

**Product name: MONTE-AIR 4mg, 5 mg, 10 mg and Sprinkles -
MSD(Pty)Ltd**

**APPROVED
PATIENT
INFORMATION
LEAFLET**

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

MONTE-AIR® 10 mg Film-coated Tablets

MONTE-AIR® 5 mg Chewable Tablets

MONTE-AIR® 4 mg Chewable Tablets

MONTE-AIR® SPRINKLES

montelukast sodium

Contains sugar:

SINGULAIR 10 mg Film-coated Tablets contain lactose

SINGULAIR 5 mg Chewable Tablets contain mannitol and aspartame

SINGULAIR 4 mg Chewable Tablets contain mannitol and aspartame

SINGULAIR SPRINKLES contain mannitol

Read all of this leaflet carefully before you start using MONTE-AIR

- 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.
- MONTE-AIR 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 MONTE-AIR is and what it is used for
2. What you need to know before you take MONTE-AIR
3. How to take MONTE-AIR
4. Possible side effects
5. How to store MONTE-AIR
6. Contents of the pack and other information

1. What MONTE-AIR is and what it is used for

MONTE-AIR is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in your lungs. Blocking leukotrienes improves asthma symptoms and helps prevent asthma attacks. Leukotrienes also cause allergy symptoms. Blocking leukotrienes improves allergic rhinitis (seasonal and perennial, also known as outdoor and indoor nasal allergies).

MONTE-AIR 10 mg film-coated tablets are indicated in adults and children 15 years of age and older for the prevention and treatment of asthma.

In adult patients, in whom MONTE-AIR is used for asthma, MONTE-AIR may provide some symptomatic relief of seasonal allergic rhinitis (hayfever).

MONTE-AIR 5 mg chewable tablets are indicated in paediatric patients over 6 years of age for the prevention and treatment of asthma.

MONTE-AIR 4mg chewable tablets and SPRINKLES are indicated in paediatric patients 2 to 5 years of age for the prevention and treatment of asthma.

2. What you need to know before you take MONTE-AIR:

Do not take, or give your child MONTE-AIR:

- If he/she/you are allergic to montelukast or to any of the other ingredients of MONTE-AIR.

Do not give your child MONTE-AIR 10 mg Film-coated Tablets:

- if he/she is below the age of 15 years as safety and efficacy have not been demonstrated.

Do not give your child MONTE-AIR 5 mg Chewable Tablets:

- if he/she is below the age of 6 years, as safety and efficacy have not been demonstrated.

Do not give your child MONTE-AIR 4 mg Chewable Tablets and SPRINKLES to take:

- if he/she is below the age of 2 years, as safety and efficacy have not been demonstrated.

Warnings and precautions

Take special care with MONTE-AIR

- It is important that you or your child continue taking MONTE-AIR daily as prescribed by your doctor, even when you or your child has no asthma symptoms or if you or your child has an asthma attack.
- Do not take or give your child MONTE-AIR for the immediate relief of an asthma attack. If you or your child gets an asthma attack, you should follow the instructions your-doctor gave you for treating asthma attacks.

- Always have your or your child's inhaled rescue medicine for asthma attacks with you.
- If you or your child's asthma symptoms get worse or more frequent, or if you or your child needs to use more of you or your child's inhaled rescue medicine for asthma attacks, you should contact your doctor immediately.
- Do not stop giving or lower the dose of you or your child's other asthma medicines unless your doctor tells you to.
- If your doctor has prescribed a medicine to use before exercise, that medicine should be continued to be used unless the doctor recommends stopping.
- It is important that you or your child take all asthma medicines prescribed by your doctor. MONTE-AIR should not be replaced with other asthma medicines your doctor has prescribed.
- If you or your child's asthma is known to be made worse by aspirin, aspirin and other non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen should not be taken.
- 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, tell your-doctor immediately.
- Behaviour and mood-related changes have been reported in patients taking MONTE-AIR. Tell your doctor if you or your child experiences these changes while taking MONTE-AIR (see Possible Side Effects).

Children

MONTE-AIR 5 mg chewable tablets are for children 6 to 14 years of age.

MONTE-AIR 4 mg chewable tablets and SPRINKLES are for children 2 to 5 years of age.

Other medicines and MONTE-AIR

Always tell your healthcare provider if you or your child are taking any other medicine. (This includes all complementary or traditional medicines.)

Some medicines may affect how MONTE-AIR works, or MONTE-AIR may affect how your other medicines work. It is important to tell your doctor about all medicines that you or your child are using, including those obtained without a prescription.

MONTE-AIR with food and drink

MONTE-AIR can be taken with or without food.

Pregnancy and Breastfeeding

The safety of MONTE-AIR in pregnant and breastfeeding women has not been established.

Pregnancy

Women who are pregnant or intend to become pregnant should consult their doctor before taking MONTE-AIR.

Breastfeeding

It is not known if MONTE-AIR is excreted in human milk. Therefore, MONTE-AIR should not be used if you are pregnant or breastfeeding.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine

Driving and using machines

MONTE-AIR may cause side effects, such as drowsiness and dizziness, which may affect your ability to drive or operate machines.

MONTE-AIR 10 mg Film-coated Tablets contain lactose and MONTE-AIR 4 and 5 mg

Chewable Tablets contain aspartame

MONTE-AIR 10 mg Film-coated Tablets contain lactose. If you or your child have the rare hereditary condition of lactose intolerance, you or your child should not take MONTE-AIR. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

If you or your child has phenylketonuria, you should note that MONTE-AIR 5 mg and 4 mg chewable tablets contain aspartame, which is a source of phenylalanine. It may be harmful to patients with phenylketonuria as it contains aspartame.

3. How to take MONTE-AIR

Always take MONTE-AIR exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

You or your child should take MONTE-AIR once a day in the evening with or without food, as the doctor has prescribed.

MONTE-AIR 10 mg Film-coated Tablets:

The dose for adults and adolescents 15 years of age and older for treatment of asthma is one 10 mg tablet each evening.

MONTE-AIR 5 mg Chewable Tablets:

The dose for children 6 to 14 years of age for the treatment of asthma is one 5 mg chewable tablet each evening. MONTE-AIR 5 mg Chewable Tablets have not been studied in seasonal hay fever in children with asthma.

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

It is important to continue taking MONTE-AIR for as long as your doctor prescribes it in order to maintain control of your or your child's asthma. MONTE-AIR can treat your or your child's asthma only if you or your child continues to take it.

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

MONTE-AIR 4 mg Chewable Tablets:

The dose for children 2 to 5 years of age for the treatment of asthma is one 4 mg chewable tablet each evening.

MONTE-AIR SPRINKLES:

The dose for children 2 to 5 years of age is one whole packet of SPRINKLES each evening.

Do not open a packet until you are ready to use it.

MONTE-AIR SPRINKLES can be given:

- directly into the mouth or
- by mixing one whole packet with a spoonful of cold or room temperature soft food (for example, apple sauce).

Give all this food mixture immediately (within 15 minutes).

IMPORTANT: Never store any of this mixture for use at a later time.

MONTE-AIR SPRINKLES are not intended to be dissolved in liquid. However, your child may take liquids after swallowing MONTE-AIR SPRINKLES.

If you or your child took more MONTE-AIR than you/she/he should

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

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

If you or your child forgets to take MONTE-AIR

Try to take MONTE-AIR as prescribed. However, if you or your child misses a dose, just resume the usual schedule of one tablet each evening.

Do not take or give your child a double dose to make up for the forgotten individual doses.

4. Possible side effects

MONTE-AIR can have side effects.

Not all side effects reported for MONTE-AIR are included in this leaflet. Should your general health worsen while taking MONTE-AIR, or if you experience any untoward effects while taking MONTE-AIR, please consult your healthcare provider for advice.

If any of the following happens, stop taking MONTE-AIR and tell your doctor immediately or go to the casualty department at your nearest hospital, 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, as it may be an increase in certain white blood cells (eosinophils) and possible inflamed blood vessels throughout the body (systemic vasculitis):
- develops allergic reactions, including sudden life-threatening allergic reactions, such as swelling of the face, lips, mouth, tongue or throat which-may cause difficulty in swallowing or breathing; hives, itching, rash, bruising
- develops hepatitis (symptoms may include fatigue, abdominal discomfort, nausea or yellowing of the skin or whites of the eyes).

These are all very serious side effects. If you or your child has them, this may be a serious reaction to MONTE-AIR that may need urgent medical attention or hospitalisation.

If any of the following happens, stop taking MONTE-AIR and tell your doctor immediately or go to the casualty department at your nearest hospital:

- thoughts and attempted actions of suicide
- seizure (fits)

Tell your doctor immediately if you notice any behaviour and mood-related changes that have been reported with the use of MONTE-AIR:

- abnormal dreams
- seeing, feeling or hearing things that are not there (hallucinations)
- agitation, including aggressive behaviour
- depression
- disturbance in attention
- memory impairment
- obsessive-compulsive symptoms
- feeling anxious
- inability to sleep
- irritability, restlessness
- tremor (shaking or trembling)
- uncontrolled muscle movements (tic)
- hostility
- disorientation
- sleep walking
- stuttering

Tell your doctor if you notice any of these side effects reported with use of MONTE-AIR:

- increased bleeding tendency; (low blood platelet Count)
- palpitations
- dizziness, drowsiness, pins and needles/decreased feeling or sensitivity (especially in the skin)
- nose bleed, swelling (inflammation) of the lungs

- diarrhoea, indigestion, nausea, vomiting
- joint pain, aching muscles including muscle cramps
- bedwetting in children
- swelling, fever
- weakness
- tiredness
- upper respiratory infections

Tell your doctor if you notice any of the following side effects frequently reported in clinical studies:

- headache
- thirst
- abdominal pain
- increased liver enzymes, as determined by laboratory tests

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. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of MONTE-AIR .

5. How to store MONTE-AIR

Do not use MONTE-AIR after the month and year following Exp./~~Ver.~~: on the cartons.

Return all unused medicines to your pharmacist.

Do not dispose of unused medicine in drains or the sewerage system (e.g. toilets).

Store at or below 30 °C, protected from moisture and light.

MONTE-AIR SPRINKLES: The packet should not be opened until ready to use. The full dose must be administered immediately (within 15 minutes). If mixed with food, it must not be stored for future use.

Store all medicines out of reach and sight of children.

6. Contents of the pack and other information

What MONTE-AIR contains

MONTE-AIR (montelukast sodium) contains montelukast sodium as the active ingredient.

It is available as:

- a 10 mg Film-coated Tablet for adults and adolescents 15 years and older.
- a 5 mg Chewable Tablet for children 6 to 14 years of age
- a 4 mg Chewable Tablet for children 2 to 5 years of age
- a packet of SPRINKLES for children 2 to 5 years of age

Each 10 mg Film-coated Tablet contains 10 mg of montelukast and each 5 mg chewable tablet contains 5 mg of montelukast.

Each 4mg Chewable Tablet contains 4mg of montelukast and each packet of SPRINKLES contains 4 mg of montelukast.

In addition, MONTE-AIR contains the following inactive ingredients:

MONTE-AIR 10 mg Film-coated Tablets contains: carnauba wax, croscarmellose sodium, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, methyl hydroxypropyl cellulose, microcrystalline cellulose, red ferric oxide, titanium dioxide, yellow ferric oxide. Contains sugar (lactose monohydrate).

MONTE-AIR 5 mg and 4 mg Chewable Tablets contain: artificial cherry flavour, aspartame, croscarmellose sodium, hydroxypropyl cellulose, magnesium stearate, mannitol, microcrystalline cellulose, red ferric oxide.

MONTE-AIR 5 mg and 4 mg Chewable Tablets contain sugar (mannitol and aspartame).

MONTE-AIR SPRINKLES contains: hydroxypropyl cellulose, magnesium stearate, mannitol.

MONTE-AIR SPRINKLES contains sugar (mannitol).

What MONTE-AIR looks like and contents of the pack

MONTE-AIR 10 mg Film-coated Tablets: A beige, rounded square film-coated tablet with 'MSD 117' engraved on one side of the tablet.

MONTE-AIR 10 mg Film-coated Tablets are available in OPA/Al/PVC blister packs of 14 and 28.

MONTE-AIR 5 mg Chewable Tablets: A pink, round, biconvex tablet with 'MSD 275' engraved on one side of the tablet.

MONTE-AIR 5 mg Chewable Tablets are available in OPA/Al/PVC blister packs of 14 and 28.

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MONTE-AIR 4 mg Chewable Tablets: A pink, oval, biconvex tablet with a cherry taste and odour. 'MSD 711' is engraved on one side of the tablet.

MONTE-AIR 4 mg Chewable Tablets are available in OPA/Al/PVC blister packs of 14 and 28.

MONTE-AIR SPRINKLES: White, granular, coarse, free-flowing homogenous solid, with no extraneous particles present.

MONTE-AIR SPRINKLES (500 mg net weight) is available in low density polyethylene/aluminium /polyester film foil packets in pack sizes of 28 or 30 per carton.

Holder of Certificate of Registration

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MONTE-AIR 10 mg film-coated tablets: 44/10.2.2/0061

MONTE-AIR 5 mg chewable tablets: 44/10.2.2/0060

MONTE-AIR 4 mg chewable tablets: 44/10.2.2/0059

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MONTE-AIR SPRINKLES: 44/10.2.2/0062