

## Package leaflet: Information for the user

### Montelukast Bluefish 10mg 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. 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 asthma, preventing your asthma symptoms during the day and night.

- Montelukast Bluefish is used for the treatment of adults and adolescents 15 years of age and older who are not adequately controlled on their medication and need additional therapy.
- Montelukast Bluefish also helps prevent the narrowing of airways triggered by exercise.
- In those asthmatic patients in whom Montelukast Bluefish is indicated in asthma, Montelukast Bluefish can also provide symptomatic relief of seasonal allergic rhinitis.

Your doctor will determine how Montelukast Bluefish 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. 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 are 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 asthma or breathing gets worse, tell your doctor immediately.
- Oral Montelukast Bluefish 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 or 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 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.

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 you develop such symptoms while taking Montelukast Bluefish, you should consult your doctor.

### **Children and adolescents**

Do not give this medicine to children less than 15 years of age.

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 other medicines work.

Tell your doctor if you are taking 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)
- Gemfibrozil (used for treatment of high lipid levels in plasma)

**Montelukast Bluefish with food and drink**

Montelukast Bluefish 10 mg film-coated tablet 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 Montelukast Bluefish.

Pregnancy

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**

Montelukast Bluefish 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 with Montelukast Bluefish may affect some patients' ability to drive or operate machinery.

**Montelukast Bluefish contains lactose and sodium**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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

**3. How to take Montelukast Bluefish**

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 Montelukast Bluefish 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 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 Montelukast Bluefish, be sure that you do not take any other products that contain the same active ingredient, montelukast.

This medicine is for oral use.

You can take Montelukast Bluefish 10 mg with or without food.

**If you take more Montelukast Bluefish 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 Bluefish**

Try to take Montelukast Bluefish 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 Bluefish**

Montelukast Bluefish can treat your asthma only if you continue to take it.

It is important to continue taking Montelukast Bluefish for as long as your doctor prescribes. It will help control your 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, the most commonly reported side effects (may affect up to 1 in 10 people) thought to be related to montelukast were:

- 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).

**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 HPRC 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 10 mg of montelukast.
- The other ingredients are:  
*Tablet core:* Lactose monohydrate, mannitol (E 421), croscarmellose sodium (E 468), hydroxypropyl cellulose (E 463), cellulose microcrystalline (E 460), magnesium stearate.  
*Film coating:* Hypromellose 6cP (E 464), titanium dioxide (E 171), hydroxy propyl cellulose (E 463), carnauba wax, iron oxide yellow (E 172), iron oxide red (E 172).

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

Film-coated tablet

Beige, rounded square-shaped (7.9 x 7.9 mm), film-coated tablets debossed with 'I' on one side and '114' on the other side.

Available in Aluminium-Aluminium blister packs of 28 tablets.

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

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

Poland	Montelukast Bluefish Pharma
Ireland	Montelukast Bluefish 10 mg film-coated tablets
Portugal	Montelucaste Bluefish

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