

## Package leaflet: Information for the user

### Montelukast Bluefish 4 mg/ 5 mg chewable 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. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Montelukast Bluefish is and what it is used for
2. What you need to know before you take Montelukast Bluefish
3. How to take Montelukast Bluefish
4. Possible side effects
5. How to store Montelukast Bluefish
6. Contents of the pack and other information

#### **1. What Montelukast Bluefish is and what it is used for**

##### **What Montelukast Bluefish is**

Montelukast Bluefish is a leukotriene receptor antagonist that blocks substances called leukotrienes.

##### **How Montelukast Bluefish works**

Leukotrienes cause narrowing and swelling of airways in the lungs and also cause allergy symptoms. By blocking leukotrienes, Montelukast Bluefish improve asthma symptoms, help control asthma and improve seasonal allergy symptoms (also known as hay fever or seasonal allergic rhinitis).

##### **When Montelukast Bluefish should be used**

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

- Montelukast Bluefish is used for the treatment of children from 2 to 5 years (4 mg dose) and 6 to 14 years (5 mg dose) who are not adequately controlled on their medication and need **additional therapy**.
- Montelukast Bluefish may also be used as an **alternative treatment to inhaled corticosteroids** for children from 2 to 5 year/6-14 years who have not recently taken oral corticosteroids for their asthma and have shown that they are unable to use inhaled corticosteroids
- Montelukast Bluefish also helps **prevent the narrowing of airways** triggered by exercise for children from 2 years of age and older.

Your doctor will determine how Montelukast Bluefish 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.

### **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 Montelukast Bluefish**

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

### **Do not take Montelukast Bluefish**

- If you or your child is allergic to montelukast or any of the other ingredients of this medicine (listed in section 6).

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Montelukast Bluefish.

- If your child's asthma or breathing gets worse, tell your doctor immediately.
- Oral Montelukast Bluefish **is not meant to treat acute asthma attacks**. If an asthma 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 take all asthma medicines prescribed by your doctor. Montelukast Bluefish 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 symptoms, and/or rash, you should consult your doctor.
- Your child should not take **acetyl-salicylic acid** (aspirin) or other **anti-inflammatory medicines** (also known as non-steroidal anti-inflammatory drugs or NSAIDs) if they make his/her asthma worse.
- Patients should be aware that various **neuropsychiatric events (for example behaviour and mood related changes)** have been reported in adults, adolescents and children with montelukast (see section 4). If your child develops such symptoms while taking Montelukast Bluefish, you should consult your child's doctor.

### **Children and adolescents**

There are different forms of this medicine available for paediatric patients under 18 years of age based on age range.

### **Other medicines and Montelukast Bluefish**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines may affect how Montelukast Bluefish works, or Montelukast Bluefish may affect how your child's other medicines work.

Tell your doctor if your child is taking one of the following medicines before starting Montelukast Bluefish:

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

#### **Montelukast Bluefish with food and drink**

Montelukast Bluefish 4 mg/ 5 mg chewable tablets should not be taken immediately with 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 Bluefish 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.

##### *Pregnancy*

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

##### *Breast-feeding*

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

#### **Driving and using machines**

This subsection is not applicable for the Montelukast Bluefish 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 Bluefish is 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 Bluefish may affect some patients' ability to drive or operate machinery.

#### **Montelukast Bluefish contains aspartame and sodium**

This medicine contains 1.2 mg (4 mg dose) and 1.5 mg (5 mg dose) aspartame in each tablet. Aspartame is a source of phenylalanine. It may be harmful if your child has phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

### **3. How to take Montelukast Bluefish**

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

This medicine is to be given to a child under adult supervision.

- Your child should take only one table of Montelukast Bluefish 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.
- 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 Bluefish 4 mg chewable tablets should **not** be taken immediately with food; it should be taken at least 1 hour before or 2 hours after food.

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

**For children 6 to 14 years of age:**

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

If you or your child is taking Montelukast Bluefish, be sure that you or your child does not take any other medicines that contain the same active ingredient, montelukast.

**If your child takes more Montelukast Bluefish 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 Bluefish to your child**

Try to give Montelukast Bluefish 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 Bluefish**

Montelukast Bluefish can treat your child's asthma only if he/she continues taking it.

It is important for your child to continue taking Montelukast Bluefish for as long as your doctor prescribes. It will help control your child's asthma.

If you have any further questions on the use of this medicine, ask your child's 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 4 mg chewable tablets, the most commonly reported side effects (may affect up to 1 in 10 people) thought to be related to montelukast chewable tablets were:

- abdominal pain
- thirst

Additionally, the following side effect was reported in clinical studies with montelukast 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).

### **Serious side effects**

**Talk with your doctor immediately** if you notice any of the following side effects, which may be serious, and for which you may need urgent medical treatment.

Uncommon: may affect up to 1 in 100 people

- allergic reactions including swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing
- behaviour and mood related changes: agitation including aggressive behaviour or hostility, depression
- seizure

Rare: may affect up to 1 in 1,000 people

- increased bleeding tendency
- tremor
- palpitations

Very rare: may affect up to 1 in 10,000 people

- 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) (see Section 2)
- low blood platelet count
- behaviour and mood related changes: hallucinations, disorientation, suicidal thoughts and actions
- swelling (inflammation) of the lungs
- severe skin reactions (erythema multiforme) that may occur without warning
- inflammation of the liver (hepatitis)

### **Other side effects while the medicine has been on the market**

Very common: may affect more than 1 in 10 people

- upper respiratory infection

Common: may affect up to 1 in 10 people

- diarrhoea, nausea, vomiting
- rash
- fever
- elevated liver enzymes

Uncommon: may affect up to 1 in 100 people

- behaviour and mood related changes: dream abnormalities, including nightmares, trouble sleeping, sleepwalking, irritability, feeling anxious, restlessness
- dizziness, drowsiness, pins and needles/numbness
- nosebleed
- dry mouth, indigestion
- bruising, itching, hives
- joint or muscle pain, muscle cramps
- bedwetting in children
- weakness/tiredness, feeling unwell, swelling

Rare: may affect up to 1 in 1,000 people

- behaviour and mood related changes: disturbance in attention, memory impairment, uncontrolled muscle movements

Very rare: may affect up to 1 in 10,000 people

- tender red lumps under the skin, most commonly on your shins (erythema nodosum)
- behaviour and mood related changes: obsessive-compulsive symptoms, stuttering

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie)

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

## **5. How to store Montelukast Bluefish**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister after EXP. The expiry date refers to the last date of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Montelukast Bluefish contains**

- The active substance is montelukast. Each tablet contains montelukast sodium which corresponds to 4 mg/ 5 mg of montelukast.
- The other ingredients are mannitol (E 421), croscarmellose sodium (E 468), hydroxypropyl cellulose (E 463), ferric oxide, cellulose microcrystalline (E 460), aspartame (E 951), cherry flavour and magnesium stearate.

### **What Montelukast Bluefish looks like and contents of the pack**

Chewable tablet

4 mg: Light pink coloured, speckled, oval, biconvex shaped, chewable tablets debossed with 'T' on one side and '112' on the other side.

5 mg: Light pink coloured, speckled, round, biconvex shaped, chewable tablets debossed with 'I' on one side and '113' on the other side

Available in Aluminium-Aluminium blister packs of 28 tablets.

### **Marketing Authorisation Holder and Manufacturer**

#### Marketing Authorisation Holder

Bluefish Pharmaceuticals AB

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Manufacturer

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**This medicinal product is authorised in the Member States of the EEA under the following names:**

Ireland	Montelukast Bluefish 4 mg/5 mg Chewable Tablets
Poland	Montelukast Bluefish Pharma
Portugal	Montelucaste Bluefish

**This leaflet was last approved in MM/YYYY.**