



Dirección Nacional de Medicamentos

República de El Salvador, América Central



UNIDAD DE INSPECCIÓN Y FISCALIZACIÓN

COMUNICACIÓN DE ALERTA

Santa Tecla, 06 de Julio de 2016

LA DIRECCIÓN NACIONAL DE MEDICAMENTOS (DNM) ALERTA SOBRE *PRODUCTO: KING-WOLF TABLETS*

Nivel de alerta: 1

Nombre del producto: King-Wolf Tablets

Presentación/Forma Farmacéutica: Tabletas

Número de registro sanitario: No posee

Laboratorio Fabricante: No se detalla

Lote(s): No se detalla

Fecha de vencimiento: No se detalla

Entidad emisora de la Alerta: Administración de Productos Terapéuticos (TGA por sus siglas en inglés)

País de Origen: Australia

Fecha de emisión de la Alerta: 27 de Junio de 2016

Descripción del problema encontrado: No se encontró registro sanitario alguno ni importaciones del producto, de acuerdo a la investigación realizada por la DNM.

La DNM alerta a toda la población a abstenerse de adquirir y/o suministrar éste producto, en virtud de que su uso representa un riesgo para la salud de la persona que lo consuma. En razón de que el producto King-Wolf Tablets NO cumple con los requerimientos de calidad que avale su seguridad, calidad y eficacia.

La DNM recomienda no adquirir este tipo de producto ya que pueden generar un riesgo a la salud. Así mismo recuerda adquirir los medicamentos en lugares autorizados por la DNM. Cualquier duda puede recurrir a ésta Dirección llamando al teléfono gratuito 136.

Se informa que la DNM continuará las acciones de vigilancia, como el aseguramiento de productos, para evitar la venta de los mismos porque representan un riesgo a la población.

Medicamentos a tu alcance



ANEXOS

The screenshot shows the TGA website's 'Safety information' section for 'King-Wolf tablets'. The page includes a navigation menu, a search bar, and a sidebar with categories like 'Reporting problems & complaints', 'Alerts', 'Recalls', and 'Early warning system'. The main content area features a 'Safety advisory' dated 27 June 2016, stating that King-Wolf tablets pose a serious risk due to undeclared sildenafil. It includes an image of the product packaging and a yellow pill. Below the advisory, there are sections for 'Information for consumers' and 'Action the TGA is taking', both providing instructions on what to do if consumers find these tablets. A 'Report counterfeit medicines and medical devices' section is also present, with contact information for the TGA.

Safety information

- Reporting problems & complaints
- Alerts
 - Current year alerts
 - All alerts
- Recalls
- Early warning system
- Safety information & education

King-Wolf tablets

Safety advisory

27 June 2016

King-Wolf tablets pose a serious risk to your health and should not be taken.

The Therapeutic Goods Administration (TGA) has tested product labelled King-Wolf tablets and found that:

- the capsules contain the undeclared substance sildenafil

Consumers are advised that sildenafil is a prescription-only substance in Australia.

The supply of King-Wolf tablets containing undisclosed sildenafil is illegal.

King-Wolf tablets have not been assessed by the TGA for quality, safety or efficacy as required under Australian legislation, and the place of manufacture is not approved by the TGA.

Information for consumers

- Stop taking King-Wolf tablets and take any remaining tablets to your local pharmacy for safe disposal¹.
- If you have any concerns arising from your use of this product, consult your health care practitioner.

Action the TGA is taking

The TGA is working with the Australian Border Force (ABF) to help stop future shipments of King-Wolf tablets from entering Australia.

If these tablets are found at the border by the ABF they will be seized and destroyed.

The TGA is advising consumers to exercise extreme caution when purchasing medicines from unknown overseas Internet sites. Products purchased over the Internet:

- may contain undisclosed and potentially harmful ingredients
- may not meet the same standards of quality, safety and efficacy as those approved by the TGA for supply in Australia.

Report counterfeit medicines and medical devices

If you are worried about counterfeit medicines or medical devices, and want to report an issue, you can report the matter to the TGA:

Phone:	1800 020 653
Online:	Report a perceived breach of the Therapeutic Goods Act or questionable practices relating to therapeutic products
Email:	info@tga.gov.au ²

Category: Alert/Advisory, Medicines safety
Tags: buying online, unapproved therapeutic goods
URL: <https://www.tga.gov.au/frontend/718216>

<https://www.tga.gov.au/alert/king-wolf-tablets>

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