

**SINGAPORE, 24 AUGUST 2011**

## **HSA UPDATES**

***“HSA UPDATES” addresses topics of current public interest, and is subject to change as more information becomes available.***

**HSA UPDATES NO 5/2011**

### **HSA ALERTS PUBLIC ON BAYER’S VOLUNTARY RECALL OF BAYER CONTOUR™ TS 2x25-COUNT, 25-COUNT & 10-COUNT TEST STRIP VIALS**

The Health Sciences Authority (HSA) is overseeing the voluntary market recall of Bayer Contour™ TS 2x25-count, 25-count & 10-count test strip vials by Bayer (South East Asia) Pte Ltd. Please refer to the list of affected product codes and frequently asked questions in Annexes 1 and 2.

2 The affected test strips may give inaccurate results to diabetic patients, showing readings that are lower than their actual blood sugar level. This could lead to patients failing to control and manage their actual blood glucose adequately due to the inaccurate reading.

3 The Contour TS blood monitoring device and Bayer Contour TS 50-count test strip vials (product code 1831) are not affected by this recall.

4 This recall, which is also taking place in other countries, affects the Bayer Contour Test Strips as well. However, only the Bayer Contour TS test strips have been imported and supplied in Singapore by Bayer (South East Asia) Pte Ltd.

5 Based on information provided by the company, the inaccurate readings were related to a packaging issue which, under certain conditions, could cause some test strips packaged in some small-count vials to produce a reading of blood glucose level which is lower than the actual blood glucose level during testing.

6 As all Contour TS 2x25-count, 25-count & 10-count test strip vials are affected by this recall, Bayer (South East Asia) Pte Ltd has made sufficient provision for stocks of 50-count test strip vials to ensure continued, uninterrupted market access to unaffected strips. This recall is expected to be completed within a week.

## Public Advisory

7 HSA advises patients to do the following:

- i. If you have purchased a Bayer Contour TS Glucose Meter, stop using the affected Bayer Contour 2x25-count, 25-count & 10-count test strips as soon as you obtain replacements for those strips with the unaffected Contour TS 50-count test strip vials.
- ii. If you have purchased the strips overseas, check with Bayer (South East Asia) Pte Ltd if the test strips are affected.
- iii. Consult your doctor if you have used these affected test strips and experienced symptoms of high or low blood sugar and feel unwell after treatment upon acting on readings obtained from the affected strips.
- iv. Contact your health care provider to determine other testing options if you are in doubt and especially if you need to adjust your insulin therapy or oral diabetic medications.

8 For return of the affected test strips and other additional information, patients are advised to contact Bayer's appointed distributor, DKSH Singapore Pte Ltd, at Tel: 64157287 (operates Monday to Friday from 8.30am to 5.30pm, excluding public holiday) or Bayer customer care at Tel: 64961974 (operates Monday to Friday from 8.30am-5.30pm and Saturday from 8.30am to 1.00pm, excluding public holiday) or email to [customercare.sin@dksh.com](mailto:customercare.sin@dksh.com)

9 HSA will continue to monitor the situation closely and will take all appropriate actions to protect public health and safety.

## HEALTH SCIENCES AUTHORITY 24 AUGUST 2011

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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](http://www.hsa.gov.sg).

### ▪ About HSA Updates

The "HSA Updates" seeks to provide current information, in a consistent and accurate manner, on topics of public interest. For all issues of HSA Updates, please visit [www.hsa.gov.sg](http://www.hsa.gov.sg), click "News", and select "HSA Updates".

**Media representatives are welcome to send any queries to the Corporate Communications Department @ HSA.**

## HSA ALERTS PUBLIC ON BAYER'S VOLUNTARY RECALL OF BAYER CONTOUR™TS 2x25-COUNT, 25-COUNT & 10-COUNT TEST STRIP VIALS



### Product Codes of Affected test strips

1833 – Bayer Contour TS 2x25-count test strip vials

1832 – Bayer Contour TS 25-count test strip vials

1837 – Bayer Contour TS 10-count test strip vials (has been previously supplied as samples in Bayer test kits)

## **HSA ALERTS PUBLIC ON BAYER'S VOLUNTARY RECALL OF BAYER CONTOUR™TS 2x25-COUNT, 25-COUNT & 10-COUNT TEST STRIP VIALS**

### **Frequently-Asked Questions**

#### **1 What are the products affected in this recall?**

Products being recalled in Singapore include Contour TS 2x25-count, 25-count & 10-count test strip vials by Bayer (South East Asia) Pte Ltd.

Under certain conditions, the packaging material can cause some test strips packaged in some small-count vials to produce a low-bias reading during blood glucose testing. This does not affect the other Bayer test strips such as the 50-count vial.

#### **2 What actions did Bayer take to ensure strip supply?**

To ensure un-interrupted market access in Singapore, the 50-count vials which is unaffected by this issue will be used to replace the affected stocks and to furnish to new orders.

#### **3 How are blood glucose readings affected by this issue?**

Chemical compounds circulating in an individual's blood (maltose, galactose and medications and vitamins, such as paracetamol and vitamin C/ascorbic acid) can affect or interfere with the accuracy of blood glucose readings.

Bayer blood glucose meters and strips work together to correct for interference in testing.

The packaging issue affects the ability of the strips to correct for the interference in testing and thus gives rise to a lower than accurate reading.