PATIENT INFORMATION LEAFLET

Information for the Patient about

MONTASH

SCHEDULING STATUS:

S3

MONTASH 4 CHEW (4 mg montelukast) chewable tablets.

MONTASH 5 CHEW (5 mg montelukast) chewable tablets.

MONTASH 10 (10 mg montelukast) film-coated tablets.

Each chewable tablet of **MONTASH 4 CHEW** contains 4,2 mg montelukast sodium, which is equivalent to 4 mg montelukast.

MONTASH 4 CHEW is sugar free.

Contains sweetener. This medicine contains 0,6 mg aspartame per tablet.

Each chewable tablet of **MONTASH 5 CHEW** contains 5,2 mg montelukast sodium, which is equivalent to 5 mg montelukast.

MONTASH 5 CHEW is sugar free.

Contains sweetener. This medicine contains 0,743 mg aspartame per tablet.

Each film-coated tablet of **MONTASH 10** contains montelukast sodium 10,4 mg equivalent to 10 mg montelukast.

MONTASH 10 is sugar free.

Contains sweetener. This medicine contains 1,5 mg aspartame per tablet.

Montash 10 Each film-coated tablet contains montelukast sodium equivalent to 10 mg montelukast
Montash 4/5 Chew Each chewable tablet contains montelukast sodium equivalent to 4/5 mg montelukast

Read all of this leaflet carefully before you start taking MONTASH

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

1. What MONTASH is and what it is used for

MONTASH blocks the substances responsible for narrowing and swelling of the lungs, called leukotrienes. When montelukast blocks leukotrienes, it helps control asthma and improves the symptoms associated with asthma.

MONTASH has been prescribed to treat you or your child's asthma, which may be worsened by allergies as well as preventing asthma symptoms.

MONTASH 4 CHEW is used in children from ages 2 – 5 years old.

MONTASH 5 CHEW is used in children from ages 6 – 14 years old.

MONTASH 10 is used in adults and children over the age of 15 years old.

MONTASH 10 may also assist with in relieving the symptoms associated with seasonal allergies, in adults with asthma.

2. What you need to know before you take MONTASH

Do NOT take MONTASH:

- If you are hypersensitive (allergic) to montelukast or any of the other ingredients of **MONTASH** (listed in section 6).
- **MONTASH 4 CHEW** should not be given to your child if he/she is under the age of 2 years old.
- **MONTASH 5 CHEW** should not be given to your child if he/she is under the age of 6 years old.
- **MONTASH 10** should not be given to your child if he/she is under the age of 15 years old.

Warnings and precautions:

Special care should be taken with MONTASH

- If you have sudden asthma attacks, **MONTASH** does not relieve asthma symptoms immediately. Always keep your inhaler with you for acute attacks. Please consult your doctor if more inhalations are needed than usual.
- If you have other medicines prescribed for you/your child. **MONTASH** is not a substitute for other asthma medicines such as inhaled or oral corticosteroids (used to relief inflammation).
- If you have medicines used to treat asthma, including **MONTASH**, may cause a reaction. Contact your doctor immediately if you experience rash, difficulty breathing, heart pain or pins and needles or weakness/numbness in your hands, feet, arms or legs.
- If you are sensitive to aspirin and other steroidal anti-inflammatories, **MONTASH** does not change the need for asthma patients to avoid these medicines.

Children and adolescents

Montash 10 Each film-coated tablet contains montelukast sodium equivalent to 10 mg montelukast
Montash 4/5 Chew Each chewable tablet contains montelukast sodium equivalent to 4/5 mg montelukast

MONTASH 4 CHEW is used in children from ages 2 – 5 years old.

MONTASH 5 CHEW is used in children from ages 6 - 14 years old.

MONTASH 10 is used in adults and children over the age of 15 years old.

Other medicines and MONTASH

Always tell your healthcare provider if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Please discuss the use of the following medicines or substances in combination with **MONTASH** with your doctor or pharmacist:

- Phenytoin and phenobartital (medicine used to treat epilepsy).
- Rifampicin (a medicine used to treat TB and other infections).
- Gemfibrozil (a medicine used to treat high blood cholesterol levels).

MONTASH with food and drink:

MONTASH can be taken with or without a meal.

Pregnancy and 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 health care provider for advice before taking this medicine.

Pregnancy:

The safety of **MONTASH** in pregnant women has not been established.

Breastfeeding:

Montash 10 Each film-coated tablet contains montelukast sodium equivalent to 10 mg montelukast
Montash 4/5 Chew Each chewable tablet contains montelukast sodium equivalent to 4/5 mg montelukast

Do not take **MONTASH** if you are breastfeeding or intend to breastfeed your baby.

Driving or using machinery:

You may experience drowsiness and dizziness when taking **MONTASH**. It is not always possible to predict to what extent **MONTASH** may interfere you're your daily activities. Therefore, you should not drive, operate complex machinery or engage in other potentially hazardous activities until it is known whether **MONTASH** affects your ability to perform such activities.

MONTASH contains aspartame (an artifical sweetener), a source of phenylalanine (amino acid). This should be taken into account if you have been diagnosed with phenylketonuria (a birth defect that causes amino acid to build uo in your body).

- Each chewable tablet of **MONTASH 4 CHEW** contains 0,6 mg aspartame.
- Each chewable tablet of **MONTASH 5 CHEW** contains 0,743 mg aspartame.
- Each tablet of **MONTASH 10** contains 1,5 mg aspartame.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. HOW TO TAKE MONTASH:

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

Always take **MONTASH** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Oral.

MONTASH 4 CHEW and **MONTASH 5 CHEW** must be chewed before swallowing.

The usual dose is one tablet at night.

Your doctor will determine how **MONTASH** should be used depending on the symptoms and severity of your or your child's asthma.

MONTASH 4 CHEW is used in children from ages 2 – 5 years old.

MONTASH 5 CHEW is used in children from ages 6 - 14 years old.

MONTASH 10 is used in adults and children over the age of 15 years old.

Your doctor may add **MONTASH** to your existing asthma medicines.

Do not stop taking **MONTASH** if your asthma is under control.

If you or child's asthma or breathing gets worse, tell your doctor immediately.

Do not exceed the recommended daily dosage.

If you take more MONTASH 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.

Signs and symptoms of overdose include stomach pain, headache, feeling restless or hyperactive, drowsiness, thirst and vomiting.

Always take **MONTASH** as prescribed (see **"HOW TO TAKE MONTASH"**).

If you forget to take MONTASH:

Always take **MONTASH** as prescribed (see **"HOW TO TAKE MONTASH"**). If you have missed a dose, take it as soon as you remember. Do not take a double dose of **MONTASH** to make up for forgotten individual doses.

If you stop taking MONTASH:

DO NOT stop taking **MONTASH** without discussing this with your doctor, even if you feel better. If your doctor thinks that you should stop using **MONTASH**, he/she will reduce your dose gradually over at least 2 weeks and then stop treatment completely.

4. POSSIBLE SIDE EFFECTS:

MONTASH can have side effects.

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

If any of the following happens, stop taking / using **MONTASH** and 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
- Rash or itching
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to **MONTASH**. You may need urgent medical attention or hospitalisation.

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

- Having suicidal thoughts
- Changes in the way your heart beats, for example, if you notice it beating faster
- Worsening of pulmonary symptoms and/or rash (Churg-Strauss syndrome) (see **Warnings and precautions**)

- Yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Stomach pain, headache and thirst
- Chest infections
- Diarrhoea, nausea and vomiting
- Increase in liver enzymes
- Increase in body temperature.

Less frequent side effects:

- Increased bleeding tendency, low number of platelets in the blood
- Abnormal dreams (including nightmares), sleeplessness, sleepwalking, feeling anxious, agitated (including aggressive behaviour or being hostile), or depressed; mood disorders (including feeling irritable, restless or having seizure), disturbance in attention, loss of memory, sudden uncontrolled body movements, hallucinating (seeing things/objects not there), feeling disoriented, obsessive compulsive disorders, stuttering
- Dizziness, drowsiness, “pins and needles” sensation, loss or decrease in sensation, fits
- Nose bleeds
- Dry mouth, indigestion
- Inflammation of the liver
- Swelling under the skin, bruising, lesions on the skin, bumps under the skin
- Joint pain, muscle pain and muscle cramps
- Bedwetting in children

- Weakness and tiredness, a general feeling of illness, swelling.

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 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.

Report all side effects to Unicorn Pharmaceuticals (Pty) Ltd to enquiries@unicornpharma.co.za

By reporting side effects, you can help provide more information on the safety of **MONTASH**.

5. How to store MONTASH

Store at or below 30 ºC.

Store in the original packaging.

Protect from light and moisture.

Do not take after the expiry date stated on the package.

Return all unused **MONTASH** to your pharmacist.

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

KEEP OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What MONTASH contains

The active substance is montelukast.

Montash 10 Each film-coated tablet contains montelukast sodium equivalent to 10 mg montelukast
Montash 4/5 Chew Each chewable tablet contains montelukast sodium equivalent to 4/5 mg montelukast

The other ingredients are: Aspartame, croscarmellose sodium, iron oxide red (E 172), low-substituted hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose and spray dried mannitol.

MONTASH 4 CHEW & 5: cherry flavour (containing arabic gum E414, flavouring substances, maltodextrin and propylene glycol E1520).

MONTASH 10: banana flavour (containing flavouring substances, maltodextrin, modified starch E1450, propylene glycol E1520) and Opadry yellow 20A33251 (containing hypromellose 3cP, hydroxypropylcellulose, talc, titanium dioxide, iron oxide yellow (E172), iron oxide red (E172)).

What MONTASH looks like and contents of the pack

MONTASH 4 CHEW: Pink, flat round tablets with beveled edges, marked with “4” on one side and plain on the other side.

MONTASH 5 CHEW: Pink, flat round tablets with beveled edges.

MONTASH 10: Beige, round, biconvex, film-coated tablets.

MONTASH 4 CHEW & MONTASH 5 CHEW chewable tablets are packed in Aluminium/Aluminium blisters, which are subsequently packed into cartons.

MONTASH 10 film-coated tablets are packed in Aluminium/Aluminium blisters, which are subsequently packed into cartons.

Pack size:

MONTASH 4 CHEW: 7, 10, 14, 20, 28, 30, 50, 56, 98, 100, 140 and 200 tablets.

MONTASH 5 CHEW: 7, 10, 14, 20, 28, 30, 50, 56, 84, 90, 98, 100, 140 and 200 tablets.

MONTASH 10: 7, 10, 14, 20, 28, 30, 50, 56, 84, 90, 98, 100, 140 and 200 tablets.

Not all pack sizes may be marketed.

Montash 10	Each film-coated tablet contains montelukast sodium equivalent to 10 mg montelukast
Montash 4/5 Chew	Each chewable tablet contains montelukast sodium equivalent to 4/5 mg montelukast

Holder of Certificate of Registration

Unicorn Pharmaceuticals (Pty) Ltd

Corner of Searle and Pontac Streets

Cape Town

8001

Registration number(s)

MONTASH 4 CHEW: 55/10.2.2/0906

MONTASH 5 CHEW: 55/10.2.2/0907

MONTASH 10: 55/10.2.2/0914

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