



FOR IMMEDIATE RELEASE

**HEALTH SCIENCES AUTHORITY
PRESS RELEASE
6 FEBRUARY 2018**

HSA ALERT: WOMAN HOSPITALISED FOR SERIOUS SKIN REACTIONS AFTER TAKING MODAFINIL TO IMPROVE ALERTNESS

The Health Sciences Authority (HSA) is alerting members of the public not to consume modafinil, a potent prescription medicine that is not registered locally without appropriate medical supervision.

ADVERSE EVENT REPORTED TO HSA

2 A woman in her 30s developed Stevens-Johnson syndrome (SJS), a life-threatening skin condition with blistering and severe peeling of the skin after taking modafinil. She obtained the product from her friend and was taking it on alternate days for more than three weeks to increase alertness for her long hours of work. She first developed an itchy rash which subsequently spread to the whole body. This was followed by severe peeling of the skin, accompanied with painful throat, multiple mouth ulcers and conjunctivitis (red eyes). She was admitted to a hospital for her condition. Please refer to **Annex A** for the picture of the product.

BACKGROUND ON MODAFINIL

3 Modafinil is available in some countries as a prescription drug that reduces excessive sleepiness associated with specific medical conditions such as narcolepsy. These patients experience excessive daytime sleepiness and a tendency to fall asleep suddenly in inappropriate situations.

4 There have been reports of students and adults taking modafinil for the purpose of improving alertness or as 'cognitive enhancers' (to improve focus and memory). Self-medication with modafinil for these purposes is not appropriate and can be harmful. Due to the stimulant effects it has on the brain, modafinil carries a potential risk of dependency. It can also cause serious side effects such as heart problems, hypertension, and psychiatric conditions such as anxiety, hallucinations or mania. Serious skin reactions including SJS and toxic epidermal necrolysis (TEN)¹ have also been reported with the use of modafinil, and they can lead to hospitalisation, serious complications or even death. Those who recover may suffer from long-term side

¹ 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.

effects such as skin scarring and visual impairment including blindness. Other vital organs including the lungs may also be permanently affected.

ADVISORY TO CONSUMERS

5 Consumers are advised:

- Modafinil is a potent medicine and is not registered in Singapore. Inappropriate use of modafinil by healthy individuals, such as to stay alert or improve focus, can be harmful.
- Be cautious when obtaining or purchasing health products from unfamiliar sources including online, even if they are recommended by friends or relatives. You cannot be certain what these products contain, and where and how they were made or their safety profile.
- Do not share or supply potent western medicines to your friends or relatives, even if their medical condition may seem similar to yours. The medicine 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.

ADVISORY TO SELLERS AND SUPPLIERS

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

7 Members of the public who have any information on the sale and supply of modafinil from unauthorised sources may contact HSA's Enforcement Branch at Tel: 6866-3485 during office hours (Monday to Friday) or email: hsa_is@hsa.gov.sg.

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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.

About HSA's Health Products Regulation Group

The Health Products Regulation Group (HPRG) of HSA ensures that drugs, 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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*As provided by patient. The name of the product appears to be "Modalert 200".