PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

Montelukast Oral Granules Unicorn

Active ingredient: montelukast sodium equivalent to 4,00 mg of montelukast.

MONTELUKAST ORAL GRANULES UNICORN contains sweetener (484,70 mg mannitol per sachet).

Read all of this leaflet carefully before you start taking MONTELUKAST ORAL GRANULES UNICORN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- MONTELUKAST ORAL GRANULES 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.

What is in this leaflet

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

2. What you need to know before you give MONTELUKAST ORAL GRANULES UNICORN to your child.

3. How to take MONTELUKAST ORAL GRANULES UNICORN.

4. Possible side effects.

5. How to store MONTELUKAST ORAL GRANULES UNICORN.

6. Contents of the pack and other information.

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

MONTELUKAST ORAL GRANULES UNICORN contains the active substance montelukast and is used in children (2 to 5 years) for the chronic treatment of atopic (allergic) asthma and to prevent asthma symptoms.

How it works

Montelukast, the active ingredient in MONTELUKAST ORAL GRANULES UNICORN is a leukotriene receptor antagonist that blocks substances called leukotrienes.
Leukotrienes cause narrowing and swelling of airways in the lungs. By blocking leukotrienes, MONTELUKAST ORAL GRANULES UNICORN improves asthma symptoms and helps control asthma.

2. What you need to know before you give MONTELUKAST ORAL GRANULES UNICORN to your child

Do not give MONTELUKAST ORAL GRANULES UNICORN to your child:

- If your child is hypersensitive (allergic) to montelukast or any of the other ingredients of MONTELUKAST ORAL GRANULES UNICORN (listed in section 6).
- If your child is younger than 2 years old.

Warnings and precautions

Talk to your doctor or pharmacist before giving MONTELUKAST ORAL GRANULES UNICORN to your child:

- If your child’s asthma or breathing gets worse, tell your doctor immediately.
- MONTELUKAST ORAL GRANULES 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 emergency asthma pump or emergency medicine for asthma attacks with you.

- If your child's gets asthma attacks during exercise and your child's doctor has prescribed an emergency asthma pump medicine for your child to use before or during exercise, your child should keep using that medicine.
- It is important that your child take all asthma medications prescribed by his/her doctor. MONTELUKAST ORAL GRANULES 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.
- 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.
- If your child develops symptoms such as behaviour changes or mood changes while taking MONTELUKAST ORAL GRANULES UNICORN, you should consult your child's doctor.

Other medicines and MONTELUKAST ORAL GRANULES UNICORN

Always tell your healthcare provider if your child is taking any other medicine. This includes all complementary or traditional medicines.

Some medicines may affect how MONTELUKAST ORAL GRANULES UNICORN works, or MONTELUKAST ORAL GRANULES UNICORN may affect how your child's other medicines work. Tell your doctor if your child is taking the following medicines before starting MONTELUKAST ORAL GRANULES UNICORN:

- phenobarbital (used for treatment of epilepsy).
- phenytoin (used for treatment of epilepsy).
- rifampicin (used to treat tuberculosis and some other infections).
- gemfibrozil (used to treat high fat levels in your blood).

MONTELUKAST ORAL GRANULES UNICORN with food and drink

You can give MONTELUKAST ORAL GRANULES UNICORN to your child with or without food. For more information see section 3 on “How to take MONTELUKAST ORAL GRANULES UNICORN” below.

Pregnancy and breastfeeding

This subsection is not applicable for MONTELUKAST ORAL GRANULES UNICORN since they are intended for use in children 2 to 5 years of age.

Driving and using machines

This subsection is not applicable for the MONTELUKAST ORAL GRANULES UNICORN 4 mg granules since they are intended for use in children 2 years to 5 years of age, however the following information is relevant to the active ingredient, montelukast.
MONTELUKAST ORAL GRANULES UNICORN is not expected to affect your ability to drive a car or operate machinery. However, individual responses to medication may vary. Certain side effects (such as dizziness and drowsiness) that have been reported with MONTELUKAST ORAL GRANULES UNICORN may affect some patients’ ability to drive or operate machinery.

3. How to take MONTELUKAST ORAL GRANULES UNICORN

Do not share medicines prescribed for your child with any other person.
Always have your child take MONTELUKAST ORAL GRANULES UNICORN exactly as your doctor or pharmacist has told you. Check with your child’s doctor or pharmacist if you are not sure.

- You should give MONTELUKAST ORAL GRANULES UNICORN to your child under supervision every evening.
- Keep giving MONTELUKAST ORAL GRANULES UNICORN to your child even when your child has no symptoms.

For children 2 to 5 years of age

The recommended dose is one sachet of MONTELUKAST ORAL GRANULES UNICORN to be taken by mouth each evening.

If you are giving MONTELUKAST ORAL GRANULES UNICORN to your child, be sure that your child does not take any other products that contain the same active ingredient, montelukast. Check with your doctor, pharmacist or other healthcare provider if you are not sure.

How should I give MONTELUKAST ORAL GRANULES UNICORN to my child?

This medicine is for oral use.

- Do not open the sachet until ready to use.
- MONTELUKAST ORAL GRANULES UNICORN can be given either:
    - directly in the mouth;
    - OR mixed with a spoonful of cold or room temperature soft food (for example, applesauce, ice cream, carrots and rice).
- Mix all of the contents of the MONTELUKAST ORAL GRANULES UNICORN into a spoonful of cold or room temperature soft food, taking care to see that the entire dose is mixed with the food. Be sure the child is given the entire spoonful of the granule/food mixture immediately (within 15 minutes).

  IMPORTANT: Never store any granule/food mixture for use at a later time.
- MONTELUKAST ORAL GRANULES UNICORN is not intended to be dissolved in liquid. However, your child may take liquids after swallowing MONTELUKAST ORAL GRANULES UNICORN.
- MONTELUKAST ORAL GRANULES UNICORN can be taken without regard to the timing of food intake.

Your doctor will tell you how long your child’s treatment with MONTELUKAST ORAL GRANULES UNICORN will last.

If you have the impression that the effect of MONTELUKAST ORAL GRANULES UNICORN is too strong or too weak, tell your doctor or pharmacist.

If your child takes more MONTELUKAST ORAL GRANULES UNICORN than he/she should

In the event of overdosage, consult your doctor, pharmacist or other healthcare provider. If neither is available, contact the nearest hospital or poison control centre and take your child's box of MONTELUKAST ORAL GRANULES UNICORN with you.

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

If you forget to give MONTELUKAST ORAL GRANULES UNICORN to your child

Give MONTELUKAST ORAL GRANULES UNICORN to your child exactly as your doctor has told you. However, if you forget to give MONTELUKAST ORAL GRANULES UNICORN to your child, just give the usual amount of one sachet once daily.

Do not give your child a double dose to make up for a forgotten dose.

If your child stops taking MONTELUKAST ORAL GRANULES UNICORN

MONTELUKAST ORAL GRANULES UNICORN can treat your child's asthma only if he/she continues taking it.

It is important for your child to continue taking MONTELUKAST ORAL GRANULES UNICORN for as long as your doctor has told you. 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 ORAL GRANULES UNICORN can have side effects.

Not all side effects reported for MONTELUKAST ORAL GRANULES UNICORN are included in this leaflet. Should your child's general health worsen or if your child experiences any untoward effects while taking MONTELUKAST ORAL GRANULES UNICORN, please consult your healthcare provider for advice.

If any of the following happens, your child should stop taking MONTELUKAST ORAL GRANULES UNICORN and you should tell your doctor immediately or go to the casualty department at your nearest hospital*:*

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.

These are all very serious side effects. If your child has them, he/she may have had a serious allergic reaction to MONTELUKAST ORAL GRANULES UNICORN and may need urgent medical attention.

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

- behaviour and mood related changes: agitation including aggressive behaviour or hostility, depression, hallucinations, disorientation, suicidal thoughts and actions
- seizure
- increased bleeding tendency
- tremor
- rapid or fast heart beating (palpitations)
- combination of symptoms such as flu-like illness, pins and needles or numbness of arms and legs, worsening of lung symptoms and/or rash (Churg-Strauss syndrome) (see section 2)
- low blood platelet count (that your doctor will see from a blood test)
- severe skin reactions (erythema multiforme) that may occur without warning
- inflammation of the liver (hepatitis)

These are all serious side effects. If your child has them, he/she may need urgent medical attention.

Other side effects while the medicine has been on the market

Frequent:

- upper respiratory infection
- diarrhoea, nausea, vomiting
- rash
- fever
- elevated liver enzymes (that your doctor will see from a blood test)

Less frequent:

- behaviour and mood related changes: dream abnormalities, including nightmares, trouble sleeping, sleepwalking, irritability, feeling anxious, restlessness, disturbance in attention, memory impairment, uncontrolled muscle movements, obsessive-compulsive symptoms, stuttering
- 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
- tender red lumps under the skin, most commonly on your shins (erythema nodosum)

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 MONTELUKAST ORAL GRANULES UNICORN. Suspected adverse reactions can also be reported directly to the HCR via Patientsafety.sacg@novartis.com.

5. How to store MONTELUKAST ORAL GRANULES UNICORN

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

- Store at or below 25 °C.
- Store in the original package in order to protect from light and moisture.
- The sachets should not be opened until required for use.
- Do not use after the expiry date stated on the sachet / carton.
- Return all unused medicines to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MONTELUKAST ORAL GRANULES UNICORN contains

Each sachet of MONTELUKAST ORAL GRANULES UNICORN contains 4,15 mg of montelukast sodium equivalent to 4,00 mg of montelukast.

MONTELUKAST ORAL GRANULES UNICORN contains sweetener (mannitol 484,70 mg per sachet).

Excipients: Hydroxypropyl cellulose (klucel LF), mannitol (Pearlitol DC300) and magnesium stearate.

What MONTELUKAST ORAL GRANULES UNICORN looks like and contents of the pack

Oral granules.

White to off white granules.

Pouch laminate sachet (PET/Aluminium foil/PE).

The sachets are packed in an outer cardboard carton.

Packs sizes of 7, 10, 14, 20, 28, 30 and 100 sachets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

Waterfall 5-lr

Magwa Crescent West

Waterfall City

Jukskei View

2090

Marketed by **UNICORN PHARMACEUTICALS (PTY) LTD**

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Not applicable.

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