

GOVERNMENT OF TELANGANA DRUGS CONTROL ADMINISTRATION



Press Release

Drugs Control Administration, Telangana seized medicines at Mancherial that were falsely manufactured and sold under the guise of 'food products/nutraceuticals'.

The product 'Thiamine Hydrochloride Tablets 100 mg,' which is a medicine used to treat 'beriberi', neuritis associated with pellagra or pregnancy, and to treat and prevent 'Wernicke-Korsakoff syndrome', is being falsely manufactured under a food license at Space Healthcare, Kambohpura, Haryana. It is being marketed illegally by Medkline Life Sciences Pvt. Ltd., Haryana, as a food product/nutraceutical.

The details are as follows:

Drugs Control Administration, Telangana officials, on intelligence gathered, raided premises of Sri Ram Medical Agencies, Mancherial, on 15th February, 2024, and detected the product **Klinthia 100 mg tablets (Thiamine Hydrochloride Tablets 100 mg)**, which is manufactured illegally at Space Healthcare, Ansal Road, Kambohpura -132001, Haryana under a 'food licence (FSSAI licence)' falsely claiming it as a food product/nutraceutical.

The product 'Klinthia 100 mg tablets' containing 100 mg of Thiamine Hydrochloride is a 'drug' as per Drugs and Cosmetics Act. Additionally, the composition of this product is listed as a 'medicine' under the National List of Essential Medicines (NLEM)-2022.

The product 'Thiamine Hydrochloride Tablets 100 mg' must be manufactured only under a 'drug license' issued under the Drugs and Cosmetics Act, adhering strictly to the 'Good Manufacturing Practices' (GMP) outlined in Schedule-M of the Drugs Rules. Additionally, it must meet the quality standards prescribed in the 'Indian Pharmacopoeia' (IP) as mandated.

During the raid at Sri Ram Medical Agencies, Mancherial, DCA officers seized 'Klinthia 100 mg tablets' (Thiamine Hydrochloride Tablets 100 mg), Quantity: 1800 tablets, B. No. ST-4211, labelled with composition 'Each film-coated tablet contains: Thiamine Hydrochloride 100 mg along with other ingredients', bearing food licence / FSSAI Licence No. 10019064001714, Manufactured by: Space Healthcare, Ansal Road, Kambohpura -132001 and Marketed by: Medkline Life Sciences Pvt. Ltd., 4F, 1st Floor, D.A.V. Market, Opp. Mahindra Petrol Pump, Yamuna Nagar-135001, Haryana.

The total worth of the seized tablets was Rs. 30,000. Samples were lifted for analysis.

Sri. M. Srinivasulu, Assistant Director, Karimnagar, Smt. T. Chandana, Drugs Inspector, Mancherial are among the officers who carried out the raid.

Similar cases of 'drugs' being manufactured under a 'food license' were previously detected by the Drugs Control Administration, Telangana, in November 2023 and January 2024, which were declared as 'spurious' by the Drugs Control Laboratory, Hyderabad, as the content of the active ingredient was found to be 'NIL' (i.e., zero drug) in the said products.

The drugs that are falsely manufactured and sold under a food license are not produced in accordance with 'Good Manufacturing Practices' (GMPs) and often fail to meet the quality standards prescribed in the Indian

Pharmacopoeia (IP). Such products pose serious risks to patients' health and may have severe implications.

Manufacturing and selling 'drugs' without a valid 'drug license' is punishable under the Drugs and Cosmetics Act, with imprisonment for up to five years.

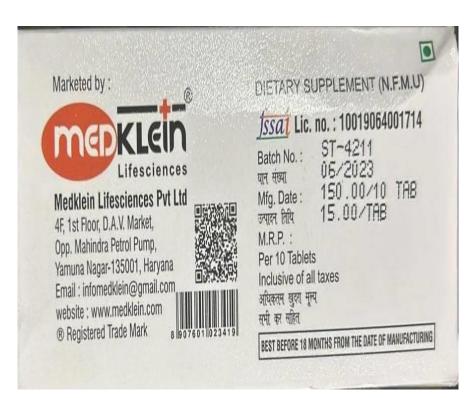
16-02-2024

V.B. KAMALASAN REDDY, IPS

DIRECTOR GENERAL

Photographs of the product seized





Composition:

Each film coated tablet contains:

Nutritional Information (Approximate Values)

Per Serving (Per Tablet)

0.52 kcal Energy Carbohydrate 0.01 gm. 0.000 gm. Fat 0.000 gm. Cholesterol

Thiamine Hydrochloride 100 mg. **Excipients**

Appropriate overages added to compensate for any loss on storage.

Colour: Approved colour used.

This product is not intended to Diagnose, Treat, Cure or Prevent any disease. Consult your doctor in case you are pregnant, lactating or taking any other medication

Other Ingredients: Starch, Lactose, Talcum, Silicon Dioxide etc.

Recommended usage: One tablet daily after meals or as directed by the Dietician.

Keep the medicine out of reach of children Storage: Store in a cool, dry & dark place.

Mfd by : SPACE HEALTHCARE Ansal Road, Kambohpura 132001

q.s.

Photographs of Seizure at Mancherial

