



FOR IMMEDIATE RELEASE

HEALTH SCIENCES AUTHORITY
PRESS RELEASE

18 NOVEMBER 2010

HSA ALERTS PUBLIC ON THE RECALL OF “ORAL GUARD ANTISEPTIC-ANTIPLAQUE MOUTHWASH”

The Health Sciences Authority (HSA) is overseeing the voluntary market recall of all batches of ‘Oral Guard Antiseptic-Antiplaque Mouthwash’, imported by Medimex Singapore Pte Ltd and distributed by IDS Pharmaceutical Division.

2 This recall was initiated due to the detection of the bacteria, *Burkholderia cepacia* (*B. cepacia*), in three batches of the mouthwash during a product quality testing conducted by HSA.

Background

3 Samples of “Oral Guard Antiseptic-Antiplaque Mouthwash” were sent for microbial tests as part of HSA’s product quality sampling testing. The microbial test reports revealed the presence of the bacteria, *B. cepacia* in the following batches of the product: 060813, 070813 and 080813. Results of the other batches are still pending. Due to the potential risk of infections associated with *B. cepacia* in susceptible individuals, a voluntary recall by the company to the consumer level of all batches of “Oral Guard Antiseptic-Antiplaque Mouthwash” is being implemented as a precautionary measure.

4 “Oral Guard Antiseptic-Antiplaque Mouthwash” contains chlorhexidine gluconate as the active ingredient and is labelled for use as an antiseptic oral aid for inflammation of the gums, dental plaque, mouth ulcers, sore throat and maintenance of oral hygiene. It is manufactured by Group Pharmaceuticals Ltd, India and distributed to healthcare institutions such as hospitals, specialist institutions, dental clinics and polyclinics and a limited number of retail outlets.

***Burkholderia cepacia* (*B. cepacia*)**

5 *B. cepacia* is a bacterium that can be found in water, soil and other moist environmental sources. *B. cepacia* poses little medical risk to healthy people. However, people who have certain health problems like weakened immune systems or chronic lung diseases may be more susceptible to infections with *B. cepacia*. There have been reported cases of *B. cepacia* contaminated chlorhexidine solution in other parts of the world.

Actions taken

6 In addition to recalling the product from the market, HSA has directed IDS Pharmaceutical Division to publish a print advertisement to notify users of the affected mouthwash to stop using the product and return the product to retailers, pharmacies, clinics or health institutions where the product was bought. The consumer recall is a precautionary measure as the contaminated product may pose a health risk to susceptible members of the public who have weakened immune systems or chronic lung diseases. Healthcare professionals have also been informed by HSA of this issue.

Consumer advisory

7 Consumers should stop the use of “Oral Guard Antiseptic-Antiplaque Mouthwash” and seek medical attention if they feel unwell after using the product.

8 Consumers who have queries related to the return of the product may wish to contact Medimex Singapore at tel: 6779-5579 between 9am-5pm (Monday to Friday) or email: enquiry@medimex.com.sg.

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▪ About the Health Sciences Authority (HSA)

The Health Sciences Authority (HSA) is a multidisciplinary agency that applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services, Applied Sciences, to protect and advance national health and safety. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. It operates the national blood bank, Bloodbank@HSA, securing the nation’s blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit www.hsa.gov.sg.

▪ About HSA’s Health Products Regulation Group

The Health Products Regulation Group (HPRG) of HSA contributes to the development of biomedical sciences in Singapore by administering a robust, scientific and responsive regulatory framework. It ensures that drugs, innovative therapeutics, medical devices and health-related products are wisely regulated and meet appropriate safety, quality and efficacy standards.

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Picture of “Oral Guard Antiseptic-Antiplaque Mouthwash”

