PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

MONTECET 10 mg/5 mg film-coated tablets

Montelukast (as montelukast sodium)

Levocetirizine dihydrochloride

Contains sugar: 83,3 mg lactose monohydrate

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- MONTECET 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 MONTECET is and what it is used for
2. What you need to know before you take MONTECET
3. How to take MONTECET
4. Possible side effects
5. How to store MONTECET
6. Contents of the pack and other information.

1. What MONTECET is and what it is used for

MONTECET is a combination of montelukast and levocetirizine dihydrochloride. Montelukast is a leukotriene receptor antagonist that blocks substances called leukotrienes and levocetirizine dihydrochloride is an antihistamine.

MONTECET is used for the relief of allergic rhinitis (seasonal and perennial [if symptoms are present throughout the year]) in adults.

Seasonal allergic rhinitis is an allergic response often caused by airborne pollens from trees, grasses and weeds. Symptoms of allergic rhinitis includes runny or blocked nose, sneezing, red, itchy, watery and swollen eyes.

2. What you need to know before you take MONTECET

Do not take MONTECET

- If you are hypersensitive (allergic) to montelukast, levocetirizine dihydrochloride, cetirizine, hydroxyzine, any other piperazine derivatives or any of the other ingredients of MONTECET (see section 6 Contents of the pack and other information, What MONTECET contains).
- If you have end-stage kidney failure with creatinine clearance below 10 mL/min.

Warnings and precautions

Take special care with MONTECET

- If you have asthma and experience any difficulty in breathing, contact your doctor immediately.
  - MONTECET is not indicated for the treatment of acute asthma attacks.
  - Always have your inhaled rescue medicine for acute asthma attacks with you.
- If you have asthma, do not take aspirin and anti-inflammatory medicines as it may make your asthma worse.
- If you experience symptoms such as flu-like symptoms, pins and needles or numbness of the arms and legs, difficulty in breathing and/or rash while taking MONTECET, contact your doctor immediately.
- If you are likely to be unable to empty your bladder as MONTECET may increase your risk of not being able to empty your bladder.
- If you suffer from epilepsy or are at risk of convulsions as MONTECET may cause aggravation of convulsions.

- If you are scheduled for a skin allergy test as MONTECET may affect your allergy test results. Stop taking MONTECET three days before you have to go for the skin allergy test.

Children and adolescents

Do not give MONTECET to adolescents under the age of 18 years because it is unlikely to be safe.

Other medicines and MONTECET

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

Tell your doctor or pharmacist if you are currently taking or using:

- phenytoin (used to treat epilepsy)
- phenobarbital (used to treat anxiety and certain types of seizures [fits])
- rifampicin (used to treat tuberculosis [TB])
- gemfibrozil (used to lower the “bad” cholesterol [LDL])
- theophylline (used to treat symptoms associated with long-term asthma)
- ritonavir (used in the treatment of HIV [human immunodeficiency virus] and AIDS [acquired immune deficiency syndrome]).

MONTECET with food and alcohol

MONTECET can be taken with or without food.

Do not take MONTECET with alcohol.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care povider for advice before taking MONTECET. Do not use MONTECET during pregnancy and breastfeeding.

Driving and using machines

MONTECET may cause side effects, such as dizziness and drowsiness, and can affect your ability

to drive a vehicle and use machines (see section 4. Possible side effects). Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how MONTECET affects you.

MONTECET contains lactose monohydrate

MONTECET contains sugar (lactose monohydrate). Each film-coated tablet contains 83,3 mg lactose monohydrate.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking MONTECET.

3. How to take MONTECET

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

Always take MONTECET exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Adults and adolescents (18 years and older)

The recommended dose is one (1) tablet daily in the evening.

Elderly patients

No dose adjustment is necessary in elderly patients with normal kidney function. Adjustment of the dose is recommended in elderly patients with moderate to severe kidney function impairment.

Kidney function impairment

Your dose will be determined by the severity of your kidney disease. Your doctor will tell you how to take MONTECET.

Liver function impairment

No dose adjustment is necessary in patients with liver function impairment.

If you have both kidney and liver function impairment, your dose will be determined by the severity

of your kidney disease. Your doctor will tell you how to take MONTECET.

Your doctor will tell you how long your treatment with MONTECET will last.

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

If you take more MONTECET than you should

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and the remaining MONTECET with you so the doctor will know what you have taken.

Should overdose occur, symptomatic and supportive treatment is recommended. Activated charcoal may be given orally within the first hour post overdose.

If you forget to take MONTECET

If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take MONTECET at the next regularly scheduled time.

Do not take a double dose of MONTECET to make up for the forgotten individual doses.

If you stop taking MONTECET

Pruritus (intense itching) may occur if you stop taking MONTECET, even if this symptom was not present before you started to take MONTECET. This may resolve spontaneously. In some cases, the itching may be intense and it may be necessary to restart treatment with MONTECET. The itching should resolve when the treatment is restarted.

4. Possible side effects

MONTECET can have side effects.

Not all side effects reported for MONTECET are included in this leaflet. Should your general health

worsen or if you experience any untoward effects while taking MONTECET, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop taking MONTECET 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.

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

Less frequent:

- bleeding or bruising more easily than normal
- thinking of killing yourself
- seizures (fits)
- fast or irregular heartbeats, also called palpitations
- yellowing of the skin and eyes, also called jaundice.

Frequency unknown:

- changes in the way your heart beats, if you notice it beating faster
- painful or difficulty in passing urine
- passing less urine than is normal for you.

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

Tell your doctor as soon as possible if you notice any of the following:

Frequent:

- blocked and/or runny nose, sneezing, sore or scratchy throat, coughing, fever.

Less frequent:

- abdominal pain, weight loss, tiredness
- abnormal dreams including nightmares
- inability to sleep, sleepwalking
- feeling anxious, agitated, aggressive, hostile, depressed, irritable, restless, disorientated
- problems with your memory, hallucinations
- thinking of killing yourself
- dizziness, drowsiness, headache
- tingling or numbness of your hands and feet (pins and needles)
- decreased feeling or sensitivity, especially of your skin
- nose bleeds, dry mouth, indigestion
- diarrhoea, nausea, vomiting
- erythema multiforme (red, often itchy spots, similar to the rash of measles which starts on the limbs and sometimes on the face and the rest of the body; the spots may blister or may progress to form raised, red, pale-centred marks)
- painful red bumps and bruises on your shins
- pain in a muscle or group of muscles, joint pain
- abnormal physical weakness or lack of energy
- generally feeling unwell.

Frequency unknown:

- increased appetite, gaining weight
- feeling faint
- foul, salty or metallic taste in your mouth
- tremors (involuntary trembling or shaking of hands and feet)
- visual disturbances, blurred vision
- vertigo (sensation of spinning or swaying)
- abnormal liver function tests when blood tests are performed.

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of MONTECET.

5. How to store MONTECET

- Store at or below 30 °C.
- Protect from moisture.
- Keep blister strips 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 carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MONTECET contains

The active substances per film-coated tablet are 10 mg montelukast (as montelukast sodium) and 5 mg levocetirizine dihydrochloride.

The other ingredients are croscarmellose sodium, hydroxypropyl cellulose, hypromellose, iron oxide red (E172), iron oxide yellow (E172), lactose monohydrate, microcrystalline cellulose, magnesium stearate and titanium dioxide (E171).

What MONTECET looks like and contents of the pack

Light yellow to yellow coloured, round shaped, bevelled edge, biconvex, film-coated tablets, debossed with “ML” on one side and plain on the other side.

Aluminium/PVC blister strip containing 7 or 10 tablets. 4 blister strips containing 7 tablets, or 3 blister strips containing 10 tablets are packed in an outer cardboard carton.

Pack sizes: 28 and 30.

Holder of Certificate of Registration

Zydus Healthcare SA (Pty) Ltd

Southdowns Office Park, Building B, Ground Floor

22 Karee Street

Centurion

Pretoria 0157

Tel: 012 748 6400

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