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What *MONTULAR* is used for

Use to treat:

- Asthma, including preventing your asthma symptoms during the day and night. *MONTULAR* also prevents the narrowing of airways triggered by exercise.
- Allergic rhinitis (seasonal and perennial), including daytime and nighttime symptoms: nasal congestion, runny nose, nasal itching, and sneezing; nasal congestion upon awakening, difficulty going to sleep, and nighttime awakenings; tearing, itchy, red, and puffy eyes.

How *MONTULAR* works

The mechanism of action of Montelukast is based on the blockage of cysteinyl leukotriene (CysLT) receptors. The cysteinyl leukotrienes (LTC₄, LTD₄, LTE₄) are potent inflammatory eicosanoids and have been correlated with the pathophysiology of asthma and allergic rhinitis.

Before you use *MONTULAR*

- When you must not use it

Patients should be advised never to use oral montelukast to treat acute asthma attacks

Montelukast should not be substituted abruptly for inhaled or oral corticosteroids.

Use in pregnancy

Women who are pregnant or intend to become pregnant should consult their doctor before taking *MONTULAR*.

Use in breast-feeding

It is not known if *MONTULAR* appears in breast milk. You should consult your doctor before taking *MONTULAR* if you are breast-feeding or intend to breast-feed.

- Before you start to use it

Your doctor needs to know before you take *MONTULAR*, if you have or have had any of the following conditions:

- allergies you have now or have had
- And if you are taking any medication, such as phenytoin, phenobarbital and rifampicin, as these medicines should not be taken together with *MONTULAR*.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

How to use *MONTULAR*

- How much to use

Take *MONTULAR* once a day with or without food, as your doctor has prescribed.

- The dose for adults and adolescents 15 years and older for the treatment of asthma and/or allergic rhinitis is one 10-mg tablet daily.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking *MONTULAR* for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

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

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause adverse events including included abdominal pain, somnolence, thirst, headache, vomiting, and psychomotor hyperactivity. In the event of over dosage general symptomatic and general supportive measures are indicated as required.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking *MONTULAR*.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not take *MONTULAR* if allergic to any of its components.

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give *MONTULAR* to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

MONTULAR is not expected to affect a patient's ability to drive a car or operate machinery. However, in very rare cases, individuals have reported drowsiness or dizziness.

Side effects

Like all medicines, *MONTULAR* can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

- allergic reactions including rash, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing (uncommon)
- tender red lumps under the skin most commonly on your shins (erythema nodosum), severe skin reactions (erythema multiforme) that may occur without warning (very rare)
- suicidal thoughts and actions (very rare)

Tell your healthcare provider right away if you notice any of the following behavior and mood related changes

- Obsessive compulsive symptoms

The most common side effects that occur when taking *MONTULAR* are listed below. These may go away during treatment as your body adjusts to the medicine. Tell your doctor if any of these side effects continue to bother you.

Very common side effects (occurring in at least 1 in 10 people taking *MONTULAR*):

- Upper respiratory infection

Common side effects (likely to occur in less than 1 in 10 people)

- diarrhoea, nausea, vomiting
- rash
- fever

Uncommon side effects that occur in less than 1 in 100 people taking *MONTULAR* are:

- behaviour and mood related changes [dream abnormalities, including nightmares, trouble sleeping, sleep walking, irritability, feeling anxious, restlessness, agitation including aggressive behaviour or hostility, depression]
- dizziness, drowsiness, pins and needles/numbness, seizure nosebleed
- dry mouth, indigestion
- bruising, itching, hives
- joint or muscle pain, muscle cramps
- weakness/tiredness, feeling unwell, swelling

Rare side effects that occur in less than 1 in 1,000 people taking *MONTULAR* are:

- increased bleeding tendency
- disturbance in attention, memory impairment
- palpitations
- tremor;

Very Rare side effects that occur in less than 1 in 10,000 people taking *MONTULAR* are:

- hallucinations, disorientation
- hepatitis (inflammation of the liver)
- swelling (inflammation) of the lungs

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.moh.gov.my (Public à Reporting Medicinal Problems / Side Effects / AEFI).

Storage and Disposal of *MONTULAR*

- Storage

Store in dry place, temperature below 30°C.

Keep medicine out of reach of children.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Beige colored, round shape, biconvex film coated tablets plain on both sides.

- Ingredients

Active ingredient: Montelukast

Inactive ingredients: Microcrystalline Cellulose (Avicel PH102), croscarmellose sodium, sodium lauryl sulphate, magnesium stearate, purified water and opadry 20A520035 yellow.

- MAL number(s): MAL19016008AZ

Manufacturer

Kusum Healthcare Private Limited

SP-289 (A), RIICO Industrial Area, Chopanki, Bhiwadi, Alwar, (Rajasthan), India

Phone: 91-1493-516560

Fax: 91-1493-516562

Product Registration Holder

Synerrv Sdn Bhd,

SO-29-2, Menara 1, KL Eco City, Jalan Bangsar, KG Haji Abdullah Hukum, 59200 Kuala Lumpur, Wilayah Persekutuan Kuala Lumpur, Malaysia

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