**IMPORTANT MEDICINE SAFETY INFORMATION**

**BUSCOPAN 20 mg/1 ml ampoules and BUSCOPAN COMPOSITUM 20 mg/2,5 g injection: RISK OF SERIOUS ADVERSE EFFECTS INCLUDING DEATH IN PATIENTS WITH UNDERLYING CARDIAC DISEASE**

Date: 15 June 2018

Dear Healthcare Professional

Ingelheim Pharmaceuticals (Pty) Ltd and Sanofi-Aventis South Africa (Pty) Ltd in collaboration with SAHPRA wish to inform you of the following safety information update regarding the use of hyoscine butylbromide injection as contained in BUSCOPAN 20 mg/1 ml ampoules and BUSCOPAN COMPOSITUM 20 mg/2,5 g injection.

This safety update is based on 8 global reports of patients who died after receiving hyoscine butylbromide injection. In most of these cases, the fatal adverse reaction was reported as acute myocardial infarction or cardiac arrest.

BUSCOPAN 20 mg/1 ml ampoules and BUSCOPAN COMPOSITUM 20 mg/2,5 g injection can cause adverse effects including tachycardia, hypotension, and anaphylaxis. These effects can be more serious in patients with underlying cardiac disease (e.g. 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.

- BUSCOPAN 20 mg/1 ml ampoules and BUSCOPAN COMPOSITUM 20 mg/2,5 g 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.
- BUSCOPAN 20 mg/1 ml ampoules and BUSCOPAN COMPOSITUM 20 mg/2,5 g 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.
- BUSCOPAN 20 mg/1 ml ampoules and BUSCOPAN COMPOSITUM 20 mg/2,5 g injection remain contraindicated in patients with tachycardia.

The Professional Information will be updated to reflect this information.

Healthcare professionals should report all suspected adverse events associated with the use of hyoscine butylbromide to:

National Adverse Event Monitoring Centre (NADEMC)
Tel.: 021 447 1618
Fax: 021 448 6181

Or

SAHPRA - Pretoria Pharmacovigilance Office
Tel.: 012 395 9133
Fax: 086 620 7253
Email: adr@health.gov.za

Or

Tel.: 011 256 3700
Email: za.drugsafety@sanofi.com

Yours sincerely

**Mrs Ilse Cukrowski**
**Responsible Pharmacist**
**Ingelheim Pharmaceuticals (Pty) Ltd**

**Mr Graeme James**
**Responsible Pharmacist**
**Sanofi-Aventis South Africa (Pty) Ltd**

S3 BUSCOPAN 20 mg/1 ml ampoules. Contains 20 mg hyoscine butylbromide/1 ml ampoule. Ref. No. E 500 (Act 101/1965)

S4 BUSCOPAN COMPOSITUM 20 mg/2,5 g injection. Contains 20 mg hyoscine butylbromide and 2,5 g metamizole sodium monohydrate/5 ml ampoule. Reg. No. E/11.2/504

**References:**


1. MCC PV Unit letter ref. PVC 78 Item 6.2 "HYOSCINE BUTYLBROMIDE INJECTION - RISK OF SERIOUS ADVERSE EFFECTS IN PATIENTS WITH UNDERLYING CARDIAC DISEASE" dated 03 October 2017.
2. MHRA Drug Safety Update published 20 February 2017: https://www.gov.uk/drug-safety-update/hyoscine-butylbromide-buscopan-injection-risk-of-serious-adverse-effects-in-patients-with-underlying-cardiac-disease