

نتقدم بثقة  
Moving Forward  
With Confidence



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 96 dated 21/5/23 regarding Drug Safety Update: Dupilumab & Risk of Ocular Adverse Reactions.

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





## Circular No. **96 / 2023**

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21-05-2023

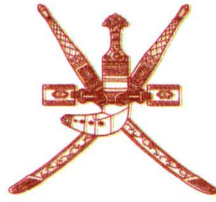
### **Subject: Drug Safety Update: Dupilumab & Risk of Ocular Adverse Reactions.**

The DGPA&DC would like to share a new safety information published in Medicines and Healthcare Products Regulatory Agency website regarding Dupilumab (Dupixent ▼) risk of ocular adverse reactions and need for prompt management. The safety information was as below:

Healthcare professionals prescribing dupilumab should be alert to the risks of ocular reactions. New onset or worsening ocular symptoms require prompt review. Referral for ophthalmological examination should be made as appropriate.

#### **Advice for healthcare professionals:**

- Dupilumab is commonly associated with cases of conjunctivitis and allergic conjunctivitis, eye pruritus, blepharitis, and dry eye and with infrequent cases of keratitis and ulcerative keratitis, especially in patients with atopic dermatitis.
- Be alert to the risks of ocular reactions and promptly review new onset or worsening ocular symptoms, referring patients for ophthalmological examination as appropriate.
- Sudden changes in vision or significant eye pain that does not settle warrant urgent review.
- Discuss with patients or caregivers the potential for, and symptoms of, ocular side effects at initiation of dupilumab, including symptoms of conjunctivitis and dry eye (which can also include paradoxical eye watering), keratitis and ulcerative keratitis.



- Advise patients to promptly report new-onset or worsening eye symptoms to their healthcare professional so that appropriate treatment can be initiated – advise patients not to self-manage ocular symptoms.
- Ensure that patients who develop conjunctivitis or dry eye that does not resolve following initial treatment, or patients with signs and symptoms suggestive of keratitis (especially eye pain and vision changes), undergo ophthalmological examination, as appropriate.

### Advice for healthcare professionals to give to patients or parents and caregivers:

- Dupilumab has been linked to side effects affecting the eye, especially in patients with atopic eczema (atopic dermatitis).
- Most side effects of the eye are mild, but some can become serious if they are not managed properly. Do not attempt to self-manage new or worsening eye problems – seek medical help.
- Talk to your doctor or another healthcare professional promptly if you have any new or worsening eye problems, such as watering, itching, redness, swelling, eye dryness, a feeling of gritty eyes, or a sensation of a foreign body in the eye.
- If you experience significant eye pain that does not settle, or changes in your vision, it is important to speak to your doctor without delay.

### Call to report

Dupilumab is registered in Oman and healthcare professionals, patients, and caregivers are asked to submit reports to the pharmacovigilance department in the DGPA&DC.

**Dr. Mohammed Hamdan Al Rubaie**

**Director General**

