

Montelukast

DESCRIPTION:

The active ingredient in **Motrinex®** tablets is montelukast, which is a leukotriene receptor antagonist.

Inactive Ingredients:

Microcrystalline cellulose, hydroxypropylcellulose, lactose monohydrate, magnesium stearate, croscarmellose sodium, red color (E172), hypromellose, titanium dioxide, macrogol.

PHARMACOLOGY:

Montelukast blocks naturally occurring chemicals in the lungs called leukotrienes which cause narrowing of the airways and inflammation in the lungs, which can lead to asthma symptoms. Leukotrienes also contribute to the symptoms of allergy. Blocking leukotrienes improves seasonal allergy symptoms (also known as seasonal allergic rhinitis or hay fever).

INDICATIONS:

Motrinex® is used for the treatment of patients who are not adequately controlled on their asthma medications and need additional therapy.

Motrinex® also helps prevent asthma symptoms which are triggered by exercise.

For patients 15 years of age and older with asthma and seasonal allergies, **Motrinex®** also treats seasonal allergy symptoms.

CONTRAINDICATIONS:

The patient should not take **Motrinex®** if he is allergic to any of its ingredients.

Motrinex® 10 mg tablets are not recommended for use in children under 15 years of age.

SIDE EFFECTS:

Like all medicines **Motrinex®** can have unintended or undesirable effects, so called side effects, in some patients. In clinical studies with montelukast in children, the most frequently reported side effects thought to be related to treatment with montelukast were abdominal pain and headache.

The following side effects have also been reported in adults and/or children: weakness and tiredness, restlessness, agitation including aggressive behavior, irritability, joint pains, dizziness, dry mouth, indigestion, drowsiness, hallucinations, dream abnormalities including nightmares, inability to sleep, a general feeling of being unwell, pins and needles/numbness, seizure, muscle pains, muscle cramps, diarrhoea, nausea and vomiting, hepatitis, palpitations, increased bleeding tendency, bruising and swelling due to fluid retention. Allergic reactions have also been reported which included swelling of the face, lips, tongue and/or throat which may cause difficulty in breathing or swallowing, itching, rash or hives. It is vital that the patient stops taking **Motrinex®** and that medical attention is sought immediately if he experiences an allergic reaction.

Very rare cases of a condition known as Churg-Strauss syndrome have been reported during montelukast treatment in asthmatic patients. If the patient experiences a combination of any of the following symptoms, particularly if they are persistent or worsening, he should seek medical attention immediately: flu-like illness, increasing breathlessness, pins and needles or numbness of limbs, and/or rash.

Behavior and mood related changes [agitation including aggressive behavior, bad/vivid dreams, depression, feeling anxious, hallucinations (seeing things that are not there), irritability, restlessness, suicidal thoughts and actions (including suicide), tremor, trouble sleeping].

The doctor should be consulted if the patient experiences any of the other above side effects or any other unusual symptoms he does not understand and particularly if they are persistent, troublesome or getting worse.

WARNINGS AND PRECAUTIONS:

- It is important that **Motrinex®** tablets are taken daily in the evening, as prescribed by the doctor, even when the patient has no symptoms, or if he experiences an asthma attack.
- Oral **Motrinex®** is NOT intended for the treatment of a sudden attack of breathlessness. It will not help him in this situation and should never be used for this purpose. If an attack occurs, the instructions that the doctor has given should be followed exactly. It is very important to have the medication needed for such an attack readily accessible at all times.
- If the patient needs to use his beta-agonist inhaler more often than usual, he should consult his doctor as soon as possible.
- It is important that he uses all the asthma medication prescribed by the doctor as intended. **Motrinex®** should not replace steroid medications (whether inhaled or taken by mouth) that he may be already using.
- Patients with aspirin-sensitive asthma taking **Motrinex®** must continue to avoid taking aspirin or other non-steroidal anti-inflammatory drugs.
- A rare condition has been seen in a very small number of patients taking asthma medications, including **Motrinex®** although **Motrinex®** has not been shown to cause it. If the patient experiences a combination of any of the following symptoms, particularly if they are persistent and worsening, he should seek medical attention immediately: flu-like illness,

increasing breathlessness, pins and needles or numbness of limbs, and/or rash.

- This product contains:

Lactose monohydrate: If the patient has been told by the doctor that he has intolerance to some sugars, he should contact his doctor before taking this medicinal product.

Use in pregnancy or breast feeding:

Pregnancy: Women who are pregnant, intend to become pregnant or think they might be pregnant should consult their doctor before taking **Motrinex®**.

Breast feeding: It is not known whether **Motrinex®** is present in human breast milk. The patient should consult her doctor before taking **Motrinex®** if she is breast feeding a baby or intend to breast feed.

Driving and operating machinery:

Motrinex® is not expected to affect the ability to drive a car or operate machinery. However, individual responses to medication may vary. Certain side effects that have been reported very rarely with **Motrinex®** may affect some patients' ability to drive or operate machinery.

DRUG INTERACTIONS:

Motrinex® may be used together with other medicines that he may be taking for asthma. However, it is important to tell his doctor about all other medicines that he is using, including those obtained without a prescription. In particular, he should tell his doctor if he is taking phenytoin, phenobarbitone or rifampicin.

DOSAGE AND ADMINISTRATION:

Motrinex® film coated tablets should be taken once a day by mouth in the evening, with or without food, as instructed by the doctor.

Motrinex® tablets should not be used together with other products that contain the same active ingredient, montelukast.

The usual dose for adults and adolescents aged 15 years upwards is one 10 mg tablet daily.

It is important to continue taking **Motrinex®** in the presence or absence of symptoms, for as long as the doctor prescribes it, in order to help maintain control of the patient's asthma. **Motrinex®** can treat asthma only with continued use.

If a tablet is forgotten or too many are taken:

If the patient forgets to take a tablet, he should just carry on with the next one as usual. He should not take an extra tablet to make up; he should just resume the usual schedule of one tablet, once daily.

If too many tablets are taken by mistake, as with all medicines, a doctor should be contacted immediately.

PRESENTATIONS:

Motrinex® 10 Film Coated Tablets: Packs of 30 tablets. Each tablet contains 10 mg Montelukast (as montelukast sodium).

STORAGE CONDITIONS:

Protect from light. Store in a dry place below 30°C.

This is a medication.

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold you the medication.
- The doctor and the pharmacist are experts in medicine, its benefits and its risks.
- Do not, by yourself, interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.