



1 2 SEP 2022

FDA ADVISORY  
No. **2022-1612**

**TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

**SUBJECT : Public Health Warning Against the Purchase and Use of the Unregistered Drug Product "Lianhua Qingwen Capsules 24's"**

The Food and Drug Administration (FDA) advises the public against the purchase and use of the unregistered drug product:

Registered	Unregistered
<p><b>Lianhua Qingwen Capsule</b></p> <p><b>YILING</b></p> <p><b>[Formulation]</b> Each capsule contains:  <i>Forsythia suspensa</i> (Thunb.) Vahl (Weeping Forsythia) Fruit 27.41mg  <i>Lonicera japonica</i> Thunb. (Japanese Honeysuckle) Flower 27.41mg  <i>Gypsum Fibrosum</i> 27.41mg  <i>Isatis indigoica</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 27.41mg  <i>Pogostemon cablin</i> (Blanca) Benth. (Cabin Patchouli) Aerial Part 9.14mg  <i>Ephedra sinica</i> Stapf (Ephedra) Herbaceous Stem 9.14mg  <i>Prunus sibirica</i> L. (Bitter Apricot) Ripse 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>I-Menthol</i> 5.47mg  <i>Rheum palmatum</i> L. (Rhubarb) Root and Rhizome 5.47mg</p> <p><b>[Indications]</b> Traditionally Used Herbal Product: Helps remove heat-toxin invasion of the lungs, including symptoms such as fever, aversion to cold, muscle soreness, stuffy and runny nose.</p> <p><b>[Dosage Form and Strength]</b> Capsules, 250mg/capsule.</p> <p><b>[Dosage and Mode of Administration]</b> 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><b>[Adverse Drug Reactions]</b> 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><b>[Contraindications/Precautions]</b> Interaction with Monoamine Oxidase (MAO) inhibitor drugs.</p> <p><b>[Caution]</b> 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 viral-cold common cold. (Storage Condition) Store at temperatures not exceeding 30°C.</p> <p><b>[Warning]</b> Keep out of reach of children.</p> <p>THPR-50</p>	<p><b>Lianhua Qingwen Capsules</b></p> <p><b>YILING</b></p> <p><b>[Ingredients]</b>  <i>Forsythiae Fructus</i>, <i>Lonicerae Japonicae Flos</i>, <i>Isatidis Radix</i>, <i>Houttuyniae Herba</i>, <i>Pogostemonis Herba</i> etc.</p> <p><b>[Administration and Dosage]</b>  For oral administration, 4 capsules once, 3 times daily.</p> <p>350mg x 24's</p> <p>SHIJIAZHANG YILING PHARMACEUTICAL CO., LTD.</p>
<p><b>Lianhua Qingwen Capsule</b></p> <p><b>YILING</b></p> <p><b>[Formulation]</b> Each capsule contains:  <i>Forsythia suspensa</i> (Thunb.) Vahl (Weeping Forsythia) Fruit 27.41mg / <i>Lonicera japonica</i> Thunb. (Japanese Honeysuckle) Flower 27.41mg / <i>Gypsum Fibrosum</i> 27.41mg / <i>Isatis indigoica</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 27.41mg / <i>Pogostemon cablin</i> (Blanca) Benth. (Cabin Patchouli) Aerial Part 9.14mg / <i>Ephedra sinica</i> Stapf (Ephedra) Herbaceous Stem 9.14mg / <i>Prunus sibirica</i> L. (Bitter Apricot) Ripse 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 9.14mg / <i>I-Menthol</i> 7.50mg / <i>Rheum palmatum</i> L. (Rhubarb) Root and Rhizome 5.47mg</p> <p><b>[Indications]</b> Traditionally Used Herbal Product: Helps remove heat toxin invasion of the lungs, including symptoms such as fever, aversion to cold, muscle soreness, stuffy and runny nose.</p> <p>THPR-50</p> <p><b>Manufacturer:</b> Shijiazhuang Yiling Pharmaceutical Co., Ltd.  Address: 238 Lianhua Street, High-Tech Area, Shijiazhuang, Hebei Province, China</p> <p><b>Importer/Distributor:</b> Phil. Ancestral Herbal Training Corp.  Address: 11th Ave 3-Cg, 1838 LUISA Aquino Santos, Bldg. 2, Quezon City, Metro Manila, NCR - 1108</p> <p>Not for individual sale</p> <p>350mg/capsule 2 Blister packs x 12 Capsules</p>	<p><b>Lianhua Qingwen Capsules</b></p> <p><b>YILING</b></p> <p><b>[Functions and Indications]</b>  Clear scourage and remove toxicity, diffuse the lung and discharge heat. Used in treatment of epidemic influenza and lung heat, symptom as fever or high fever, aversion to cold, muscular soreness, stuffy and runny nose, cough, headache, dry and sore throat, reddish tongue, yellow or yellow and greasy tongue coating.</p> <p>350mg x 24's</p> <p>Please refer to leaflet before taking.</p> <p>SHIJIAZHANG YILING PHARMACEUTICAL CO., LTD.</p>
<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>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>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

FDA Post-Marketing Surveillance (PMS) activities have verified that the abovementioned drug product has not gone through the registration process of the Agency and has not been issued with proper authorization in the form of Certificate of Product Registration. Thus, the Agency cannot guarantee its quality and safety. Therefore, consumption of such violative product may pose potential danger or injury to health.

Pursuant to Republic Act No. 9711, otherwise known as the “Food and Drug Administration Act of 2009”, the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, promotion, advertising or sponsorship of health products without proper authorization from FDA is prohibited.

All concerned establishments and/or entities are warned not to distribute the above-identified violative drug product until it has been covered by the appropriate authorization, otherwise, regulatory actions and sanctions shall be strictly pursued. Always check if a product is registered with the FDA by using the **FDA Verification Portal** feature accessible at <https://verification.fda.gov.ph>.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that this product is not sold or made available in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at [info@fda.gov.ph](mailto:info@fda.gov.ph). To report continuous sale or distribution of unregistered health products, kindly e-mail us via [ereport@fda.gov.ph](mailto:ereport@fda.gov.ph). You may also call the Center for Drug Regulation and Research at telephone number (02) 8809-5596. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: <https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH> and fill out all the required fields.

Dissemination of the information to all concerned is requested.

  
DR. SAMUEL A. ZACATE  
Director General

DTN:



20220830090557