

# Country : Rawanda / Kipel 4-5



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

## KIPeL

Montelukast chewable 4 mg and 5 mg tablets

**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 for your child only. 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 your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

### In this leaflet:

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

### 1. What Kipel is and what it is used for?

#### What Kipel is?

- Kipel is a leukotriene receptor antagonist that blocks substances called leukotrienes.

#### How Kipel works

- Leukotrienes cause narrowing and swelling of airways in the lungs. By blocking leukotrienes, Kipel improves asthma symptoms and helps control asthma.

#### When Kipel should be used

- Your doctor has prescribed Kipel to treat your child's asthma, preventing asthma symptoms during the day and night.
- Kipel 4 mg is used for the treatment of 2 to 5 year old patients and Kipel 5 mg 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.
- Kipel 4 mg or 5 mg may also be used as an alternative treatment to inhaled corticosteroids for patients who have not recently taken oral corticosteroids for their asthma and have shown that they are unable to use inhaled corticosteroids as per the age group.
- Kipel also helps prevent the narrowing of airways triggered by exercise for patients 2 years of age and older.

**Your doctor will determine how Kipel 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 Kipel

- Tell your doctor about any medical problems or allergies your child has now or has had.
- Do not give Kipel to your child if he/she is allergic to montelukast or any of the other ingredients of this medicine

#### Warnings and precautions

Talk to your doctor or pharmacist before you give Kipel to your child.

- If your child's asthma or breathing gets worse, tell your doctor immediately.
- Oral Kipel is 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 take all asthma medications prescribed by your doctor. Kipel 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 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 Kipel. If your child develops such symptoms while taking Kipel, you should consult your child's doctor.

#### Children and adolescents

- Do not give Kipel 4 mg to children less than 2 years of age.
- Do not give Kipel 5 mg to children less than 6 years of age.
- There are different form(s) of this medicine available for paediatric patients under 18 years of age based on age range.

#### Other medicines and Kipel

- Tell your doctor or pharmacist if your child is taking or has recently been given or might be given any other medicines including those obtained without a prescription.
- Some medicines may affect how Kipel works, or Kipel may affect how your child's other medicines work.

Tell your doctor if your child is taking the following medicines before starting Kipel:

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

#### Kipel with food and drink

- Kipel 4 and 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 Kipel 4 chewable tablets since they are intended for use in children 2 to 5 years of age.
- 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 Kipel 5 mg.

#### Pregnancy

- Your doctor will assess whether you can take Kipel 5 mg during this time.

#### Breast-feeding

- It is not known if Kipel 5 mg appears in breast milk. You should consult your doctor before taking Kipel 5 mg if you are breast-feeding or intend to breast-feed.

#### Driving and using machines

- This subsection is not applicable for the Kipel 4 and 5 mg chewable tablets since they are intended for use in children 2 to 5 years of age

#### In Phenylketonuria

- Kipel 4 and 5 mg chewable tablets contain aspartame, a source of phenylalanine and sodium
- If you or your child has phenylketonuria (a rare, hereditary disorder of the metabolism) you should take into account that chewable tablet contains phenylalanine (equivalent to 1.123 mg phenylalanine per 4 mg chewable tablet and 1.403 mg per 5 mg chewable tablet).
- This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

#### 3. How to take Kipel

Always have your child take this medicine exactly as your doctor or pharmacist has told you. Check with your child's 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 chewable tablet of Kipel 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.

#### For children 2 to 5 and 6 to 14 years of age:

- The recommended dose for children of 2 to 5 years of age is one 4 mg chewable tablet daily to be taken in the evening.
- The recommended dose for children of 6 to 14 years of age is one 5 mg chewable tablet daily to be taken in the evening.
- If your child is taking Kipel, be sure that he/she does not take any other

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medicines that contain the same active ingredient, montelukast.

- This medicine is for oral use.
- The tablets are to be chewed before swallowing.
- Kipel 4 and 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 your child takes more Kipel than he/she/you 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 Kipel to your child or you forget to take it

- Try to give Kipel as prescribed.
- However, if you or 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 a forgotten dose.

#### If you or your child stops taking Kipel

- Kipel can treat your child's asthma only if he/she continues taking it.
- It is important for your child to continue taking Kipel for as long as your doctor prescribes. It will help control you and 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 Kipel 4 mg chewable tablets, the most commonly reported side effects (may affect up to 1 in 10 people) thought to be related to Kipel were:
  - abdominal pain
  - thirst
- Additionally, the following side effect was reported in clinical studies with Kipel 10 mg film-coated tablets and 5 mg chewable tablets:
  - headache
- These were usually mild and occurred at a greater frequency in patients treated with Kipel than placebo (a pill containing no medication).

#### **Serious side effects**

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

- **Uncommon:** the following 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:** the following may affect up to 1 in 1,000 people
- increased bleeding tendency
- tremor
- palpitations

- **Very rare:** the following 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)
- 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:** the following may affect more than 1 in 10 people
- upper respiratory infection

- **Common:** the following may affect up to 1 in 10 people
- diarrhoea, nausea, vomiting
- rash
- fever
- elevated liver enzymes

- **Uncommon:** the following 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:** the following may affect up to 1 in 1,000 people
- behaviour and mood related changes: disturbance in attention, memory impairment, uncontrolled muscle movements

- **Very rare:** the following 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 such as obsessive-compulsive symptoms, stuttering

#### **5. How to store Kipel**

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date. The expiry date refers to the last date of that month.
- Store in the original package in order to protect from light and moisture.
- 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 Kipel contains**

- The active substance is montelukast.
- Each Kipel 4 mg chewable tablet contains montelukast sodium which corresponds to 4 mg of montelukast.
- Each Kipel 5 mg chewable tablet contains montelukast sodium which corresponds to 5 mg of montelukast.

##### **The other ingredients are:**

- Lactose anhydrous (20mg/Kipel 4 tablet, 25mg/Kipel 5 tablet) USP/NF, Mannitol (DC-grade) USP/NF, Hydroxypropyl cellulose USP/NF, Sodium starch glycolate USP/NF, Aspartame USP/NF, Trusil Pineapple flavor, Colloidal silicon dioxide USP/NF, Magnesium stearate USP/NF.

##### **What Kipel looks like and contents of the pack**

- Kipel 4 mg chewable tablets
- Each 4 mg tablet is available as white to off-white, pineapple flavoured, and sweet round shaped biconvex chewable tablets.
- Kipel 5 mg chewable tablets
- Each 5 mg tablet is available as white to off-white coloured round shaped uncoated tablets.

Kipel is available as packs of 3x10's

##### **Marketing Authorization Holder:**

Manufactured by :  
**MEGA LIFESCIENCES (AUSTRALIA) PTY LTD**  
Victoria 3810, Australia.



Manufactured by :  
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