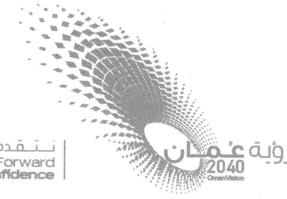


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To:

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. Health Institutions)
Director General of Health Services in all Governorates
Director of Rational Use of Medicine (MOH)
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 Defense
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
The Head of Medical Services in LNG Oman
Director of Pharmacy of Qaboos Comprehensive Cancer Care & Research Center
Director of Pharmacy & Medical Stores in all Governorate (for distribution pls.)
Marketing Authorization Holders & Pharmaceutical Companies
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 153 dated 18/7/23 regarding the (Febuxostat) updated advice for the treatment of patients with a history of major cardiovascular disease.

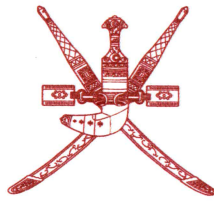
Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Director of Medical Device Control, DGPA&DC
- Section Head PV for Herbal Medicine & Health Products.
- Section Head PV for Human Medicine
- Section Head of Central Drug Information



PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical
Affairs & Drug Control





Circular No:153/2023

30 -12-1444 H
18 -07-2023

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***Febuxostat: updated advice for the treatment of
patients with a history of major cardiovascular disease.***

The DGPA&DC would like to share a safety update issued by the Medicine and Healthcare Products Regulatory Authority (MHRA) as below:

Following a review of the FAST study findings and advice from the Pharmacovigilance Expert Advisory Group of the Commission on Human Medicines, the product information for febuxostat has been updated to include the results. The product information retains the warning for cardiovascular disorders and now advises that treatment of patients with pre-existing major cardiovascular diseases with febuxostat should be exercised cautiously.

In particular, treatment should be exercised cautiously in patients with pre-existing major cardiovascular diseases with evidence of high urate crystal and tophi burden or those initiating urate lowering therapy. Prescribing clinicians should titrate febuxostat appropriately to minimize gout flares following initiation, thus minimizing additional inflammation.

Advice for healthcare professionals:

- In patients with pre-existing major cardiovascular diseases, febuxostat therapy should be used cautiously, particularly in those with evidence of high urate crystal and tophi burden or those initiating urate-lowering therapy.
- Following initiation of febuxostat, prescribers should titrate the febuxostat dose to minimize gout flares and inflammation.
- Note that clinical guidelines for gout recommend that allopurinol should be offered as first-line treatment for people with gout who have major cardiovascular disease.
- Report suspected adverse drug reactions associated with febuxostat.



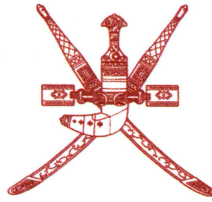
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Directorate General of Pharmaceutical
Affairs & Drug Control



ص ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩

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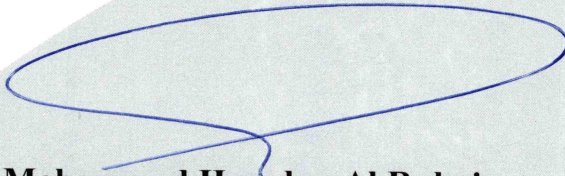
Advice for healthcare professionals to give to patients:

- Febuxostat is used to treat gout by reducing an excess of a chemical called uric acid (urate) in the body, which prevents attacks of gout in the long term; it can also be used to treat and prevent high blood levels of uric acid that may occur when you start to receive chemotherapy for blood cancer.
- There are new recommendations to healthcare professionals about use of febuxostat in patients with previous heart problems.
- If you currently have or have previously had heart failure, heart problems or stroke, it is recommended to talk to your doctor before taking febuxostat.
- No action is needed from patients already on febuxostat, but talk to a healthcare professional if you are concerned.

Call to report

Febuxostat is registered in Oman, healthcare professionals, patients, and caregivers are requested to submit adverse drug reactions reports to the pharmacovigilance department in the DGPA&DC.

Yours faithfully,


Dr. Mohammed Hamdan Al Rubaie
Director General

