SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the finished pharmaceutical product

Propylthiouracil tablet USP 100mg

2. Qualitative and quantitative composition for excipients

The composition of Propylthiouracil tablets is shown as the table below:

Ingredients	Quantitative/Unit dosage (in mg)
Propylthiouracil	100mg

3. Pharmaceutical form

Tablet.

4. Clinical particulars

4.1 Therapeutic indications

It is indicated for various types of hyperthyroidisms, especially for:

1. Patients of mild condition, or mild to moderate thyromegaly;

2. Adolescent, children and elderly patients;

3. Patients with relapse following thyroid surgery not applicable for ^{131}I radioactive therapy;

4. Preoperative preparation;

5. As adjuvant therapy of ^{131}I chemotherapy

4.2 Posology and method of administration

Dosage: Oral. Shake before use.

It is indicated for adult hyperthyroidism, generally by the initial dose of 300 mg/3 tablets per day, between 150-400 mg (a tablet and half – 4 tablets) according to disease condition, and taken orally by times with daily maximum dose of 600 mg/6 tablets. The dose is reduced gradually after control of the condition, at maintenance dose of 50-150 mg (half tablet - a tablet and half) per day; the dose for children is 4 mg/kg body weight, and taken orally by times, and the maintenance dose was reduced as appropriate.

4.3 Contraindications

Patients with severe liver function impairment, severe leucopenia and allergy to thioureas are prohibited from using it.

4.4 Special warnings and special precautions for use

1. Regular receive hemogram and liver function examination.

2. Interference with diagnosis: prolong prothrombin time and increase AST, ALT, ALP and Bil.

3. Patients with decreased peripheral white blood cells and abnormal liver functions should use it with caution.

4.5 Interaction with other FPPs and other forms of interaction

The combined use of this product with oral anticoagulant drug can increase the efficacy of the latter. Sulfonamides, p-aminosalicylic acid, butazodine, barbiturates, phentolamine, tolazoline, vitamin B12 and sulfonylurea, etc, can all inhibit the effect of thyroid functions and cause thyromegaly, so caution should be taken for their combined use with this product. Besides, intake of high-iodine food or drugs can aggravate the condition of hyperthyroidism, increasing the dose of drugs for thyroid drugs or prolong medication time, so iodine preparation should be avoided before using this product.

4.6 Pregnancy and lactation

Pregnant woman should use it with caution, and lactating woman is prohibited from using it.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Common adverse reactions include headache, dizziness, joint pain, salivary gland and thyroid

gland enlargement and gastrointestinal reactions; also include allergy reactions such as rash and drug fever, etc, and some rash may develop into exfoliative dermatitis. It may cause jaundice and toxic hepatitis in individual patients. The most severe adverse reactions include agranulocytosis, so hemogram should be examined regularly during drug administration: when the white blood cells are lower than 4×10^9/L or neutrophile granulocytes are lower than 1.5×10^9/L, the drug should be withdrawn or adjusted as instructed by physician.

4.9 Overdose

In case of decreased thyroid function, the dose should be reduced in time and thyroid tablets should be added.

5. Pharmcological properties

5.1. Pharmacology and toxicology property

Antithyroid drug. The action mechanism is to inhibit the peroxidase in thyroid gland and inhibit the synthesis of thyroxine by preventing tyrosine iodization and iodotyrosine condensation in the thyroid gland. At the same time, it inhibits the transformation of T4 to T3 in peripheral tissues, makes the content of T3 with strong activity in serum rapidly decrease.

5.2. Pharmacokinetics

It is easily absorbable via oral route, and distributed overall the body, reaching thyroid gland within 20-30 min. 60% are metabolized in the liver. Its T1/2 is 2 h. The product can be secreted from uterus and milk.

5.3. Preclinical safety data

Previously there was no long-term PTU animal toxicology studies, but there was evidence of animal carcinogenesis. At the time of early introduction, some short-term studies suggested that high-dose PTU can lead to significant hypothyroidism, thyroid hyperplasia, adenoma, cancer, pituitary tumor and parathyroid hyperplasia in rodents and rodents. But other anti-thyroid drugs, as long as the continued inhibition of thyroid function, as well as dietary iodine deficiency, thyroid incomplete resection or implantation of spontaneous thyroid hormone secretion of pituitary tumors, can also see such results.

There is no sufficient evidence that PTU can cause cancer. But on the whole, the drug may cause cancer.

6. Pharmaceutical particulars

6.1 List of excipients

Excipients for Propylthiouracil tablet:

Pregelatinized starch	USP
Microcrystalline cellulose	USP
Povidone K30	USP
Sodium carboxymethyl starch	USP
Magnesium stearate	USP
Purified Water	USP

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months from the date of manufacture.

6.4 Special precautions for storage

Store at 25℃; excursions permitted to 15℃-30℃.

Protect from light and moisture.

Keep container tightly closed.

6.5 Nature and contents of container

15 Tablets in a Aluminium PVC blister & such 2blisters in a carton along with the inserts.

6.6 Instructions for use and handling

Keep the medicine out of reach of children.

7.Marketing authorization holder

Name: Humanwell Pharmaceutical Ethiopia PLC.

Name: Humanwell Pharmaceutical Ethiopia PLC.
Address: Tuleffa kebele, Bulga Town, North Shewa Zone,Amhara region, Ethiopia
Tel: +251 18903393, +251 902888222E-mail:chengpeng@renfu.com.cn

8. Numbers in the national register of finished pharmaceutical products

Not applicable.

9. Date of first authorisation/renewal of the authorisation

Not applicable.

10. Date of revision the text

Not applicable.