed or swallowed.
- If swallowed it should be taken with a sufficient amount of fluid (e. g. with a glass of water).

For children 6 to 14 years of age:

One Montelukast 5 mg chewable tablet daily to be taken in the evening. Montelukast 5 mg chewable tablets should not be taken at the same time as food; it should be taken at least 1 hour before or 2 hours after food.

If your child is taking Montelukast chewable tablets, be sure that he/she does not take any other products that contain the same active ingredient, montelukast.

For children 2 to 5 years old, Montelukast 4 mg chewable tablets are available.

For children 6 to 14 years old, Montelukast 5 mg chewable tablets are available.

If your child takes more Montelukast chewable tablets than he/she should

Contact your child's 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 give Montelukast chewable tablets to your child

Try to give Montelukast chewable tablets as prescribed. However, if your child misses a dose, just resume the usual schedule of one tablet once daily.

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

If your child stops taking Montelukast chewable tablets

Montelukast chewable tablets can treat your child's asthma only if he/she continues taking them.

It is important for your child to continue taking Montelukast chewable tablets for as long as your doctor prescribes. They will help control your child's 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, Montelukast chewable tablets can cause side effects, although not everybody gets them.

If you notice any of the following serious side effects that have been reported with montelukast, stop taking Montelukast tablets or giving Montelukast tablets to your child and contact a doctor immediately:

- rash, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing (severe allergic reaction).
- flu-like illness, pins and needles or numbness of arms and legs, worsening of pulmonary symptoms and/or rash (Churg-Strauss syndrome).
- behaviour and mood related changes such as suicidal thoughts and actions.
- severe skin reactions (erythema multiforme) that may occur without warning.

The frequency of possible side effects listed below is defined using the following convention:

Very common (affects more than 1 user in 10)

Common (affects 1 to 10 users in 100)

Uncommon (affects 1 to 10 users in 1,000)

Rare (affects 1 to 10 users 10,000)

Very rare (affects less than 1 user in 10,000)

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

Common side effects

In clinical studies the following side effects were reported:

- abdominal pain
- headache.

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

Additionally, while montelukast has been on the market, 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*)

- behaviour and mood related changes [dream abnormalities, including nightmares, trouble sleeping, sleepwalking, irritability, feeling anxious, restlessness, agitation including aggressive behaviour or hostility, depression (*Uncommon*); tremor (*Rare*); hallucinations, disorientation, suicidal thoughts and actions (*Very rare*)]
- dizziness, drowsiness, pins and needles/numbness, seizure (*Uncommon*)
- palpitations (*Rare*)
- nosebleed (*Uncommon*)
- diarrhoea, 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 reaction (erythema multiforme) that may occur without warning (*Very rare*)
- joint or muscle pain, muscle cramps (*Uncommon*)
- fever (*Common*); tiredness, feeling unwell, swelling (*Uncommon*)
- 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) (*Very rare*)

Ask your doctor or pharmacist for more information about side effects. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your child's doctor or pharmacist.

5. HOW TO STORE MONTELUKAST CHEWABLE TABLETS

Keep out of the reach and sight of children.

Do not use Montelukast chewable tablets after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions.

Store in the original package in order to protect from light and moisture.

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. FURTHER INFORMATION

What Montelukast chewable tablets contain

- The active substance is montelukast. Each tablet contains 5.2 mg montelukast sodium which corresponds to 5 mg of montelukast.
- The other ingredients are: microcrystalline cellulose, croscarmellose sodium, magnesium stearate, aspartame (E951), iron oxide red (E172), mannitol (E421), cherry flavour (Firmenich CHERRY 501027 AP0551).

What Montelukast chewable tablets look like and contents of the pack

Montelukast 5 mg chewable tablets are pink coloured, round, uncoated tablets, with breakline on both sides.

Tablets are packed into Alu/Alu blisters. The blisters are packed into cartons.

Pack sizes: 28 tablets

Marketing Authorisation Holder and manufacturer

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PACKAGE LEAFLET: INFORMATION FOR THE USER

Montelukast 10 mg tablets

For adolescents and adults from 15 years

Montelukast

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Montelukast tablets are and what they are used for
2. Before you take Montelukast tablets
3. How to take Montelukast tablets
4. Possible side effects
5. How to store Montelukast tablets
6. Further information

1. WHAT MONTELUKAST TABLETS ARE AND WHAT THEY ARE USED FOR

Montelukast tablets are a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in your lungs and also cause allergy symptoms. By blocking leukotrienes, Montelukast tablets improve asthma symptoms, help control asthma and improve seasonal allergy symptoms (also known as hay fever or seasonal allergic rhinitis).

Your doctor has prescribed Montelukast tablets to treat asthma, preventing asthma symptoms during the day and night.

- Montelukast tablets are used for the treatment of patients who are not adequately controlled on their medication and need additional therapy.
- Montelukast tablets also help prevent the narrowing of airways triggered by exercise.
- In those asthmatic patients in whom Montelukast tablets are indicated in asthma, Montelukast tablets can also provide symptomatic relief of seasonal allergic rhinitis.

Your doctor will determine how Montelukast tablets should be used depending on the symptoms and severity of your 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.

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. BEFORE YOU TAKE MONTELUKAST TABLETS

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

Do not take Montelukast tablets if you are

- allergic (hypersensitive) to montelukast or any of the other ingredients of Montelukast tablets (see section 6. Further information).

Take special care with Montelukast tablets

- If your asthma or breathing gets worse, tell your doctor immediately.
- Montelukast tablets are not meant to treat acute asthma

attacks. If an attack occurs, follow the instructions your doctor has given for 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. Montelukast tablets should not be used instead of 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 (lung) 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.

Use in children

For children 2 to 5 years old, Montelukast 4 mg chewable tablets are available.

For children 6 to 14 years old, Montelukast 5 mg chewable tablets are available.

Taking other medicines

Some medicines may affect how Montelukast tablets work, or Montelukast tablets may affect how other medicines work.

Please tell your doctor or pharmacist if you are taking or have recently taken other medicines, including those obtained without a prescription.

Tell your doctor if you are taking the following medicines before starting Montelukast tablets:

- 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)

Taking Montelukast tablets with food and drink

Montelukast tablets may be taken with or without food.

Pregnancy and breast-feeding

Use in pregnancy

Women who are pregnant or intend to become pregnant should consult their doctor before taking Montelukast tablets. Your doctor will assess whether you can take Montelukast tablets during this time.

Use in breast-feeding

It is not known if Montelukast appears in breast milk. You should consult your doctor before taking Montelukast tablets if you are breast-feeding or intend to breast-feed.

Driving and using machines

Montelukast tablets are not expected to affect your ability to drive a car or operate machinery. However, individual responses to medication may vary. Certain side effects (such as dizziness and drowsiness) that have been reported very rarely with Montelukast tablets may affect some patients' ability to drive or operate machinery.

Important information about some of the ingredients of Montelukast tablets

Montelukast tablets contain aspartame, a source of phenylalanine. May be harmful for patients with phenylketonuria. If you have phenylketonuria (a rare, hereditary disorder of the metabolism), you should take into account that each 10 mg tablet contains phenylalanine (equivalent to 0.421 mg phenylalanine per 10 mg tablet).

3. HOW TO TAKE MONTELUKAST TABLETS

- You should take only one Montelukast tablet once a day as prescribed by your doctor.
- It should be taken even when you have no symptoms or have an acute asthma attack.
- Always take Montelukast tablets as your doctor has told you.
- You should check with your doctor or pharmacist if you are not sure.
- To be taken by mouth. The tablet should be swallowed with a

sufficient amount of fluid (e.g. with a glass of water).

For adults 15 years of age and older:

One 10 mg tablet to be taken daily in the evening. Montelukast 10 mg tablets may be taken with or without food.

If you are taking Montelukast tablets, be sure that you do not take any other products that contain the same active ingredient, montelukast.

For children 2 to 5 years old, Montelukast 4 mg chewable tablets are available.

For children 6 to 14 years old, Montelukast 5 mg chewable tablets are available.

If you take more Montelukast tablets 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 Montelukast tablets

Try to take Montelukast tablets as prescribed. However, if you miss a dose, just resume the usual schedule of one tablet once daily. Do not take a double dose to make up for a forgotten dose.

If you stop taking Montelukast tablets

Montelukast tablets can treat your asthma only if you continue taking them.

It is important to continue taking Montelukast tablets for as long as your doctor prescribes. They 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, Montelukast tablets can cause side effects, although not everybody gets them.

If you notice any of the following serious side effects that have been reported with montelukast, stop taking Montelukast tablets and contact a doctor immediately:

- rash, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing (severe allergic reaction).
- flu-like illness, pins and needles or numbness of arms and legs, worsening of pulmonary symptoms and/or rash (Churg-Strauss syndrome).
- behaviour and mood related changes such as suicidal thoughts and actions.
- severe skin reactions (erythema multiforme) that may occur without warning.

The frequency of possible side effects listed below is defined using the following convention:

Very common (affects more than 1 user in 10)

Common (affects 1 to 10 users in 100)

Uncommon (affects 1 to 10 users in 1,000)

Rare (affects 1 to 10 users 10,000)

Very rare (affects less than 1 user in 10,000)

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

Common side effects

In clinical studies the following side effects were reported:

- abdominal pain
- headache.

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

Additionally, while montelukast has been on the market, 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*)
- behaviour and mood related changes [dream abnormalities, including nightmares, trouble sleeping, sleepwalking, irritability, feeling anxious, restlessness, agitation including aggressive behaviour or hostility, depression, (*Uncommon*); tremor (*Rare*); hallucinations, disorientation, suicidal

thoughts and actions (*Very rare*)

- dizziness, drowsiness, pins and needles/numbness, seizure (*Uncommon*)
- palpitations (*Rare*)
- nosebleed (*Uncommon*)
- diarrhoea, 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*); tiredness, feeling unwell, swelling (*Uncommon*)
- 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) (*Very rare*)

Ask your doctor or pharmacist for more information about side effects. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE MONTELUKAST TABLETS

Keep out of the reach and sight of children.

Do not use Montelukast tablets after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from light and moisture

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. FURTHER INFORMATION

What Montelukast tablets contain

- The active substance is montelukast. Each tablet contains 10.4 mg montelukast sodium which corresponds to 10 mg of montelukast.
- The other ingredients are: mannitol (E421), cellulose microcrystalline, croscarmellose sodium, magnesium stearate, aspartame (E951), cherry flavour (Firmenich CHERRY 501027 AP0551), iron oxide yellow (E172), iron oxide red (E172).

What Montelukast tablets look like and contents of the pack

Montelukast 10 mg tablets are light brown coloured, round biconvex shaped, uncoated tablet, with breakline on both sides.

Tablets are packed into Alu/Alu blisters. The blisters are packed into cartons.

Pack sizes: 28 tablets.

Marketing Authorisation Holder and Manufacturer

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This leaflet was last approved in 02/2013.

Colour Black

LOCATION : Indrad	COUNTRY : UK	Supersedes A / W No.:		
SIZE : 180 x 300 mm_Front/Back Side	CODE : 8044757-7803	DATE : 07-01-2014		
REMARK : Folding Length 35 mm				
SUBSTRATE :				
Activities	Department	Name	Signature	Date
Prepared By	Pkg.Dev			
Reviewed By	Pkg.Dev			
Reviewed By	RA			
Approved By	CQA			



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