



FDA ADVISORY
No. 2022-1873-A

07 NOV 2022

PARA : SA LAHAT NG HEALTHCARE PROFESSIONALS AT SA PUBLIKO

PAKSA : Babala sa Publiko Tungkol sa Pagbili at Paggamit ng mga Sumusunod na Hindi Rehistradong Gamot:

1. OTC Natural Green Leaf Scar Removal Cream 20 g
2. OTC Natural Green Leaf Aloe Vera Anti-Itch Cream 20 g
3. OTC Natural Green Leaf Herbal Anti-Itch Cream 10 g
4. OTC Natural Green Leaf Gout Pain Relief Cream 15 g (Label with foreign characters)

Pinapayuhan ng Food and Drug Administration (FDA) ang publiko laban sa pagbili at paggamit ng mga sumusunod na hindi rehistradong gamot:



Product Description: Natural Green Leaf Scar Removal Cream helps repair scarred skin caused by surgery, acne, minor cuts and burns. It lightens dark spots and stretch marks. It also has anti-bacterial properties.
Main ingredients: Radix notoginseng, curcumae rhizoma, fructus crudi, chinamom rhizoma, gall (rhus chinensis mill), bletilla (bleilla scabra), safflower (carthamus tinctorius L.), ganoderma lucidum, lavender (lavandula angustifolia miller), olive fruit, aloe vera, propolis, liquid paraffin, lanolin, hydroxyethyl cellulose, chlorhexidine acetate (0.2%-0.3%), sodium hyaluronate, glycerin, water.
Directions: Clean and apply over the affected area. Gently massage onto skin twice daily.
Precautions: For external use only. Do not ingest or get into eyes. Discontinue use if irritation occurs or if you have allergies. Do not use on children under two years old. This product should not be used by pregnant women. Keep out of children's reach.
Shelf life: 3 years. Store in a cool dry place away from sunlight.



OTC Natural Green Leaf Scar Removal Cream 20 g
Imported by: Cha-Ken Consumer Goods Trading – 602A, 611 Tytana Bldg. Tytana St, Plaza Lorenzo Ruiz, Binondo, Manila

Larawan 1. Hindi rehistradong gamot



Natural Green Leaf Aloe Vera Anti-Itch Cream
Quick soothing relief for irritated skin.
20g OTC

Imported by: Cha-Ken Consumer Goods Trading.
Address: 602A, 611 Tytana Bldg., Tytana St., Plaza Lorenzo Ruiz, Binondo, Manila.

Made in P.R.C.

Usage: Fast-acting cooling relief for itch. Protects, soothes and hydrates skin.
Main ingredients: Aloe vera, sophora, ginseng, sophora, phellodendron, cridonia, hibiscus bark, pseudolaric, dictamn, borneol, camphor, lanolin, petrolatum, chlorhexidine acetate, water, chlorhexidine acetate (0.30%-0.35%)
Directions: Apply over the affected area. Gently massage onto skin 2-3 times daily.
Precautions: For external use only. Discontinue use if irritation occurs or if you have allergies. Do not use on children under two years old. This product should not be used by pregnant women. Keep out of children's reach.
Shelf Life: 3 years. Store in a cool dry place away from sunlight.

OTC Natural Green Leaf Aloe Vera Anti-Itch Cream 20 g
Imported by: Cha-Ken Consumer Goods Trading – 602A, 611 Tytana Bldg. Tytana St, Plaza Lorenzo Ruiz, Binondo, Manila

Larawan 2. Hindi rehistradong gamot

Natural Green Leaf Herbal Anti-Itch Cream
10g OTC

Imported by: Cha-Ken Consumer Goods Trading.
Address: 602A, 611 Tytana Bldg., Tytana St., Plaza Lorenzo Ruiz, Binondo, Manila.

Made in P.R.C.

Indications: Help relieve pruritus or itchy skin brought about by dermatitis, eczema, linae, psoriasis, peeling, blister, pruritus vulvae insect bites, rashes and skin dryness or damage.
Main ingredients: Cortex phellodendri, sophora, camphor, lanolin, petrolatum, cneidium, pseudolaric chlorhexidine acetate (0.40%-0.45%).
This product is against candida albicans and staphylococcus aureus. escherichia coli has an inhibitory effect.
Directions: Apply over the affected area. Gently massage onto skin 2-3 times daily.
Precautions: For external use only. Discontinue use if irritation occurs or if you have allergies. Do not use on children under two years old. This product should not be used by pregnant women. Keep out of children's reach.
Shelf life: 3 years. Store in a cool dry place away from sunlight.

OTC Natural Green Leaf Herbal Anti-Itch Cream 10 g
Imported by: Cha-Ken Consumer Goods Trading – 602A, 611 Tytana Bldg. Tytana St, Plaza Lorenzo Ruiz, Binondo, Manila

Larawan 3. Hindi rehistradong gamot

FAST ACTING

Soothing relief from pain and swelling.

Natural Green Leaf

Gout 痛風膏

pain relief CREAM

15g

Indications: Relieves pain and discomfort caused by gout in the joint at the base of the big toe, ankles, knees, wrists, fingers, and elbows.
 Main Ingredients: *Carthamus tinctorius* L., *Panax notoginseng*, *Phytolacca leptostachya* subsp. *asiatica* (Hara) Klamura, *Prunus persica*, *Lycopodium japonicum* Thunb., *Homalomena occulta*(Lour.)Schott, *Asarum sieboldii* Miq., *Liquidambar formosana* Hance.
 Directions: Apply over the affected area twice daily.
 Precautions: For external use only. Discontinue use if irritation occurs or if you have allergies. Keep out of children's reach. This product should not be used by pregnant women.
 Shelf Life: 3 years. Store in a cool dry place.

Imported by: Cha-Ken Consumer Goods Trading.
 Address: 602A, 611 Tytana Bldg., Tytana St., Plaza Lorenzo Ruiz, Binondo, Manila.
 Product no.: 058420

Made in P.R.C.

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OTC Natural Green Leaf Gout Pain Relief Cream 15 g (Label with foreign characters)
 Imported by: Cha-Ken Consumer Goods Trading – 602A, 611 Tytana Bldg. Tytana St, Plaza Lorenzo Ruiz, Binondo, Manila

Larawan 4. Hindi rehistradong gamot

Napatunayan sa pamamagitan ng isinagawang *Post-Marketing Surveillance* (PMS) ng FDA na ang mga nasabing gamot ay hindi dumaaan sa proseso ng rehistrasyon ng Ahensya at hindi nabigyan ng kaukulang awtorisasyon tulad ng *Certificate of Product Registration* (CPR). Dahil dito, hindi masisiguro ng Ahensya ang kalidad, kaligtasan at bisa nito. Samakatuwid, ang paggamit ng nasabing mga ilegal na produkto ay maaaring magdulot ng panganib sa kalusugan.

Alinsunod sa *Republic Act No. 9711*, o ang *Food and Drug Administration Act of 2009*, ang paggawa, pag-angkat, pagbenta, pamamahagi, paglipat, promosyon, pagpapatalastas o *sponsorship* ng produktong pangkalusugan nang walang kaukulang awtorisasyon mula sa FDA ay ipinagbabawal.

Ang lahat ng establisyamento at/o entidad ay binabalaang huwag mamahagi ng nasabing mga ilegal na produkto hanggang sa ito ay mabigyan ng kaukulang awtorisasyon. Karampatang parusa ay mahigpit na ipatutupad sa mga lalabag. Ugaliing tignan kung rehistrado ang produkto sa FDA sa pamamagitan ng *FDA Verification Portal feature* na makikita sa <https://verification.fda.gov.ph>.

Hinihiling sa lahat ng *Local Government Units* (LGUs) at *Law Enforcement Agencies* (LEAs) na tiyaking ang mga produktong ito ay hindi maibebenta o magagamit sa kanilang mga nasasakupan.

Para sa karagdagang impormasyon at katanungan, maaaring mag-email sa info@fda.gov.ph. Upang mag-report ng patuloy na pagtitinda o pangangalakal ng mga hindi rehistradong

gamot, mag-email sa ereport@fda.gov.ph. Maaari ring tumawag sa *Center for Drug Regulation and Research* (CDRR) sa numerong **(02) 8809-5596**. Para sa mga hinihinalang hindi kanais-nais na reaksyon sa gamot, i-report agad sa FDA gamit ang *link* na ito: <https://primary-reporting.who-umc.org/Reporting/Reporter? OrganizationID=PH> at kumpletuhin ang mga kinakailangang impormasyon.

Ang lahat ay hinihikayat na palaganapin ang mga nakasaad na impormasyon.

DTN:



20221027075922


DR. SAMUEL A. ZACATE
Director General