PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

MONTELUKAST UNICORN 10 (film-coated tablets)

Montelukast Sodium

Contains sugar (lactose monohydrate 89,10 mg per tablet).

Please read this leaflet carefully before using MONTELUKAST UNICORN 10 film-coated tablets.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- **MONTELUKAST UNICORN 10** 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.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What **MONTELUKAST UNICORN 10** is and what it is used for
2. What you need to know before you take **MONTELUKAST UNICORN 10**
3. How to take **MONTELUKAST UNICORN 10**
4. Possible side effects
5. How to store **MONTELUKAST UNICORN 10**
6. Contents of the pack and other information.

1. What MONTELUKAST UNICORN 10 is and what it is used for

*What **MONTELUKAST UNICORN 10** is:*

MONTELUKAST UNICORN 10 is a leukotriene receptor antagonist that blocks substances called leukotrienes.

*How **MONTELUKAST UNICORN 10** works:*

Leukotrienes cause narrowing and swelling of airways in the lungs and also cause allergy symptoms. By blocking leukotrienes, **MONTELUKAST UNICORN 10** improves asthma symptoms, helps control asthma and improves seasonal allergy symptoms (also known as hayfever or seasonal allergic rhinitis).

*When **MONTELUKAST UNICORN 10** should be used:*

Your doctor has prescribed **MONTELUKAST UNICORN 10** to treat asthma, preventing your asthma symptoms during the day and night.

- **MONTELUKAST UNICORN 10** is used for the treatment of adults and adolescents 15 years of age and older who are not adequately controlled on their medication and need additional therapy.
- **MONTELUKAST UNICORN 10** also helps prevent the narrowing of airways triggered by exercise.
- In those asthmatic patients in whom **MONTELUKAST UNICORN 10** is indicated in asthma, **MONTELUKAST UNICORN 10** can also provide symptomatic relief of seasonal allergic rhinitis.

Your doctor will determine how **MONTELUKAST UNICORN 10** should be used depending on the symptoms and severity of your asthma.

What is asthma?

Asthma is a long-term disease.

Asthma includes:

- difficulty breathing because of narrowed airways. This narrowing of airways worsens and improves in response to various conditions.

- sensitive airways that react to many things, such as cigarette smoke, pollen, cold air, or exercise.
- swelling (inflammation) in the lining of airways.

Symptoms of asthma include: Coughing, wheezing, and chest tightness.

What are seasonal allergies?

Seasonal allergies (also known as hayfever or seasonal allergic rhinitis) are an allergic response often caused by airborne pollens from trees, grasses and weeds. The symptoms of seasonal allergies typically may include stuffy, runny, itchy nose; sneezing; watery, swollen, red, itchy eyes.

2. What you need to know before you take MONTELUKAST UNICORN 10

Tell your doctor about any medical problems or allergies you have now or have had.

Do not take MONTELUKAST UNICORN 10 if:

- You are allergic (hypersensitive) to montelukast or any other inactive ingredients (see "**WHAT MONTELUKAST UNICORN 10 CONTAINS**").
- You are pregnant or breastfeeding your baby.
- Safety and efficacy have not been established with **MONTELUKAST UNICORN 10** in children under the age of 15 years.

Take special care with MONTELUKAST UNICORN 10:

Talk to your doctor or pharmacist before taking **MONTELUKAST UNICORN 10**.

- If your asthma or breathing gets worse, tell your doctor immediately.
- It is important that you or your child take all asthma medications prescribed by your doctor. **MONTELUKAST UNICORN 10** should not be substituted for other asthma medications your doctor has prescribed for you.
- Any patient on anti-asthma medicines should be aware that if you develop a combination of symptoms such as a flulike illness, pins and needles or numbness of arms or legs, worsening of pulmonary symptoms, and/or rash, you should consult your doctor.

- Oral **MONTELUKAST UNICORN 10** 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.
- Do not decrease the dose or stop taking any other anti-asthma medications unless instructed to do so by your doctor.
- You should not take acetylsalicylic acid (aspirin) or anti-inflammatory medicines (also known as non-steroidal anti-inflammatory drugs or NSAIDs) if they make your asthma worse.
- Seek medical attention if, while using **MONTELUKAST UNICORN 10**, short-acting inhaled bronchodilators are needed more often than usual, or if more than the maximum number of inhalations of short-acting bronchodilator treatment prescribed for a 24-hour period is needed.
- If you have exacerbations of asthma after exercise, continue to use the usual dose of inhaled beta-agonists as prophylaxis unless otherwise instructed by your doctor.

Patients should be aware that various neuropsychiatric events (for example, behaviour and mood-related changes) have been reported in adults, adolescents and children with **MONTELUKAST UNICORN 10** (see section 4). If you develop such symptoms while taking **MONTELUKAST UNICORN 10**, you should consult your doctor.

Children and adolescents

Do not give this medicine to children less than 15 years of age.

There are different form(s) of this medicine available for paediatric patients under 18 years of age based on age range.

Using other medicines with MONTELUKAST UNICORN 10:

- Always tell your doctor or healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)
- If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

- Some medicines may affect how **MONTELUKAST UNICORN 10** works, or **MONTELUKAST UNICORN 10** may affect how other medicines work. It is important to consult your doctor about all medicines that you are using or planning to use.
- Tell your doctor if you or your child is using any of the following medicines, before taking **MONTELUKAST UNICORN 10**:
    - Phenobarbital (used for the treatment of epilepsy).
    - Phenytoin (used for the treatment of epilepsy).
    - Rifampicin (used for the treatment of certain infections such as tuberculosis (TB)).
    - Gemfibrozil (used for treatment of high lipid levels in plasma).

Important information about some of the ingredients of MONTELUKAST UNICORN 10:

MONTELUKAST UNICORN 10 contains lactose monohydrate which may have an effect on the control of your blood sugar if you have diabetes mellitus. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take **MONTELUKAST UNICORN 10**.

MONTELUKAST UNICORN 10 with food and drink:

MONTELUKAST UNICORN 10 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 **MONTELUKAST UNICORN 10**.

Driving and using machinery:

MONTELUKAST UNICORN 10 may make you drowsy which may impair your ability to drive and use machinery. Take care if you feel dizzy, tired or drowsy while using **MONTELUKAST UNICORN 10**.

3. How to take MONTELUKAST UNICORN 10

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

Always take **MONTELUKAST UNICORN 10** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The recommended dosage of **MONTELUKAST UNICORN 10** is one tablet a day in the evening with or without food for the prevention and treatment of asthma.

If you have the impression that the effect of **MONTELUKAST UNICORN 10** is too strong or too weak, talk to your doctor or pharmacist.

It is important to continue taking **MONTELUKAST UNICORN 10** for as long as your doctor prescribes it in order to maintain control of your asthma. **MONTELUKAST UNICORN 10** can treat your asthma only if it is taken continuously.

If you have any questions about the proper dose or usage of **MONTELUKAST UNICORN 10**, ask your doctor or pharmacist.

If you take more MONTELUKAST UNICORN 10 than you should:

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

If you forget to take MONTELUKAST UNICORN 10:

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

If you stop taking MONTELUKAST UNICORN 10:

MONTELUKAST UNICORN 10 can treat your asthma only if you continue to take it.

It is important to continue taking **MONTELUKAST UNICORN 10** for as long as your doctor prescribes. It will help control your asthma.

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

4. Possible side effects

MONTELUKAST UNICORN 10 can have side effects.

Not all side effects reported for **MONTELUKAST UNICORN 10** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **MONTELUKAST UNICORN 10**, please consult your doctor, pharmacist or other healthcare professional for advice.

Serious side effects

Talk with your doctor immediately if you notice any of the following side effects, which may be serious, and for which you may need urgent medical treatment.

Less frequent:

- allergic reactions including swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing, hives
- behaviour and mood related changes: agitation including aggressive behaviour or hostility, depression
- seizure
- increased bleeding tendency
- tremor
- racing or pounding heart (palpitations)
- combination of symptoms such as flu-like illness, pins and needles or numbness of arms and legs, worsening of pulmonary symptoms and/or rash (Churg-Strauss syndrome) (see section 2)

- low blood platelet count
- behaviour and mood-related changes: hallucinations, disorientation, suicidal thoughts and actions
- swelling (inflammation) of the lungs
- severe skin reactions (erythema multiforme) that may occur without warning
- yellowing of the skin and whites of the eyes, inflammation of the liver (hepatitis)

Other side effects while the medicine has been on the market

Frequent:

- sleeplessness
- abdominal (stomach) pain
- headache
- upper respiratory tract infections
- diarrhoea, nausea, vomiting
- rash
- fever
- elevated liver enzymes

Less Frequent:

- stuffy nose, coughing
- heartburn
- toothache
- behaviour and mood related changes: disturbance in attention, memory impairment, uncontrolled muscle movements
- tender red lumps under the skin, most commonly on your shins (erythema nodosum)
- behaviour and mood related changes: obsessive-compulsive symptoms, stuttering
- joint or muscle pain, muscle cramps
- bedwetting in children

- weakness/tiredness, feeling unwell, swelling

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. 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 **MONTELUKAST UNICORN 10**. Suspected side effects can also be reported directly to the Holder of the Certificate of Registration (HCR) via Patientsafety.sacg@novartis.com.

5. How to store MONTELUKAST UNICORN 10

- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Store at or below 25 °C. Store in the original package. The product is sensitive to light and moisture.
- Container: Keep the bottle tightly closed.
- Do not use after the expiry date printed on the label or 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 MONTELUKAST UNICORN 10 contains

Active ingredient:

The active substance is montelukast.

Each **MONTELUKAST UNICORN 10** film-coated tablet contains montelukast sodium equivalent to 10 mg montelukast.

Inactive ingredients:

Tablet core: cellulose microcrystalline, croscarmellose sodium, hydroxypropylcellulose, lactose monohydrate and magnesium stearate.

Film-coating layer: opadry beige (II) composed of ferric oxide red (E172), ferric oxide yellow (E172), macrogol 400, polyvinyl alcohol, talc and titanium dioxide (E171).

What MONTELUKAST UNICORN 10 looks like and contents of the pack

MONTELUKAST UNICORN 10 film-coated tablets are beige, round, biconvex, coated tablets, that are plain on both sides.

MONTELUKAST UNICORN 10 film-coated tablets are packed as 10, 14, 20, 28, 30, 35 or 50 tablets in: OPA/Al/PVC/Aluminium blisters or white, opaque polyethylene containers and tamper evident polypropylene closures with desiccant insert.

Not all packs may be marketed.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

Magwa Crescent West

Waterfall City

Jukskei View

Midrand

2090

Marketed by: Unicorn Pharmaceuticals (Pty) Ltd

Corner of Searle and Pontac Streets, Woodstock, Cape Town, 8001

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Access to the corresponding Professional Information

Not applicable.

[1]Company Reg. No.: 1990/001979/07