



Dirección Nacional de Medicamentos

República de El Salvador, América Central



UNIDAD DE INSPECCIÓN Y FISCALIZACIÓN

COMUNICACIÓN DE ALERTA

Santa Tecla, 26 de Julio de 2016

LA DIRECCIÓN NACIONAL DE MEDICAMENTOS (DNM) ALERTA SOBRE *PRODUCTO: WONDERBLUE Y B-HARD ON DEMAND*

Nivel de alerta: 1
Nombre del producto: Wonderblue y B-Hard on Demand
Presentación/Forma Farmacéutica: No se detalla
Número de registro sanitario: No posee
Laboratorio Fabricante: No se detalla
Lotes: No se detalla
Fecha de vencimiento: No se detalla
Entidad emisora de la Alerta: Health Canadá
País de Origen: Canadá
Fecha de emisión de la Alerta: 23 de Julio de 2016

Descripción del problema encontrado: Se han encontrado dos productos no autorizados, siendo promocionados como productos naturales para el realce sexual, los cuales contienen activos de prescripción que no fueron declaradas y otras sustancias que pueden plantear serios riesgos para la salud. De acuerdo a la investigación realizada por la DNM No se encontró registro sanitario alguno ni importaciones de los productos.

La DNM alerta a toda la población a abstenerse de adquirir y/o suministrar éstos producto, en virtud de que su uso representa un riesgo para la salud de la persona que lo consuma. En razón de que los productos Wonderblue y B-Hard on Demand NO cumplen con los requerimientos de calidad que avale su seguridad, calidad y eficacia.

La DNM recomienda no adquirir este tipo de producto ya que puede 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

Blv. Merliot y Av. Jayaque, Edif. DNM, Urb. Jardines del Volcán, Santa Tecla, La Libertad, El Salvador, América Central
PBX: (503) 2522-5000 / e-mail: info@medicamentos.gob.sv



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ANEXOS

Recalls and safety alerts

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Two unauthorized products "B-Hard on Demand" and "Wonderblue" seized at Désirs et Plaisirs in St-Jérôme, QC may pose serious health risks

Starting date: July 23, 2016
Posting date: July 23, 2016
Type of communication: Advisory
Subcategory: Natural health products
Source of recall: Health Canada
Issue: Unauthorized products
Audience: General Public
Identification number: RA-59546

[Report a Concern](#)

• Issue • Public enquiries • Who is affected • Report health or safety concerns • Media enquiries • Images

Issue

Health Canada has seized two unauthorized products being promoted as natural health products for sexual enhancement from Désirs et Plaisirs in St-Jérôme, Quebec. These products were found to contain undeclared prescription drug substances and other drug substances that may pose serious risks to the health of Canadians.

Photo	Product	Ingredient
	B-Hard on Demand	Undeclared sildenafil as well as thiodimethylsildenafil and/or thiomethisosildenafil
	Wonderblue	Undeclared sildenafil as well as thiodimethylsildenafil and/or thiomethisosildenafil

Who is affected

Consumers who have bought or used any of the affected products.

What consumers should do

- Consult with your health care practitioner if you have used this product and have health concerns.
- Read product labels to verify that health products have been authorized for sale by Health Canada. Authorized products have an eight-digit DIN, DIN-HM or NPN.
- Verify if products have been authorized for sale by searching the [Drug Product Database](#) and the [Licensed Natural Health Product Database](#).
- Report any adverse events to [Health Canada](#).
- Report complaints about health products to Health Canada by calling toll-free 1-800-267-9675, or by completing an [online complaint form](#).

Background

Thiodimethylsildenafil and thiomethisosildenafil are unauthorized substances similar to sildenafil.

Products containing sildenafil should only be used under the supervision of a healthcare practitioner. Sildenafil should never be used by individuals taking any kind of nitrate drug (e.g. nitroglycerine) as it can cause potentially life-threatening low blood pressure. Individuals with heart problems, including high blood pressure, a history of heart attack, stroke, abnormal heart beat or chest pain, are at higher risk of cardiovascular side effects. Other possible side effects of using sildenafil include headache, facial flushing, indigestion, dizziness, abnormal vision and hearing loss.

Report health or safety concerns

- Call toll-free at 1-866-234-2345
- Visit MedEffect Canada's web page on [Adverse Reaction Reporting](#) for information on how to report online, by mail or by fax.

Stay connected with Health Canada and receive the latest advisories and product recalls using [social media](#) tools.

What Health Canada is doing

Health Canada has seized these products from the retail location. Should additional retailers or distributors of these products be identified, Health Canada will take appropriate action and inform Canadians.

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Media enquiries

Health Canada
(613) 957-2983

Public enquiries

(613) 957-2991
1-866 225-0709

Images

Select thumbnail to enlarge

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