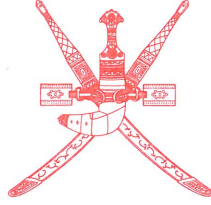


Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT



سِلاطِنَةُ عُومَانِ
وَزَارَةُ الصِّحَّةِ
وَالشَّرِيعَةِ الْعَامَّةِ لِلصِّدْقِ
وَالرَّقَابَةِ الدَّوْلِيَّةِ
مَسْقَط

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 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
Director of Pharmacy & Medical Stores in all Governorate (for distribution pls.)
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No...24..... dated 02/11/2017 regarding
Hyoscine butylbromide Injection.

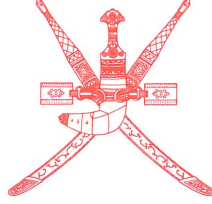
Copy to:

- 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 Instruments and Medical Device Control, DGPA&DC
- Supdt. of Central Drug Information
- Head of Cordn. & FU

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سلطنة عمان
وزارة الصحة
الدراسة العامة للصيد
والرقابة الدوائية
مسقط

Circular No. 24 / 2017

04 - 06 - 1438 H
02 - 04 - 2017

Hyoscine butylbromide Injection: *risk of serious adverse effects in patients with underlying cardiac disease*

The Medicines and Healthcare products Regulatory Agency of the United Kingdom has recently issued a drug safety update for Hyoscine butylbromide Injection stating that the prescribing information has been updated to help to minimise the risk of serious adverse reactions in patients with cardiac disease.

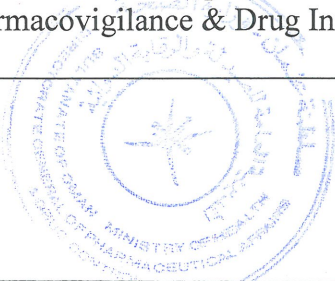
Advice for healthcare professionals:

- hyoscine butylbromide injection can cause serious adverse effects including tachycardia, hypotension, and anaphylaxis
- these adverse effects can result in a fatal outcome in patients with underlying cardiac disease, such as those with heart failure, coronary heart disease, cardiac arrhythmia, or hypertension
- hyoscine butylbromide injection should be used with caution in patients with cardiac disease
- monitor these patients, and ensure that resuscitation equipment, and personnel who are trained how to use this equipment, are readily available
- hyoscine butylbromide injection remains contraindicated in patients with tachycardia

Hyoscine butylbromide, given intravenously or intramuscularly, is indicated in acute muscular spasm, as in renal or biliary colic; in radiology for differential diagnosis of obstruction and to reduce spasm and pain in pyelography; and in other diagnostic procedures where spasm may be a problem (eg, gastroduodenal endoscopy).

Hyoscine butylbromide injection can cause adverse effects including tachycardia, hypotension, and anaphylaxis. These effects can be more serious in patients with underlying cardiac disease (eg. Heart failure, coronary heart disease, cardiac arrhythmia, or hypertension). Several reports have noted that anaphylaxis is more likely to be fatal in patients with underlying coronary heart disease compared with those without.

There are different brands of hyoscine butylbromide registered in Oman, healthcare professionals are kindly requested to report any adverse events, side effects or quality problems associated with the use of the above product or any other medicinal and health product to the Department of Pharmacovigilance & Drug Information in DGPA&DC.



Dr. Mohammed Hamdan Al Rubaie
DIRECTOR GENERAL