PROPOSED PATIENT INFORMATION LEAFLET FOR LUMONT

Please read this leaflet carefully before taking LUMONT:

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- **LUMONT** 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.

SCHEDULING STATUS

Schedule 3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

LUMONT 4 mg chewable tablets

LUMONT 5 mg chewable tablets

LUMONT 10 mg film coated tablets

1. WHAT LUMONT CONTAINS

LUMONT contains montelukast sodium as the active ingredient and is available either as a:

- 4 mg montelukast chewable tablet for children 2 to 5 years old.
- 5 mg montelukast chewable tablet for children 6 to 14 years old.
- 10 mg montelukast film coated tablet for adults and children 15 years and older.

In addition, **LUMONT** contains the following inactive ingredients:

LUMONT 4 mg and **LUMONT 5 mg:** Mannitol, microcrystalline cellulose, croscarmellose sodium, hydroxypropylcellulose, crospovidone, aspartame, cherry flavour, ferric oxide red (colourant) and magnesium stearate.

LUMONT 10 mg: Lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, crospovidone and Opadry yellow (coating material).

LUMONT 4 mg and **5 mg** contain aspartame, which is a source of phenylalanine.

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LUMONT 10 mg contains lactose.

2. WHAT LUMONT IS USED FOR

- **LUMONT** is used to improve asthma symptoms and help prevent asthma attacks.
- **LUMONT 4 mg** chewable tablets are used in children from 2 to 5 years of age.
- **LUMONT 5 mg** chewable tablets are used in children from 6 to 14 years of age.
- **LUMONT 10 mg** film coated tablets are used in adults and children from 15 years of age.

3. BEFORE YOU TAKE LUMONT

Do not take LUMONT if:

- You are allergic (hypersensitive) to montelukast or any other inactive ingredients (see **WHAT LUMONT CONTAINS**).
- You are pregnant or breastfeeding your baby.

Safety has not been established with **LUMONT 4 mg** in children under the age of 2 years.

Safety has not been established with **LUMONT 5 mg** in children under the age of 6 years.

Safety has not been established with **LUMONT 10 mg** in children under the age of 15 years.

Take special care with LUMONT:

- **LUMONT** chewable or film coated tablets are not used in the treatment of acute asthma attacks. If an attack occurs, you or your child should follow the instructions your doctor has given you for that situation.
- If you or your child 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, you should tell your doctor immediately.
- It is important that you or your child continue taking **LUMONT** daily as prescribed by your doctor, even when your symptoms are well controlled, as well as during periods of worsening asthma.

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- Contact your doctor immediately if you or your child's asthma symptoms worsen or if your asthma is not well controlled.
- You should seek medical attention if you require inhalation therapy more often than usual in a 24 hour period.
- You should not decrease the dose or stop any medication prescribed for the treatment of you asthma, unless your doctor instructs you to do so.
- If your asthma worsens during exercise, you should use your usual inhalation medication as prescribed for prevention of an asthma attack.
- **LUMONT** should not be substituted with other asthma medications. You or your child should take all asthma medications prescribed by your doctor.
- If you are allergic (hypersensitive) to aspirin and it worsens your asthma, do not take aspirin or other non-steroidal anti-inflammatory medicine while taking **LUMONT**.
- Take **LUMONT** daily as prescribed, even if you don't have symptoms, as well as during periods of worsening asthma, and contact your doctor if your asthma is not well controlled.
- Do not take oral **LUMONT** tablets for the treatment of acute asthma attacks. Rather use appropriate short-acting inhaled beta-agonist medication available to treat increased occurrence of asthma symptoms.
- While taking **LUMONT,** please seek medical attention if you need to take your short-acting inhaled bronchodilators more often than usual, or if you exceed the maximum number of inhalations of short-acting bronchodilator treatment prescribed for a 24 hour period.
- Do not decrease the dose or stop taking any other anti-asthma medications while taking **LUMONT** unless you are instructed to do so by your doctor.
- If you experience an increased occurrence of asthma symptoms after exercise, you should continue your usual regimen of inhaled beta-agonists as prophylaxis unless otherwise instructed by your doctor. Always ensure that you have a short-acting inhaled beta-agonist available for rescue.

Taking LUMONT with food and drink:

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LUMONT can be taken with or without food.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **LUMONT**.

DO NOT take **LUMONT** if you are pregnant, planning to become pregnant or breastfeeding.

Driving and using machinery:

LUMONT may make you drowsy or impair your ability to drive and use machinery. Take care if you feel dizzy, tired or drowsy while taking **LUMONT**.

Important information about some of the ingredients of LUMONT:

LUMONT 4 mg and **5 mg** chewable tablets contain aspartame (artificial sweetener used as a sugar substitute), which is metabolised to phenylalanine (an essential amino acid). Use **LUMONT** with caution if you suffer from a rare condition called phenylketonuria (when a person is born without the ability to properly break down an amino acid called phenylalanine).

LUMONT 10 mg tablets contain lactose. If you have a history of lactose intolerance (galactose intolerance, Lapp lactase disease or glucose-galactose malabsorption) you should not take **LUMONT**.

Using other medicines with LUMONT:

- Always tell your healthcare professional if you are taking any other medicine.
- If you or your child are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **LUMONT** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or healthcare professional for advice.

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- In general, **LUMONT** does not interfere with other medicines that you or your child may be taking. However, it is important to consult your doctor about all medicines that you or your child is using or planning to use.
- Tell your doctor if you or your child are taking the following medicines, before starting **LUMONT**:
  - Phenobarbital or phenytoin (used for treatment of epilepsy)
  - Rifampicin (used for treatment of infection such as tuberculosis)

4. HOW TO TAKE LUMONT

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

The recommended dosage of **LUMONT** is once a day in the evening with or without food as prescribed by your doctor.

For the treatment of asthma, the dose for:

- children from 2 to 5 years old is one **LUMONT 4 mg** chewable tablet daily.
- children from 6 to 14 years old is one **LUMONT 5 mg** chewable tablet daily.
- adults and children from 15 years and older is one **LUMONT 10** mg tablet daily.

If you have the impression that the effect of **LUMONT** is too strong or too weak, talk to your doctor or pharmacist.

It is important to continue taking **LUMONT** for as long as your doctor prescribes it in order to maintain control of you or your child's asthma. **LUMONT** can treat you or your child's asthma only if it is taken continuously.

Do not share **LUMONT** with any other person, even if their symptoms are the same as yours.

If you have any questions about the proper dose or usage of **LUMONT**, ask your doctor.

If you take more LUMONT than you should:

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

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If you or your child forgets to take LUMONT:

Take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take **LUMONT** at the next regularly scheduled time. Do not take a double dose to make up the missed dose.

5. POSSIBLE SIDE EFFECTS

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

Stop using **LUMONT** and contact your nearest hospital if you or your child have any of these signs of an allergic reaction:

- Hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

Check with your doctor if any of the following side effects continue or are bothersome which may occur frequently:

- Headache, dizziness, sleeplessness, stomach pain.

Less frequent side effects that may occur include the following:

- Stuffy nose, coughing, flu-like symptoms.
- Heart burn, gastroenteritis.
- Skin rash, weakness or unusual tiredness, tooth ache, fever.
- Aggressive behaviour or hostility.
- Hallucinations, dream abnormalities.
- Depression, anxiety, suicidal thinking and behaviour.
- Heart palpitations.
- Diarrhoea, nausea, vomiting.
- Bruising.
- Joint pain.

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- If your urine contains pus.

6. STORING AND DISPOSING OF LUMONT

- **LUMONT 4 mg and 5 mg:** Store at or below 25 °C.
- **LUMONT 10 mg:** Store at or below 30 °C.
- Keep in outer carton until required for use.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Do not use after the expiry date printed on the blister or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

7. PRESENTATION OF LUMONT

LUMONT 4 mg: Silver Aluminium / Aluminium blister strips containing either 14 or 10 tablets each. Each carton contains 28 or 30 tablets.

LUMONT 5 mg: Silver Aluminium / Aluminium blister strips containing either 7 or 10 tablets each. Each carton contains 28 or 30 tablets.

LUMONT 10 mg: Silver Aluminium / Aluminium blister strips containing either 7 or 10 tablets each. Each carton contains 28 or 30 tablets.

8. IDENTIFICATION OF LUMONT

LUMONT 4 mg: Pink coloured, oval shaped, uncoated tablets plain on both sides, having a mottled surface.

LUMONT 5 mg: Pink coloured, round shaped, uncoated tablets plain on both sides, having a mottled surface.

LUMONT 10 mg: Yellow coloured, round shaped, bevel edged, film coated tablet debossed with “285” on one side and plain on other side.

9. REGISTRATION NUMBERS

Signed: EB

LUMONT 4 mg: 44/10.2.2/0823

LUMONT 5 mg: 44/10.2.2/0824

LUMONT 10 mg: 44/10.2.2/0792

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Zydus Healthcare SA (Pty) Ltd.

Southdowns Office Park

Building B, Ground Floor

22 Karee Street

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0157

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11. DATE OF PUBLICATION

June 2012

Signed: EB