PROPOSED PATIENT INFORMATION LEAFLET FOR LEVOMONT

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

LEVOMONT (10 mg montelukast and 5 mg levocetirizine dihydrochloride) film coated tablets

Montelukast and Levocetirizine dihydrochloride

LEVOMONT contains sugar (lactose monohydrate, 83,60 mg).

Read all of this leaflet carefully before you start taking LEVOMONT.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- LEVOMONT 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

1. What LEVOMONT is and what it is used for

LEVOMONT contains the active ingredients montelukast and levocetirizine dihydrochloride.

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Montelukast is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in the lungs and also cause allergy symptoms. By blocking leukotrienes, montelukast improves seasonal allergy symptoms.
Levocetirizine is an anti-allergy medicine.

LEVOMONT is used to relieve the symptoms associated with seasonal allergic rhinitis (also known as hay fever) in adults.

2. What you need to know before you take LEVOMONT

Do not take LEVOMONT:

- If you are hypersensitive (allergic) to montelukast, levocetirizine dihydrochloride, to to hydroxyzine, or to any other piperazine, or any of the other ingredients of LEVOMONT (listed in section 6).
- If you have severe kidney problems (< 10 mL/min creatinine clearance)

Warnings and precautions

Take special care and talk to your doctor before taking LEVOMONT:

- LEVOMONT 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.
- 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 inform your doctor immediately if you start feeling agitated, aggressive, hostile, anxious, have abnormal dreams, start seeing and hearing things, feel depressed, cannot sleep, are irritable and restless, start thinking about harming yourself, including having suicidal ideas and experience tremors, after starting LEVOMONT treatment.

- If you are sensitive to aspirin you should continue to avoid the use of aspirin and anti-inflammatory medicines, known as non-steroidal anti-inflammatory drugs or NSAIDs, while taking LEVOMONT.
- If you have liver problems, tell your doctor.
- If you are likely to be unable to empty your bladder (with conditions such as spinal cord injury or enlarged prostate), please ask your doctor for advice.
- If you suffer from epilepsy or are at risk of convulsions, please ask your doctor for advice as use of levocetirizine, as contained in LEVOMONT, may cause seizure aggravation.
- If you are scheduled for allergy testing, ask your doctor if you should stop taking levocetirizine for several days before testing. This medicine may affect your allergy test results.
- Itching may occur when levocetirizine, as contained in LEVOMONT, is stopped. The symptoms may resolve by itself. In some cases, the symptoms may be intense and may require treatment to be restarted. The symptoms should resolve when the treatment is restarted.
- Behaviour and mood-related changes have been reported in patients taking LEVOMONT. Tell your doctor if you experiences these changes while taking LEVOMONT (see **Possible Side Effects**)

Children and adolescents

LEVOMONT should not be taken by children and adolescents under 18 years of age.

Other medicines and LEVOMONT

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

Tell your doctor or pharmacist if you are taking any of the following medicines:

- phenobarbital (used for the treatment of epilepsy)
- phenytoin (used for the treatment of epilepsy)
- rifampicin (used to treat tuberculosis and some other infections)
- gemfibrozil (used for the treatment of high lipid levels in plasma)
- ritonavir (used for the treatment of HIV/AIDS)
- central nervous system depressants (used as sedatives or tranquillisers).

LEVOMONT with food, drink and alcohol

Caution is advised if LEVOMONT is taken at the same time as alcohol or other medicines acting on the brain. In sensitive patients, the simultaneous use of LEVOMONT and alcohol or medicines affecting the central nervous system may have effects on alertness and impairment of performance.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding; think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

You should not take LEVOMONT is you are pregnant or breastfeeding

Driving and using machines

LEVOMONT may cause dizziness, drowsiness, sleepiness and tiredness. Therefore, caution is advised if you intend to drive, engage in potentially hazardous activities or operate machinery.

LEVOMONT contains lactose monohydrate

LEVOMONT contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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3. How to take LEVOMONT

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

Always use LEVOMONT exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults

The recommended dose is one tablet once daily to be taken orally, in the evening. The tablets should be swallowed whole, with or without food.

If you have the impression that the effect of LEVOMONT is too strong or too weak, tell your doctor or pharmacist

If you take more LEVOMONT than you should

The most frequently occurring symptoms reported with overdose included abdominal pain, sleepiness, thirst, headache, vomiting, and hyperactivity.

Overdose in children may initially show excitation and restlessness followed by sleepiness.

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

If you forget to take LEVOMONT

Always take LEVOMONT exactly as prescribed. Do not take a double dose of LEVOMONT to make up for forgotten individual doses.

If you stop taking LEVOMONT

Stopping treatment should have no negative effects. However, rarely pruritus (intense itching) may occur if you stop taking LEVOMONT, even if those symptoms were not present

before treatment initiation. The symptoms may resolve spontaneously. In some cases, the symptoms may be intense and may require treatment to be restarted. Symptoms may return, but they should not be any worse than they were prior to the treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

LEVOMONT can have side effects.

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

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

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- Rash or itching
- Fainting.

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

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

- Yellowing of your skin or eyes due to liver problems, inflammation of the liver (hepatitis) including liver injury.
- Inform your doctor immediately if you feel like hurting yourself or you experience any suicidal thoughts or tendencies.
- Changes in the way your heart beats (skipping beats or beating faster than normal).

- Churg-Strauss syndrome (hay fever, rash, bleeding of your stomach or intestines, severe pain and numbness in your hands and feet).

This is a serious side effect. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Upper respiratory tract infection, viral infection of the nose and throat (common cold), tonsillitis
- Headache, sleepiness
- Abdominal pain, diarrhoea, nausea (feeling sick), vomiting (being sick), dry mouth, gastrointestinal disorder
- Increased levels of liver enzymes when your blood is tested
- Rash
- Fever, tiredness.

Less frequent side effects:

- Low level of platelets in your blood, increased bleeding tendencies or bruising.
- Abnormal dreams (including nightmares), insomnia, sleepwalking, anxiety, agitation including aggressive behaviour or hostility, depression, psychomotor hyperactivity (including irritability, restlessness, tremor (uncontrolled movements), disturbance in attention, memory impairment, tic, hallucinations (seeing or hearing things that are not real), disorientation, obsessive-compulsive symptoms, stuttering
- Dizziness, drowsiness, numbness, tingling or burning feeling of your skin, pins and needles, reduced sense of touch or sensation, seizures (fits), fainting, altered taste
- Nosebleeds, accumulation of white blood cells (eosinophils) in the lungs causing symptoms such as fever, unexplained weight loss and severe tiredness.

- Indigestion
- Bruising, swelling under the skin, itching, hives, tender red lumps under the skin most commonly on your shins (erythema nodosum), severe skin reactions (erythema multiforme) that may occur without warning
- Joint pain, muscle pain including muscle cramps
- Weakness/tiredness, general sense of feeling unwell, swelling.

Side effects with unknown frequency:

- Urinary track infection
- A high level of disease-fighting white blood cells, known as eosinophils, in your blood.
- Increased appetite
- Visual disturbances, blurred vision, eye pain, swelling of your eyelids
- Vertigo (sensation of spinning), ear pain
- Shortness of breath, cough, throat and mouth pain, runny nose
- Constipation
- Painful or difficult urination, inability to completely empty the bladder (urinary retention), increased presence of white blood cells in urine.
- Increased weight, abnormal liver function test

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist.

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 LEVOMONT.

5. How to store LEVOMONT

Store all medicines out of reach of children.

Store at or below 25 ºC.

Protect from light and moisture.

Do not take after the expiry date stated on the package.

Return all unused medicine to your pharmacist.

Do not dispose of unused tablets in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LEVOMONT contains

Each film coated tablet contains montelukast sodium equivalent to 10 mg montelukast, and 5 mg levocetirizine dihydrochloride.

The other ingredients are anhydrous dibasic calcium phosphate, croscarmellose sodium, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose and purified water.

The tablet coating contains Opadry yellow (which consists of hypromellose, iron oxide yellow, iron oxide red, macrogol, polysorbate and titanium dioxide) and purified water.

What LEVOMONT looks like and contents of the pack

Yellow, round, biconvex, film coated tablets plain on both sides.

A 10 mL white opaque HDPE round container, containing a silica gel canister, fitted

with a polypropylene child resistant cap, packed in an outer carton.

Pack size: 28 or 30 film coated tablets.

Holder of certificate of registration

Forrester Pharma (Pty) Ltd

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Waterford Place

Century City

7441

Cape Town

South Africa

This leaflet was last revised in

Will be allocated by SAHPRA upon registration

Registration number

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