衞生署藥物辦公室
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DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG REGISTRATION AND
IMPORT/EXPORT CONTROL DIVISION
3/F., Public Health Laboratory Centre,
382 Nam Cheong Street, Kowloon, Hong Kong

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(來函請敍明此檔案號碼)
(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dear Healthcare Professionals,

Brimonidine gel (Mirvaso▼): risk of exacerbation of rosacea

Your attention is drawn to the Medicines and Healthcare products Regulatory Agency's (MHRA) announcement regarding risk of exacerbation or rebound symptoms of rosacea associated with the use of Brimonidine gel (Mirvaso▼). It is important to initiate treatment with a small amount of gel and increase the dose gradually, based on tolerability and treatment response.

Brimonidine (Mirvaso▼) is a topical gel indicated for the symptomatic treatment of facial erythema of rosacea in adults. Symptom exacerbation has been reported very commonly in patients treated with brimonidine gel, including cases of a rebound effect after the therapeutic effect wears off (approximately 8–12 hours after application) and cases in which exacerbation of symptoms (particularly erythema and flushing) occurred during treatment soon after it was applied.

Across all clinical studies, 16% of patients who were receiving brimonidine gel had symptom exacerbation. Most patients recovered on stopping treatment. The potential mechanism is currently unknown.

Following an EU-wide review, prescribing advice has been updated in the UK. Patients should start treatment with a small amount of gel (less than the maximum dose) for at least 1 week and increase the dose gradually, based on tolerability and response to treatment. This will help enable patients to find the best balance between therapeutic and adverse effects.

The MHRA advised healthcare professionals of the following:

- exacerbation of rosacea symptoms occurred in up to 16% of patients treated with brimonidine gel in clinical studies; in most cases, erythema and flushing resolve after stopping treatment
- initiate treatment with a small amount of gel (less than the maximum dose) for at least 1 week and increase the dose gradually, based on tolerability and response to treatment
- advise patients carefully on how to apply the gel and on the importance of not exceeding the maximum daily dose (which is 1 g of gel in total weight, approximately 5 pea-sized amounts)
- advise patients to stop treatment and consult a doctor if their symptoms worsen during treatment (increased redness or burning)

Please refer to the following website in MHRA for details:

https://www.gov.uk/drug-safety-update/brimonidine-gel-mirvaso-risk-of-exacerbation-of-rosacea

In Hong Kong, Mirvaso Gel 0.33% (HK-63413) containing brimonidine (as tartrate) is a pharmaceutical product registered by Galderma Hong Kong Limited (Galderma), and is a prescription only medicine. So far, the Department of Health (DH) has not received any adverse drug reaction report related to brimonidine. Galderma has updated the package insert of the product to include erythema and flushing as special warnings with precaution for use. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Pharmacovigilance Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR Reporting": http://www.drugoffice.gov.hk/adr.html. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,

(Joseph LEE)
for Assistant Director (Drug)