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HSA UPDATES

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RECALL OF TWO BATCHES OF ROMESEC 20MG CAPSULES DUE TO QUALITY DEFECT

The Health Sciences Authority (HSA) is overseeing the recall of two batches of Romesec 20mg capsules by Ranbaxy (Malaysia) Sdn. Bhd. This is due to the detection of a faster than expected degradation of the active ingredient, omeprazole, over its 3-year shelf life.

2 The quicker than expected decrease in the amount of omeprazole may make the medicine less effective for the medical conditions being treated. Romesec 20mg is used to treat gastrointestinal conditions where there is too much gastric juice produced, including indigestion, acid reflux, stomach ulcers and *Helicobacter pylori* infections¹.

3 The two affected batches are listed in Table A. They have been distributed to 26 private clinics and the Mustafa retail pharmacy from October 2018 to June 2019, as listed in **Annex A**. Public healthcare institutions are not affected.

Table A: List of recalled batches of Romesec 20mg capsule

Batch Number	Expiry
3963179	30 April 2021
19010069	31 July 2021

¹ *Helicobacter pylori* is a bacterium that can infect the stomach. The bacteria have been associated with the formation of stomach ulcers. Treatment of *Helicobacter pylori* may involve a combination of medicines including omeprazole with antibiotics.

Please refer to **Annex B** for pictures of the medicine, its packaging and where to find the batch number and expiry date.

Background

4 To ensure that local medicines adhere to HSA's regulatory requirements for safety, quality and efficacy, manufacturers are required to conduct regular quality tests on their medicines. The quality defect in the two batches of Romesec Capsule 20mg was detected during a recent routine testing by Ranbaxy (Malaysia). The amount of omeprazole in the affected batches of Romesec was found to be below 20mg, at least 20% lower than what it should have been. Investigations found that the likely cause was improper sealing of the capsule, which resulted in moisture within the capsule that degraded the omeprazole.

5 HSA is working with the company to implement the necessary measures to address the issue.

Consumer advisory

6 The recall is conducted as a precautionary measure as both batches of Romesec 20mg capsules may be less effective for the conditions being treated due to the decrease in active ingredient.

7 Patients taking the affected batches of Romesec 20mg capsules are advised to:

- a. Continue taking your medicines until you have consulted your healthcare professional. For medical conditions such as stomach ulcer and *Helicobacter pylori* infection, untreated stomach conditions may lead to a worsening of the medical conditions;
- b. Return to the clinic or pharmacy where you obtained your medicine, at your earliest convenience. Discuss your treatment options with your doctor or pharmacist. Depending on your medical condition and whether further treatment is required, your doctor or pharmacist may

provide you with a different brand of omeprazole, or an alternative medicine.

For further enquiries, members of the public may wish to contact Ranbaxy (Malaysia) at 6694 0750 from 9am to 5pm (Monday – Friday).

**HEALTH SCIENCES AUTHORITY
SINGAPORE
15 AUGUST 2019**

▪ **About the Health Sciences Authority (HSA)**

The Health Sciences Authority (HSA) applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services and Applied Sciences, to protect and advance national health and safety. HSA is a multidisciplinary authority. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. As the national blood service, it is responsible for providing a safe and adequate blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit <http://www.hsa.gov.sg/>.

For more updates on public health and safety matters, follow us on Twitter at www.twitter.com/HSAsg.

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

ANNEX A**Distributed locations of two affected batches**

No.	Name of clinics
1	BARRIE TAN ENT HEAD & NECK SURGERY
2	EDGEDALE MEDICAL AND AESTHETICS
3	FAITH MEDICAL CLINIC & SURGERY
4	GOODHEALTH MEDICAL CENTRE
5	K P TAN MEDICAL CLINIC
6	KHOO CLINIC & SURGERY
7	MAVEN MEDICAL PTE LTD
8	MHC FAMILY CLINIC (ANG MO KIO)
9	NEIGHBOURHOOD CLINIC
10	NEIGHBOURHOOD MEDICAL CLINIC P/L
11	ONEDOCTORS (AMK) PTE LTD
12	PRIMECARE MEDICAL CLINIC
13	PROHEALTH 24 HRS MEDI CLINIC
14	PSALMS FAMILY CLINIC PTE LTD
15	SINGAPORE PAIN CLINIC PTE LTD
16	SUNSHINE CLINIC FAMILY PRACTICE &
17	TAYKA MEDICAL PTE LTD
18	TH CHIA MEDICAL PRACTICE PTE LTD
19	THE RESPIRATORY PRACTICE PTE LTD
20	TOA PAYOH NORTH CLINIC & SURGERY
21	TRUE CARE MEDICAL PTE LTD
22	W M WONG CARDIAC & MEDICAL CLINIC PL
23	Y S LAU CARDIOLOGY CLINIC PTE LTD
24	MEDICARE ASSOCIATES PTE LTD
25	HEALTHBRIDGE FAMILY CLINIC
26	DOCTORS INC MEDICAL GROUP PTE LTD
27	MUSTAFA RETAIL PHARMACY

Romesec 20mg capsules

