

# Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs  
and Drug Control

MUSCAT



سلطنة عمان  
وزارة الصحة  
المديرية العامة للصيدلانية  
والرقابة الدوائية  
مسقط

To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES

Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)

Director General of Engineering Affairs, MOH

Director General of Royal Hospital

Director General of Khoula Hospital

Director General of Medical Supplies (MOH)

Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)

Hospital Director (Al Nahda Hospital)

Hospital Director (Al Massara Hospital)

The Head of Medical Services in SQU Hospital

The Head of Medical Services in Royal Oman Police

The Head of Medical Services in Ministry of Defence

The Head of Medical Services in The Diwan

The Head of Medical Services in The Sultan's Special Force

The Head of Medical Services in Internal Security Services

The Head of Medical Services in Petroleum Development of Oman

The Head of Medical Services in LNG Oman

ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No....6.2..... dated 11/03/20.. regarding  
Montelukast.

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- ~~Director of Pharmacovigilance & Drug Information Dept, DGPA&DC~~
- Director of Medical Device Control, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information

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Circular No. 62 / 2020

16 -07-1441 H

11 -03-2020

## **Singular (montelukast) and All Montelukast Generics: Strengthened Boxed Warning - Due to Restricting Use for Allergic Rhinitis**

Please be informed that the US Food & Drug Administration (FDA) is strengthening existing warnings about serious behavior and mood-related changes with montelukast (Singular and generics), which is a prescription medicine for asthma and allergy. Montelukast prescribing information already includes warnings about mental health side effects, including suicidal thoughts or actions; however, many health care professionals and patients/caregivers are not aware of the risk. It is decided that a stronger warning is needed after conducting an extensive review of available information and convening a panel of outside experts, and therefore determined that a Boxed Warning was appropriate.

Montelukast is FDA-approved for asthma and allergies. It is a prescription medicine approved to prevent asthma attacks and for the long-term treatment of asthma in adults and children 1 year and older. It is approved to prevent exercise-induced asthma in patients 6 years and older. Montelukast is also approved to control the symptoms of allergic rhinitis, also known as hay fever, such as sneezing, stuffy nose, runny nose, and itching of the nose. It is used to treat seasonal outdoor allergies in patients 2 years and older, and year-round indoor allergies in patients 6 months and older.

### **RECOMMENDATION:**

Patients should talk to their health care professional about:

- the benefits and risks of montelukast, as many other safe and effective allergy medicines are widely available.
- any history of mental illness before starting treatment.

Health Professionals should:

- Ask patients about any history of psychiatric illness prior to initiating treatment.
- Consider the risks and benefits of montelukast when deciding to prescribe or continue patients on the medicine.
- Advise all patients of the risk of neuropsychiatric events when prescribing montelukast. Warnings about these side effects are included in the existing prescribing information; however, many health care professionals and patients/caregivers are not aware of this risk, and suicides and other adverse events continue to be reported.
- Advise patients and parents/caregivers that the patient should stop taking montelukast and contact a health care professional immediately if changes in behavior or new neuropsychiatric symptoms, suicidal thoughts or behavior occur.

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- Monitor all patients treated with montelukast for neuropsychiatric symptoms. Events have occurred in patients with and without pre-existing psychiatric disease.
- Encourage patients and parents/caregivers to read the Medication Guide they receive with their montelukast prescriptions, which explains the safety risks and provides other important information.

Montelukast is registered in Oman.

Healthcare professionals are encouraged to report any adverse events suspected to be associated with the above product or any other medicinal product to the Department of Pharmacovigilance & Drug Information in DGPA&DC.

  
**Dr. Mohammed Hamdan Al Rubaie**  
**DIRECTOR GENERAL**

