



## **HSA ALERT: THREE CONSUMERS HOSPITALISED FOR SERIOUS ADVERSE REACTIONS AFTER INAPPROPRIATE USE OF MODAFINIL AND ARMODAFINIL TO IMPROVE ALERTNESS**

The Health Sciences Authority (HSA) is alerting members of the public not to obtain or consume products containing modafinil or armodafinil that are not prescribed by a doctor or used under close medical supervision. Three persons were hospitalised for serious adverse reactions after consuming modafinil or armodafinil obtained from friends or street peddlers.

### **Serious skin reactions and multiple mouth ulcers after consuming potent medicines**

2 A man in his 30s developed Stevens-Johnson syndrome (SJS), a life-threatening skin condition with blistering and severe peeling of the skin, after taking modafinil, and was hospitalised. He had obtained the product from his friend and only took it once to improve alertness. Over the next few days, he started to feel unwell with fever, multiple mouth ulcers and conjunctivitis (red eyes), accompanied with a severe rash which started on the neck and subsequently spread to other parts of the body.

3 Two men in their 30s developed serious adverse reactions after consuming armodafinil. One of them had obtained armodafinil from a friend to stay awake during the day. After taking it a few times, he developed multiple mouth ulcers, inflammation of the mouth, experienced pain when swallowing and was unable to eat or talk. He also developed conjunctivitis and was subsequently hospitalised.

4 The other man who took armodafinil developed SJS and was hospitalised. He had obtained it from an illegal peddler in Geylang and had taken it for over a month to stay alert while working. He had severe skin reaction that started with fever and rash,

and progressed to skin blistering and multiple mouth ulcers. The severe painful rashes subsequently spread to the whole body. Please refer to **Annex A** for the photo of the product that was purchased from the illegal peddler.

### **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. If there is a clinical need, doctors can apply to HSA to bring in modafinil or armodafinil for their patients' medical conditions, such as narcolepsy, and patients would have to be under strict medical supervision.

6 Modafinil and armodafinil can cause serious side effects such as heart problems, hypertension, and psychiatric conditions including anxiety, hallucinations or mania. Serious skin reactions including SJS and toxic epidermal necrolysis (TEN)<sup>1</sup> have also been reported, and can lead to hospitalisation, serious complications or even death. Those who recover may suffer from long-term complications including skin scarring, hair loss and visual impairment such as increased sensitivity to light (photophobia) and blindness. Other vital organs including the lungs may also be permanently affected. Modafinil and armodafinil also carry a potential risk of dependency due to their stimulant effects on the brain.

7 There have been reports of individuals taking modafinil or armodafinil for the purpose of improving alertness or as 'cognitive enhancers' to improve focus and memory. Self-medication with modafinil or armodafinil for these purposes is not appropriate and can be harmful.

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<sup>1</sup> 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. 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.

## **Advisory to consumers**

8 Consumers are advised on the following:

- Modafinil and armodafinil are potent medicines that should be prescribed by a doctor and used under medical supervision. Inappropriate use of modafinil or armodafinil by individuals to stay alert or improve focus can be harmful.
- Be cautious when obtaining or purchasing health products from unfamiliar sources, even if they are recommended by friends or relatives. You cannot be certain what these products contain, and where and how they were made.
- 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 managed by a doctor. You may be harming them instead of helping them.

## **Advisory to sellers and suppliers**

9 Unless authorised by HSA for use in special circumstances by a doctor for patients under his/her care, the supply and sale of an unregistered health product such as modafinil or armodafinil 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.

10 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: [hsa\\_is@hsa.gov.sg](mailto:hsa_is@hsa.gov.sg).

**HEALTH SCIENCES AUTHORITY**

**SINGAPORE**

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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 on Twitter at [www.twitter.com/HSAsg](http://www.twitter.com/HSAsg).

### **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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Photo of the product that was purchased from an illegal peddler

