HCR: LHC Pharmaceuticals (Pty) Ltd

Product Name: Antaluko 10

Dosage form and strength: Film-coated Tablets, Montelukast 10 mg

Date Approved: 31 January 2024

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SCHEDULING STATUS

S3

Antaluko 10 mg Film Coated Tablets

Active substance: Each film-coated tablet contains montelukast 10 mg as montelukast sodium.

Contains sugar: lactose monohydrate *81, 94 mg.*

Read all of this leaflet carefully before you start taking Antaluko tablets:

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse, or other healthcare provider.
- **Antaluko** tablets has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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1. What Antaluko tablet is and what it is used for

Antaluko is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in your lungs. Blocking leukotrienes improves asthma symptoms and helps prevent asthma attacks. Leukotrienes also cause allergy symptoms. Blocking leukotrienes improves allergic rhinitis (seasonal and perennial, also known as outdoor and indoor nasal allergies).

Antaluko 10 mg film-coated tablets are indicated in adults and children 15 years of age and older for the prevention and treatment of asthma.
In adult asthmatic patients who use **Antaluko** tablets for the treatment of asthma, **Antaluko** tablets may provide some symptomatic relief of seasonal allergic rhinitis.

2. What you need to know before you take Antaluko tablets

Do not take Antaluko tablets:

- If you are allergic to montelukast or any of the other ingredients of **Antaluko** tablets.
- If you are a child under the age of 15 years as safety and efficacy of the 10 mg film-coated tablets have not been demonstrated in this age group.

Warnings and precautions

Take special care with Antaluko tablets:

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- **Antaluko** tablets are not for the treatment of acute asthma attacks. If an attack occurs, you should follow the instruction your doctor has given you for treating asthma attack.
- It is important that you continue taking **Antaluko** tablets daily as prescribed by your doctor, even when you had no symptoms or if you had an asthma attack.
- If you experience worsening of your asthmatic or respiratory symptoms, heart complications, skin rash, numbness or weakness of your limbs during treatment with **Antaluko** tablets you should inform your doctor immediately as treatment with **Antaluko** tablets may need to be discontinued.
- Treatment with **Antaluko** tablets may results in a condition called eosinophilia characterized by increase in the number of white blood cells. Your doctor should discontinue your treatment with **Antaluko** tablets should this condition occur.
- If you or your child's asthma symptoms get worse or if you need to increase the use of your child's inhaled rescue medicine for asthma attack, you should contact your doctor immediately.
- Always have your inhaled rescue medication for asthma with you.
- It is important that you take all asthma medications prescribed by your doctor. **Antaluko** tablets should not be substituted for other asthma medications unless your doctor has prescribed for you.
- If your doctor has prescribed a medicine for you to use before exercise, keep using that medicine unless your doctor tells you not to.
- If your asthma is known to be made worse by aspirin, do not take aspirin and other non-steroidal anti-inflammatory medicines.
- Patients and caregivers should be aware that various neuropsychiatric events (for example behaviour and mood-related changes) have been reported in adults,

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adolescents, and children with Montelukast. If you develop such symptoms while taking **Antaluko**, you should consult your doctor.

Children and adolescents

The medicine should not be given to children under 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 Antaluko tablets:

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines)

Some medicines may affect how **Antaluko** tablets work, or **Antaluko** tablets may affect how your other medicines work but in general it does not interfere with other medicines.

If you have asthma and if your asthma is made worse by aspirin, continue to avoid aspirin or other medicines called non-steroidal anti-inflammatory drugs while taking **Antaluko** tablets.

Antaluko tablets with food and drinks:

Antaluko tablets may be taken with or without food.

Pregnancy, Breastfeeding and Fertility:

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If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other health care professionals for advice before taking **Antaluko** tablets**.**

The safety of **Antaluko** in pregnant and breastfeeding women has not been established. Women who are pregnant or intend to become pregnant should consult their doctor before taking **Antaluko.**

It is not known if **Antaluko** tablets are excreted in human milk. Therefore, **Antaluko** should not be used if you are pregnant or breastfeeding.
The effect of **Antaluko** on fertility has not been established.

Driving and using machines:
Antaluko tablets may make you feel dizzy and sleepy/drowsy which may affect ability to drive and operate machines safely. Therefore you should avoid driving or operating machinery after taking **Antaluko** tablets or until individual susceptibility is known.

Antaluko 10 tablets contains:
Lactose monohydrate:
Patients with rare inherited problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take **Antaluko 10** tablets.
Sodium:
Antaluko 10 contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially ‘sodium-free’.

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3. How to take Antaluko tablets

Do not share medicines prescribed for you with any other person.

Always take **Antaluko** tablets exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose for the treatment of asthma and/or allergic rhinitis in adults and adolescents 15 years of age and older is one tablet of **Antaluko 10** mg daily in the evening.

***Other information*:**

- **Antaluko** tablets may be taken orally with food or without food.
- Do not take **Antaluko** tablets for the immediate relief of an asthma attack. If you get an asthma attack, you should follow the instructions your doctor gave you for treating asthma attacks.
- Always have your inhaled rescue medicine for asthma attacks with you.
- If your asthma symptoms get worse, or if you need to increase the use of your inhaled rescue medicine for asthma attacks, call your doctor right away.
- Do not stop taking or lower the dose of your other asthma medicines unless your doctor tells you to.
- Do not share medicines prescribed for you with any other person.

If you take more Antaluko tablets than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control center.

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The most frequent adverse experience observed were abdominal pain, somnolence (drowsiness), thirst, headache, vomiting and psychomotor hyperactivity. It is not known whether montelukast is dialysable by peritoneal or haemodialysis.

Treatment is as per symptoms and supportive.

If you forget to take Antaluko tablets:

If you forget to take a dose, just take your next scheduled dose at the correct time.

Do not take a double dose to make up for a forgotten individual dose.

If you stop taking Antaluko tablets:

Antaluko tablets can treat asthma only if you continue taking it.

It is important to continue taking **Antaluko tablets** for as long as your doctor has prescribed it. It will help control your asthma.

4. Possible side effects

Antaluko tablets can have side effects.

Not all side-effects reported for **Antaluko** tablets are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **Antaluko** tablets, please consult your health care provider for advice.

If any of the following happens, stop taking Antaluko tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Allergic reactions including rashes, itching and skin irritation.

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- Swelling of the hands, feet, ankles, face, lips, mouth, tongue or throat which may cause difficulty in swallowing and breathing.
- Develops a combination of symptoms such as flu-like illness, pins and needles or numbness of your arms or legs, worsening of lung symptoms and/or rash, as it may be an increase in certain white blood cells (eosinophils) and possible inflamed blood vessels throughout the body (systemic vasculitis).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to Antaluko tablets. You may need urgent medical attention or hospitalization.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Chest pain
- Fever
- Palpitations (increased heartbeat)
- Develops hepatitis (symptoms may include fatigue, abdominal discomfort, nausea or yellowing of the skin or whites of the eyes).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

- Dizziness
- Drowsiness
- Inability to sleep
- Abdominal pains

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- Headache

Less frequent side effects:

- Nervousness
- Depression
- Restlessness/ irritability
- Seeing, feeling or hearing things that are not there (hallucinations)
- Behavior and mood related changes
- Convulsion
- Obsessive compulsive symptoms
- Stuttering
- Dry mouth
- Increased sweating
- Trembling
- Joint and muscle pains
- Uncontrolled muscle movements (tic)
- Thirst
- Bedwetting in children
- Nightmares or abnormal dreams
- Increased incident of respiratory tract infections
- increased bleeding tendency, (low blood platelet Count)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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Reporting of Side Effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **Montelukast LHC.**

5. How to store Antaluko tablets

Store all medicines out of reach of children.

Store at or below 30 °C, protected from moisture and light.

The blisters must be kept in the outer carton until required for use.

Do not remove tablets from blister until required for use.

Return all unused medicine to your pharmacist.

Do not dispose any unused medicines in drains or sewage systems e.g. toilets.

6. Contents of the pack and other information

What Antaluko tablets contains

- The active substance is montelukast. Each film-coated tablet contains 10 mg montelukast, which is equivalent to 10.4 mg montelukast sodium.
- The other ingredients are lactose monohydrate, powdered cellulose (E460), microcrystalline cellulose (E460), croscarmellose sodium (E468) and magnesium stearate (E470b) in the tablet core, and hypromellose (E464), titanium dioxide (E171), talc (E553b), propylene glycol (E1520), red iron oxide (E172) and yellow iron oxide (E172) in the film coating.

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What Antaluko tablets looks like and contents of the pack

The film-coated tablets are apricot-coloured, round, slightly biconvex, with bevelled edges.

Antaluko tablets are available in boxes of 30 film-coated tablets in blisters. Each blister contains10 film-coated tablets.

Holder of Certificate of Registration

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PRETORIA

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Access to the corresponding Professional Information

Corresponding PI can be accessed on the following link:

http://www.lhcpharma.com/professional-information