Australia: Imported unregistered methylene blue products

The Therapeutic Goods Administration (TGA) is issuing a safety advisory about the increasing importation and use of unregistered oral methylene blue (methylthioninium chloride) products in Australia.

These products are being promoted for unapproved (off-label) uses, such as cognitive enhancement, mood improvement, and anti-ageing effects. They have not been assessed by us for quality, safety or efficacy as required under Australian legislation.

Although methylene blue products are only prescription-only when presented for injection, they are not without significant risks when used orally.

TGA advise consumers to exercise extreme caution when purchasing medicines from unknown overseas websites.

Products purchased over the internet may be fake, may contain incorrect or undisclosed and harmful ingredients and may not meet the same standards of quality, safety and efficacy as those approved by the TGA for supply in Australia.

Most methylene blue products imported from online stores do not include clear instructions or warnings.

Key safety concerns:

- Risk of dangerous drug interactions
    - Medicines that affect serotonin levels such as some painkillers and selective serotonin reuptake inhibitors (SSRIs), a common type of antidepressant, can cause serotonin syndrome when taken with methylene blue.
    - Serotonin syndrome is a potentially life-threatening. Symptoms can include muscle spasms, sweating, tremor, confusion, and agitation.
- Risk during pregnancy
    - Methylene blue should not be used during pregnancy. It has been associated with birth defects in both humans and animals.
- Risk of blood disorders
    - People with Glucose-6-Phosphate Dehydrogenase (G6PD) deficiency (a genetic condition) may experience red blood cell damage (haemolysis) if they take methylene blue.

TGA advises consumers:

- Do not use oral methylene blue products unless advised or prescribed by a healthcare professional.
- Be aware of serious risks, including serotonin syndrome, birth defects, and haemolysis.
- Always consult your healthcare provider before using any imported or unregistered medicine.
- If you suspect you have had a side effect (also known as an adverse event) to this or a similar

medicine, report it to the TGA.

- If you are considering purchasing medicines from overseas, watch this short video - external site on the risks associated with buying medicines and medical devices online.
- If you have any concerns arising from your use of these or similar products, seek advice from your treating medical practitioner.

For your safety, always buy medicines from reputable sources and consult your healthcare provider or local registered pharmacy if you have any questions.

Health professionals also play a key role in identifying and managing the risks associated with unregistered methylene products. These include the potential for serotonin syndrome, risks during pregnancy and risks in patients with G6PD deficiency; patients should be advised accordingly.

Health professionals are encouraged to report adverse events involving medicines, including unapproved medicines. These reports assist the TGA in identifying previously unknown side effects and other safety issues.

Please refer to the following website in TGA for details: http://www.tga.gov.au/safety/safety-alerts/imported-unregistered-methylene-blue-products

In Hong Kong, there is one registered pharmaceutical products containing methylene blue (methylthioninium chloride), Methylene Blue Inj. 10mg/ml (HK-59020). This product is a prescription-only medicine. The DH will remain vigilant and continue to monitor the safety of the products concerned.

Ends/ Saturday, September 27, 2025
Issued at HKT 12:00