Product Name	**LEMONT** (Levocetirizine hydrochloride & Montelukast Tablet)	
Module 1	Administrative Information and Product Information	

1.17 Summary Product Characteristics (SPC)

1. Name of the medicinal product

LEMONT **(Levocetirizine Hydrochloride & Montelukast tablet)**

2. Qualitative and quantitative composition

2.1 Qualitative Declaration

Each Film coated tablets contains:

Levocetirizine Hydrochloride USP….5 mg.

Montelukast Sodium USP

Equivalent to Montelukast..... 10 mg

Excipients… .....q.s.

Colour: Quinoline Yellow WS & Titanium Dioxide

2.2 Quantitative Declaration

Batch Size: 1, 00,000 Tablets

Sr. No	Ingredients	Spec.	Qty. Per Tablet (mg)	Over Age (%)	* Qty. On 100 % Assay Based	Unit	Qty. Required
01	Montelukast Sodium	IHS	10	6	0.500	Kg	0.530
02	Mannitol	BP	60	---	3.000	Kg.	3.000
03	Cross Carmellose Sodium	BP	7	---	0.350	Kg.	0.350
04	Hydroxy Propyl Cellulose	BP	2	---	0.100	Kg.	0.100
05	Iso Propyl Alcohol	BP	---	---	1.500	LTR.	1.500
06	Magnesium Stearate	BP	2.1	---	0.105	Kg.	0.105
07	M.C.C.P.PH 102	BP	119	---	5.950	Kg.	5.950
08	Sodium Starch Glycolate	BP	4.2	---	0.210	Kg.	0.210
09	Levocetirizine Hydrochloride	USP	5	2	0.250	Kg.	0.255

	Total Weight		**209.3**	**---**	**10.465**	**Kg.**	**10.500**
COATING							
1	Film coat FC Titanium dioxide	IHS	6	---	0.300	Kg.	0.300
2	Isopropyl Alcohol	BP	---	---	3.300	L	3.300
3	Methylene Dichloride	BP	---	---	3.300	L	3.300
4	Diethyl phthalate	IHS	---	---	0.040	Kg.	0.040
5	Colour Lake Quinoline yellow	IHS	0.6	---	0.030	Kg.	0.030

USP = United States Pharmacopoeia IHS = In House Specification

3. Pharmaceutical form

Quinoline Yellow coloured, Round shaped, biconvex, Film coated tablet with both side plain

4. Clinical particulars

Montelukast+Levocetirizine a combined therapy is prescribed for the systemic treatment of allergic reactions such as chronic urticaria, obstructive airway diseases and rhinitis. Montelukast belongs to leucotriene receptor antagonist.

Pharmacodynamics

No information available

Pharmacokinetics

No information available

Montelukast+Levocetirizine Indications / Montelukast+Levocetirizine Uses

No information available

Montelukast+Levocetirizine Adverse Reactions / Montelukast+Levocetirizine Side Effects

Montelukast + Levocetirizine can cause somnolence, hyperactivity in children, dry mouth, mild drowsiness and GI disturbances.

Precautions

Montelukast + Levocetirizine is contraindicated in patients with an allergy to either or bothdrugs,hepatic impairment, NSAID allergy, Churg-Strauss syndrome.

Montelukast + Levocetirizine is contraindicated in children less than six months of age.

Montelukast + Levocetirizine can cause dizziness. Do not drive vehicles or operate heavy machineries that need alertness.

Special Precautions

No information available

Other Drug Interactions

Montelukast + Levocetirizine may interact with phenytoin, CNS depressants, rifampicin, prednisone and phenobarbital.

Other Interactions

Do not consume alcohol while taking Montelukast + Levocetirizine

Dosage

For treatment of allergic rhinitis and chronic asthma (Adults): Consider administration of 10 mg once a day in the evening. For Prophylaxis of exercise-induced asthma(Adults)

Consider administration of 10 mg of Montelukast + Levocetirizine, at least two hours before exercise.

Food(before/after)

No information available

List of Contraindications Montelukast+ Levocetirizine and Pregnancy

USFDA pregnancy category B. Montelukast + Levocetirizine may not cause harm to an unborn foetus. Before Montelukast treatment, the patient should discuss with the physician, if they are planning for a pregnancy.

Montelukast+ Levocetirizine and Lactation

It is unclear whether the drug could pass through the breast milk to a breast feeding baby. Consult your physician before taking Montelukast + Levocetirizine, if you are nursing mother.

Montelukast+ Levocetirizine and Children

No information available

Montelukast+ Levocetirizine and Geriatric

No information available

Montelukast+ Levocetirizine and Other Contraindications

No information available

Storage

No information available

Lab interference

No information available

6. Pharmaceutical particulars

6.1 List of excipients

- Mannitol
- Cross Carmellose Sodium
- Hydroxy Propyl Cellulose
- Iso Propyl Alcohol
- Magnesium Stearate
- M.C.C.P.PH 102
- Sodium Starch Glycolate
- Film coat FC Titanium
- dioxide
- Isopropyl Alcohol
- Methylene Dichloride
- Diethyl phthalate
- Colour Lake Quinoline

Yellow

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months from the date of manufacture.

6.4 Special precautions for storage

Store in the original packaging in order to protect from moisture

This medicinal product does not require any special temperature storage conditions

6.5 Nature and contents of container

Alu – Alu blister pack of 2 x 10 tablets, packed in an outer carton along with package insert. Such 3 mono cartons shrink wrapped and packed.

6.6 Special precautions for disposal and other handling

No special requirements

7. Marketing authorization holder

-Name : **PHARMWEB CHEMIST**

-Address : : **Nairobi, Kenya**

8. Marketing authorization number(s)

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9. Date of first authorization/renewal of the authorization

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10. Date of revision of the text
