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HSA UPDATES

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COMPANY STOPS SUPPLY OF ONE BATCH OF IKERVIS® (CICLOSPORIN) 1MG/ML EYE DROP EMULSION (BATCH NO. 6J11H) DUE TO DEFECT

Santen Pharmaceutical Asia Pte Ltd is stopping the sale and supply of one batch of single-dose “IKERVIS® 1mg/ml Eye Drop Emulsion” at clinics, hospitals and pharmacies. This is a precautionary measure as a small number of the eye drops from the affected batch may contain a lower amount of the active ingredient, ciclosporin, than is labelled on the products. This may result in the eye drops being less effective but there is no safety issue.

2 Ikervis is used to reduce eye inflammation in patients with severe dry eyes. It is supplied in single-dose plastic containers containing 0.3ml of the medicine. The affected batch (batch number: 6J11H) has been distributed to some public healthcare institutions, private hospitals, private clinics and retail pharmacies.

Product name	Active ingredient/strength	Batch no.	Local supplier
IKERVIS® Eye Drop Emulsion	Cyclosporine 1mg/ml	6J11H	Santen Pharmaceutical Asia Pte Ltd

Background

3 Santen Pharmaceutical Asia Pte Ltd has received feedback from three patients that the solution in some of the single-dose containers was found to be clear or

colourless when it should have been a milky white emulsion. The company investigated the matter and found that the containers with clear or colourless solutions have a lower amount of the active ingredient. The defect was due to a manufacturing issue, which is being rectified by the company.

4 Patients who use the affected single-use containers may find that they get lesser relief of their symptoms associated with severe dry eye syndrome, such as visual disturbances, irritation, watering and redness. Patients who have concerns on their treatment can speak to their doctor. The company is not recalling the product from patients.

5 Santen Pharmaceutical Asia Pte Ltd is working with the Health Sciences Authority to implement the necessary measures to rectify the manufacturing issue.

**HEALTH SCIENCES AUTHORITY
SINGAPORE
30 SEPTEMBER 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/>.

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