








1 2 SEP 2022

FDA ADVISORY
No. 2022-1612-A

PARA : SA LAHAT NG HEALTHCARE PROFESSIONALS AT SA PUBLIKO

PAKSA : Babala sa Publiko Tungkol sa Pagbili at Paggamit ng Hindi Rehistradong Gamot na "Lianhua Qingwen Capsules 24's"

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

Registered	Unregistered																										
<p>Lianhua Qingwen Capsule</p> <p>YILING</p> <p>[Formulation] Each capsule contains:</p> <table border="0"> <tr><td><i>Forsythia suspensa</i> (Thunb.) Vahl (Weeping Forsythia) Fruit</td><td>27.41mg</td></tr> <tr><td><i>Lonicera japonica</i> Thunb. (Japanese Honeysuckle) Flower</td><td>27.41mg</td></tr> <tr><td><i>Gypsium Fibrosum</i></td><td>27.41mg</td></tr> <tr><td><i>Isatis indigotica</i> Fort. (Isatis) Root</td><td>27.41mg</td></tr> <tr><td><i>Dryopteris crassirhizoma</i> Nakai (Male Fern) Rhizome and Frond</td><td>27.41mg</td></tr> <tr><td><i>Houttuynia cordata</i> Thunb. (Heartleaf Houttuynia) Aerial Part</td><td>9.14mg</td></tr> <tr><td><i>Pogostemon cablin</i> (Blanco) Benth. (Cabin Patchouli) Aerial Part</td><td>9.14mg</td></tr> <tr><td><i>Ephedra sinica</i> Stapf (Ephedra) Herbaceous Stem</td><td>9.14mg</td></tr> <tr><td><i>Prunus sibirica</i> L. (Bitter Apricot) Ripe Seeds</td><td>9.14mg</td></tr> <tr><td><i>Rhodiola crenulata</i> (Hook. f. et Thomson) H. Ohba (Bigflower Rhodiola) Root and Rhizome</td><td>9.14mg</td></tr> <tr><td><i>Glycyrrhiza uralensis</i> Fisch. (Licorice) Root and Rhizome</td><td>7.50mg</td></tr> <tr><td><i>Mentha</i></td><td>5.47mg</td></tr> <tr><td><i>Rheum palmatum</i> L. (Rhubarb) Root and Rhizome</td><td>5.47mg</td></tr> </table> <p>[Indication] Traditionally-Used Herbal Product: Helps remove heat-toxin invasion of the lungs, including symptoms such as fever, aversion to cold, muscular soreness, stuffy and runny nose.</p> <p>[Dosage Form and Strength] Capsules, 350mg/capsule.</p> <p>[Dosage and Mode of Administration] 4 Capsules x 3 times a day with warm water. Should not exceed the recommended daily dose and should not be taken for more than 7 days except on the advice of a doctor. If symptoms persist, consult your doctor.</p> <p>[Adverse Drug Reactions] Post-marketing monitoring data show that this product may cause gastrointestinal adverse reactions such as nausea, diarrhea, vomiting, abdominal pain, dry mouth and rash, itching, dizziness. Please seek medical attention should any adverse drug reaction appear.</p> <p>[Contraindications/Interactions] Interaction with Monoamine Oxidase (MAO) inhibitor drugs.</p> <p>[Caution] Consult your doctor prior to taking this medicine if you have a heart or thyroid disease, high blood pressure, diabetes, glaucoma, hypertension, tumor of adrenal gland, difficulty in urination due to the enlargement of the prostate gland or if you are taking any prescription drugs. Should not be given to children, pregnant and lactating individuals. Should not be used if you have wide-cold common cold.</p> <p>[Storage Condition] Store at temperatures not exceeding 30°C.</p> <p>[Warning] Keep out of reach of children.</p> <p>THPR-50</p>	<i>Forsythia suspensa</i> (Thunb.) Vahl (Weeping Forsythia) Fruit	27.41mg	<i>Lonicera japonica</i> Thunb. (Japanese Honeysuckle) Flower	27.41mg	<i>Gypsium Fibrosum</i>	27.41mg	<i>Isatis indigotica</i> Fort. (Isatis) Root	27.41mg	<i>Dryopteris crassirhizoma</i> Nakai (Male Fern) Rhizome and Frond	27.41mg	<i>Houttuynia cordata</i> Thunb. (Heartleaf Houttuynia) Aerial Part	9.14mg	<i>Pogostemon cablin</i> (Blanco) Benth. (Cabin Patchouli) Aerial Part	9.14mg	<i>Ephedra sinica</i> Stapf (Ephedra) Herbaceous Stem	9.14mg	<i>Prunus sibirica</i> L. (Bitter Apricot) Ripe Seeds	9.14mg	<i>Rhodiola crenulata</i> (Hook. f. et Thomson) H. Ohba (Bigflower Rhodiola) Root and Rhizome	9.14mg	<i>Glycyrrhiza uralensis</i> Fisch. (Licorice) Root and Rhizome	7.50mg	<i>Mentha</i>	5.47mg	<i>Rheum palmatum</i> L. (Rhubarb) Root and Rhizome	5.47mg	<p>Lianhua Qingwen Capsules</p> <p>YILING</p> <p>[Ingredients] Forsythiae Fructus, Lonicerae Japonicae Flos, Isatis Radix, Houttuyniae Herba, Pogostemonis Herba etc.</p> <p>[Administration and Dosage] For oral administration, 4 capsules once, 3 times daily.</p> <p></p> <p>350mg x 24's</p> <p>SHIJIAZHUANG YILING PHARMACEUTICAL CO., LTD.</p>
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<p>[Approved Shelf-life] 30 months</p> <p>[Packaging] Aluminum/PVC Blister pack x 12's; 2 Blister packs enclosed in an Aluminum Pouch (Box of 24's)</p> <p>[Net Content] 24 capsules</p> <p></p> <p>6 920855 052068</p> <p>www.philarchipelago.com</p>	<p>[Storage] Preserve in tightly closed containers, stored in a cool and dry place (≤20°C).</p> <p></p> <p>6 920855 052068</p>																										





Lianhua Qingwen Capsules 24's

Manufacturer: Shijiazhuang Yiling Pharmaceutical Co., Ltd - No. 238 Tianshan Street, High-tech Area, Shijiazhuang, Hebei Province, China 050035

Napatunayan sa pamamagitan ng isinagawang *Post-Marketing Surveillance* (PMS) ng FDA na ang 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 iligal 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-angat, 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 iligal 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 <http://verification.fda.gov.ph>.

Hinihiling sa lahat ng *Local Government Units* (LGUs) at *Law Enforcement Agencies* (LEAs) na tiyaking ang 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.


DR. SAMUEL A. ZACATE
Director General

DTN:



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