PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S3

MONTELUKAST UNICORN 4 (chewable tablets)

MONTELUKAST UNICORN 5 (chewable tablets)

Montelukast sodium

Each MONTELUKAST UNICORN 4 chewable tablet contains sweetener (aspartame 0,96 mg) and mannitol 155,92 mg.

Each MONTELUKAST UNICORN 5 chewable tablet contains sweetener (aspartame 1,20 mg) and mannitol 194,90 mg.

Please read this leaflet carefully before using MONTELUKAST UNICORN chewable 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 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 is and what it is used for
2. What you need to know before you take MONTELUKAST UNICORN
3. How to take MONTELUKAST UNICORN
4. Possible side effects
5. How to store MONTELUKAST UNICORN

6. Contents of the pack and other information

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

What MONTELUKAST UNICORN is

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

How MONTELUKAST UNICORN works

Leukotrienes cause narrowing and swelling of airways in the lungs. By blocking leukotrienes, MONTELUKAST UNICORN improves asthma symptoms and helps control asthma.

When MONTELUKAST UNICORN should be used

Your doctor has prescribed MONTELUKAST UNICORN to treat your child's asthma, preventing asthma symptoms during the day and night.

MONTELUKAST UNICORN 4 is used for the treatment of 2 to 5 year old patients who are not adequately controlled on their medication and need additional therapy.

MONTELUKAST UNICORN 5 is used for the treatment of paediatric patients 6 to 14 years of age who are not adequately controlled on their medication and need additional therapy.

MONTELUKAST UNICORN 4 may also be used as an alternative treatment to inhaled corticosteroids for 2 to 5 year old patients who have not recently taken oral corticosteroids for their asthma and have shown that they are unable to use inhaled corticosteroids.

MONTELUKAST UNICORN 5 may also be used as an alternative treatment to inhaled corticosteroids for 6 to 14 year old patients who have not recently taken oral corticosteroids for their asthma and have shown that they are unable to use inhaled corticosteroids.

MONTELUKAST UNICORN 4 also helps prevent the narrowing of airways triggered by exercise for patients 2 years of age and older.

MONTELUKAST UNICORN 5 also helps prevent the narrowing of airways triggered by exercise.

Your doctor will determine how MONTELUKAST UNICORN should be used depending on the symptoms and severity of your child's 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 the airways.

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

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

Tell your doctor about any medical problems or allergies your child has now or has had.

Do not take MONTELUKAST UNICORN if:

- You are allergic (hypersensitive) to montelukast or any other inactive ingredients (see "WHAT MONTELUKAST UNICORN CONTAINS").
- You are pregnant or breastfeeding your baby. Please consult your doctor before use.

Safety and efficacy have not been established with MONTELUKAST UNICORN 4 in children under the age of 2 years.
Safety and efficacy have not been established with MONTELUKAST UNICORN 5 in children under the age of 6 years.

Take special care with MONTELUKAST UNICORN:

Talk to your doctor or pharmacist before you give MONTELUKAST UNICORN to your child.

- If your child's asthma or breathing gets worse, tell your doctor immediately.
- It is important that your child take all asthma medications prescribed by your doctor. MONTELUKAST UNICORN should not be used instead of other asthma medications your doctor has prescribed for your child.
- If your child is on anti-asthma medicines, be aware that if he/she develops a combination of symptoms such as flu-like 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 is not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor has given you for your child. Always have your child's inhaled rescue medicine for asthma attacks with you.
- Your child should not take acetyl-salicylic acid (aspirin) or anti-inflammatory medicines (also known as Non-Steroidal Anti-Inflammatory drugs or NSAIDs) if they make his/her asthma worse.
- Do not decrease the dose or stop taking any other anti-asthma medications unless instructed to do so by your doctor.
- Seek medical attention if, while using MONTELUKAST UNICORN, 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 a worsening of asthma after exercise, continue to use the usual dose of inhaled beta-antagonists as prophylaxis unless otherwise instructed by your doctor.

Important information about some of the ingredients of MONTELUKAST UNICORN:

MONTELUKAST UNICORN chewable tablets contain aspartame, which is a source of phenylalanine (an essential amino acid of the body). Caution should be used if you or your child has a disorder called phenylketonuria, which is a genetic disorder that is characterised by the inability of the body to utilise phenylalanine.

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

Children and adolescents

Do not give this medicine to children less than 2 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:

- 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.

- In general, MONTELUKAST UNICORN does not interfere with other medicines that you may be taking. However, 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:

- 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)).

MONTELUKAST UNICORN with food and drink:

MONTELUKAST UNICORN can be taken with or without food.

Pregnancy and breastfeeding:

The safety of the use of MONTELUKAST UNICORN in pregnant and breastfeeding women has not been established. Do not take MONTELUKAST UNICORN if you are pregnant or breastfeeding your baby.

Driving and using machinery:

MONTELUKAST UNICORN 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.

3. How to take MONTELUKAST UNICORN

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

- The dose for children from 2 to 5 years old is one 4 mg chewable tablet daily.
- The dose for children from 6 years old is one 5 mg chewable tablet daily.

If you have the impression that the effect of MONTELUKAST UNICORN is too strong or too weak, talk to your doctor or pharmacist.
It is important to continue taking MONTELUKAST UNICORN for as long as your doctor prescribes it in order to maintain control of your child's asthma. MONTELUKAST UNICORN can treat your child's asthma only if it is taken continuously.

Do not share MONTELUKAST UNICORN with any other person, even if their symptoms are the same as your child's.

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

If you take more MONTELUKAST UNICORN than you should:
In case of an accidental or intentional overdose contact your doctor or pharmacist as soon as possible. If neither is available, seek help at the nearest hospital or poison control centre.

If your child forgets to take MONTELUKAST UNICORN:
Give your child the missed dose as soon as you remember. If it is almost time for the next dose, skip the missed dose and give the medicine at the next regularly scheduled time. Do not give a double dose to make up the missed dose.

If you stop taking MONTELUKAST UNICORN
MONTELUKAST UNICORN can treat your child's asthma only if he/she continues taking it.
It is important for your child to continue taking MONTELUKAST UNICORN for as long as your doctor prescribes.
It will help control your child's asthma.

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

4. Possible side effects

MONTELUKAST UNICORN can have side effects.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen of if you experience any untoward effects while taking this medicine, 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, hallucinations, disorientation, suicidal thoughts and actions
- 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
- 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
- Thirst
- Headache
- Upper respiratory tract infections
- Diarrhoea, nausea, vomiting
- Rash
- Fever
- Elevated liver enzymes

Less frequent:

- Stuffy nose, coughing
- Heartburn, stomach flu
- Toothache
- Behaviour and mood related changes: dream abnormalities, including nightmares, trouble sleeping, sleepwalking, irritability, feeling anxious, restlessness
- Dizziness, drowsiness, pins and needles/numbness
- Nosebleed
- Dry mouth, indigestion
- Bruising, itching, hives
- Joint or muscle pain, muscle cramps
- Bedwetting in children
- Weakness/tiredness, feeling unwell, swelling

- 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

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.

Suspected side effects can also be reported directly to the HCR via Patientsafety.sacg@novartis.com.

5. How to store MONTELUKAST UNICORN

- Store in the original package. The product is sensitive to light and moisture. Store at or below 25 °C.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Keep the container 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

Active ingredient:

MONTELUKAST UNICORN 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 from 6 years old.

Inactive ingredients:

Aspartame, cherry duarome, cherry flavour, cellulose microcrystalline, croscarmellose sodium, hydroxypropylcellulose, type EXF, magnesium stearate, mannitol and ferric oxide red (E172).

What MONTELUKAST UNICORN looks like and contents of the pack

MONTELUKAST UNICORN 4: Oval pink to slightly speckled pink tablet with odour of cherry, encoded “4” on one side.

MONTELUKAST UNICORN 5: Round pink to slightly speckled pink tablet with odour of cherry, encoded “5” on one side.

MONTELUKAST UNICORN 4 and 5 chewable tablets are packed as 28 tablets in either:

Pack of 28 tablets in either:

OPA/Al/PVC/Aluminium blisters, OPA/Al/PE 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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Registration number

MONTELUKAST UNICORN 4: 44/10.2.2/0487

MONTELUKAST UNICORN 5: 44/10.2.2/0488

Access to the corresponding Professional Information

Not applicable.

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