

HSA ALERT: NINE CONSUMERS HOSPITALISED FOR SERIOUS SKIN REACTIONS IN THE PAST YEAR AFTER USING MODAFINIL AND ARMODAFINIL

The Health Sciences Authority (HSA) is alerting members of the public not to obtain or consume products containing modafinil or armodafinil on their own. From February 2024 to February 2025, nine consumers suffered serious skin reactions after taking modafinil or armodafinil and were hospitalised. These cases follow an earlier warning by HSA in November 2023¹, when three consumers were hospitalised for serious adverse reactions after using these medicines inappropriately.

All nine consumers, seven males and two females, had obtained modafinil and armodafinil from street peddlers in Geylang or from their friends, and consumed them without a doctor's prescription and medical supervision. They were aged between 18 and 57 years old. Some of them shared that they had taken these products to improve alertness or boost energy. One had taken them as "supplements to boost energy and health".

3 Six of them developed Stevens-Johnson syndrome (SJS)², a life-threatening skin condition characterised by blistering and severe peeling of the skin and mucous membranes. For example, a male consumer in his 40s developed painful blistering rashes and peeling of the skin, and also had severe oral ulcers that left him unable to eat and speak for a few days.

¹ <u>https://www.hsa.gov.sg/announcements/press-release/hsa-alert-modafinil_armodafinil</u>

² Steven-Johnsons syndrome (SJS) is a medical condition whereby the skin blisters and sheds, forming painful raw areas which affects the mucous membranes such as the mouth and genitals.

Three others suffered toxic epidermal necrolysis (TEN)³, a more severe form of SJS. They had serious skin reactions and developed painful blistering rashes and peeling of skin that spread across the entire body. One of them, a male consumer in his 20s, experienced life-threatening blistering of his skin covering 60% of his body, including his face, chest, arms, genitals, legs and the soles of his feet. Most of the consumers are recovering and there were no mortalities.

Risks of modafinil and armodafinil medicines

5 Modafinil and armodafinil are potent medicines that are not registered in Singapore but are available in some countries as prescription medicines for patients with specific medical conditions, such as narcolepsy (a condition that impairs the ability to sleep or stay awake), and have to be prescribed by doctors and used under strict medical supervision. This is important because modafinil and armodafinil can cause lifethreatening serious skin reactions, such as SJS and TEN, other serious adverse effects such as heart problems, hypertension, and psychiatric conditions such as anxiety, hallucinations or mania. Additionally, modafinil and armodafinil carry a potential risk of dependency due to their stimulant effects on the brain.

6 Associate Professor Lee Haur Yueh, Senior Consultant, Department of Dermatology, Singapore General Hospital, who treated some of the hospitalised consumers, advised, "Although SJS and TEN are rare, they are life-threatening and can lead to widespread skin damage and in severe cases, organ failure. The fact that we are seeing a significant number of cases from armodafinil and modafinil suggests that the risk associated with these medicines is particularly high. These medicines should only be taken when prescribed by a doctor and with proper medical supervision to ensure patient safety."

Advisory to consumers

7 Consumers are strongly reminded on the following:

³ Toxic epidermal necrolysis (TEN) is a more severe skin reaction where more than 30% of the skin is affected. The eyes may also be severely affected in both conditions.

- Modafinil and armodafinil are potent medicines which should be prescribed by a doctor and used under medical supervision. Inappropriate use of these products to stay alert or improve focus can be harmful.
- Demand may continue to drive supply even though HSA actively clamps down on the illegal sale and supply of modafinil and armodafinil. Protect your health and do not obtain, purchase or use modafinil and armodafinil from any illegal, unknown, unregistered or unreliable sources, as they could be harmful to you.
- Do not share or supply potent prescription medicines to your friends or relatives, even if their medical conditions may appear similar to yours. The medicines may not be suitable or safe for them, and their medical condition may need to be assessed first and managed by a doctor. You may be harming them instead of helping them.
- Seek appropriate medical advice if you have medical conditions e.g., excessive sleepiness that affects your level of alertness or ability to focus. Your doctor will be able to assess whether you require the use of particular medicines to help improve your level of alertness.

Advisory to sellers and suppliers

8 The supply and sale of modafinil and armodafinil without HSA's authorisation is an offence under the Health Products Act. If convicted, the person can face a fine up to \$50,000 or jail term up to 2 years or both.

9 Members of the public who have any information on the illegal sale and supply of modafinil or armodafinil may contact HSA's Enforcement Branch at Tel: 6866-3485 during office hours (Monday to Friday) or email: <u>hsa_is@hsa.gov.sg</u>.

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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 at <u>www.twitter.com/HSAsg</u>.

About HSA's Health Products Regulation Group

The Health Products Regulation Group (HPRG) of HSA ensures that medicines, innovative therapeutics, medical devices and health-related products are wisely regulated and meet appropriate safety, quality and efficacy standards. It contributes to the development of biomedical sciences in Singapore by administering a robust, scientific and responsive regulatory framework.

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Stock photos of toxic epidermal necrolysis adverse reaction (Credit: National Skin Centre)



