SUMMARY PRODUCT CHARACTERISTICS

1.Name of the Medicinal Product

Montene L Tablet

2.Qualitative and Quantitative Composition

Each film coated Tablet contains:

Montelukast Sodium

Eq. to Montelukast 10 mg and Levocetirizine Dihydrochloride 5mg

For the full list of excipients, see section 6.1

3.Pharmaceutical Form

Oral Solid Film Coated Tablets.

A white, round -shaped film coated tablet with both sides plain

4.Clinical particulars

4.1 Therapeutic indications

Anti-allergic

- Relief of symptoms of allergic rhinitis [seasonal or perennial]
- As prophylaxis in seasonal allergic rhinitis and
- Treatment of comorbid asthma and allergic rhinitis in patients 15 years of age and over

4.2 Posology and method of administration

Route of administration:

Oral

Posology

Adults (> 15 years): 1 tablet once daily.

Method of administration

For oral use.

4.3 Contraindications:

Should not take the LEVOCETIRIZINE+MONTELUKAST if you are allergic to Levocetirizine or Montelukast, have severe liver or kidney problems, or have epilepsy. Check with your doctor if you're pregnant, breastfeeding, or taking other prescribed or non-prescribed medicines.
Hypersensitivity to the active substance or to any of the excipients listed in section 6.1 Porphyria

4.4 Special warnings and precautions for use

Tell your doctor if you are pregnant, plan to become pregnant, or are breastfeeding. If you have kidney problems, dose adjustment might be required; the doctor will do it depending upon your disease's condition. Please inform your doctor if you have a problem passing urine and have epilepsy (fits) before starting LEVOCETIRIZINE+MONTELUKAST. If you are supposed to undergo skin testing, the doctor might advise you to stop taking LEVOCETIRIZINE+MONTELUKAST 72 hours before the test as it decreases response to skin prick test. Patients should be cautioned against getting engaged in work that requires too much mental alertness, like operating machinery or driving a motor vehicle after intake of LEVOCETIRIZINE+MONTELUKAST. Please consult your doctor immediately if you experience aggression, anxiety, or depression after taking LEVOCETIRIZINE+MONTELUKAST. It is advised to avoid contact with known allergens (allergy-causing agents) such as pollen, dust, etc. Certain food items are known to cause allergies to you. Concurrent use of LEVOCETIRIZINE+MONTELUKAST with alcohol or other antidepressants should be avoided to reduce your mental alertness. Even if you are asymptomatic and feel good, do not stop taking the LEVOCETIRIZINE+MONTELUKAST as it stopping abruptly may lead to an acute attack of asthma.

4.5 Interaction with other medicinal products and other forms of interaction

Tell your doctor if you are pregnant, plan to become pregnant, or are breastfeeding. If you have kidney problems, dose adjustment might be required; the doctor will do it depending upon your disease's condition. Please inform your doctor if you have a problem passing urine and have epilepsy (fits) before starting LEVOCETIRIZINE+MONTELUKAST. If you are supposed to undergo

skin testing, the doctor might advise you to stop taking LEVOCETIRIZINE+MONTELUKAST 72 hours before the test as it decreases response to skin prick test. Patients should be cautioned against getting engaged in work that requires too much mental alertness, like operating machinery or driving a motor vehicle after intake of LEVOCETIRIZINE+MONTELUKAST. Please consult your doctor immediately if you experience aggression, anxiety, or depression after taking LEVOCETIRIZINE+MONTELUKAST. It is advised to avoid contact with known allergens (allergy-causing agents) such as pollen, dust, etc. Certain food items are known to cause allergies to you. Concurrent use of LEVOCETIRIZINE+MONTELUKAST with alcohol or other antidepressants should be avoided to reduce your mental alertness. Even if you are asymptomatic and feel good, do not stop taking the LEVOCETIRIZINE+MONTELUKAST as it stopping abruptly may lead to an acute attack of asthma.

4.6 Fertility, Pregnancy and Lactation

Pregnancy

Your doctor will weigh the benefits and potential risks before prescribing them. Please consult your doctor.

More information is needed about use of montelukast in early pregnancy but at present no major teratogenic effect is found and the weak effects seen are similar to those seen after other anti-asthmatic drugs and may be a result of the underlying asthma disease.

4.7 Effects on ability to drive and use machines

Not Known

4.8 Undesirable effect

Drug-Drug Interactions: LEVOCETIRIZINE+MONTELUKAST may have an interaction with other anti-allergic drugs, pain killers (ibuprofen, naproxen, diclofenac), blood thinners (aspirin), antifungals (fluconazole, miconazole, or voriconazole), heart medications (amiodarone).

Drug-Food Interactions:

LEVOCETIRIZINE+MONTELUKAST may interact with a multi-mineral or other herbal/ayurvedic supplements, St. John's wort plant (used for depression). So,

if you are using any of the OTC items,
please tell your doctor.
Drug-Disease Interactions: Patients affected with liver/kidney disease, epilepsy, and alcoholism should not take LEVOCETIRIZINE+MONTELUKAST as it has severe interaction.

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

If someone has taken too much of this medicine and shows some serious symptoms such as passing out
or trouble breathing, call a poison control center immediately. Symptoms of overdose can include
drowsiness, thirst, inability to keep still, vomiting, or severe stomach pain.

5.Pharmacological Properties

5.1 Pharmacodynamic properties

Montelukast selectively antagonizes leukotriene D4 (LTD4) at the cysteinyl leukotriene receptor, CysLT1, in the human airway. Montelukast inhibits the actions of LTD4 at the CysLT1 receptor, preventing airway edema, smooth muscle contraction, and enhanced secretion of thick, viscous mucus. Levocetirizine is an inverse agonist that decreases activity at histamine H1 receptors. This in turn prevents the release of other allergy chemicals and increased blood supply to the area, and provides relief from the typical symptoms associated with seasonal and perennial allergic rhinitis. It does not prevent the actual release of histamine from mast cells

5.2 Pharmacokinetic Properties

Peak plasma concentrations of montelukast are achieved in 3 to 4 hours after oral doses. The mean oral
bioavailability is 64%. Montelukast is more than 99% bound to plasma proteins. It is extensively metabolised in the liver by cytochrome P450 isoenzymes CYP3A4, CYP2A6, and CYP2C9, and is excreted principally in the

faeces via the bile. Levocetirizine is rapidly and extensively absorbed following oral administration. In adults, peak plasma concentrations are achieved 0.9 hour after administration of the oral tablet. Levocetirizine is poorly metabolized and undergo renal excretion.

5.3 Preclinical safety data

No adequate data available

6.Pharmaceutical particulars

6.1 List of excipients

Dummy granules

Microcrystalline cellulose

Purified Talc

Magnesium Stearate

Croscarmellose Sodium

Colloidal Silicon Dioxide

Sodium Starch Glycolate

Instacoat

PEG 400

Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf life:

24 months from the date of manufacturing.

6.4 Special precautions for storage:

Store below to 30°C. Protect from light and moisture.

6.5 Nature and contents of container:

Primary Packing: 10 tablets ALU/ALU Blister.

Secondary Packing: 3 such blisters packed in printed carton along with the pack insert.

7.Marketing authorization holder

Square Pharmaceuticals Kenya EPZ Ltd.

Simba Road, Athi River EPZ, P.O. Box: 30500,

Machakos. Cell: +254113835299; +254707708945;

+254715676588

8.Marketing authorization number(s)

H2025/CTD11932/26238

9.Date of first authorization/renewal of the authorization

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10. Date of revision of the text

24/12/2024