APPROVED PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully because it contains important information for you

- S2 Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

TANTRIN TABLETS 5 mg (Tablet)

TANTRIN TABLETS 10 mg (Tablet)

Cetirizine dihydrochloride

1. WHAT TANTRIN TABLETS CONTAIN

The active substance is cetirizine dihydrochloride.

TANTRIN TABLETS 5 mg: Each film-coated tablet contains 5 mg cetirizine dihydrochloride. Contains lactose monohydrate.

TANTRIN TABLETS 10 mg: Each film-coated tablet contains 10 mg cetirizine dihydrochloride.

Contains lactose monohydrate.

Other substances included in this product are: crospovidone (type B), hypromellose (methocel E5 LV premium), macrogol 400, magnesium stearate, starch pregelatinised and titanium dioxide.

2. WHAT TANTRIN TABLETS ARE USED FOR

TANTRIN TABLETS is an antihistamine which provides relief of allergy symptoms such as runny nose (rhinitis). It is also used for hives.

3. BEFORE YOU TAKE TANTRIN TABLETS

Do not take TANTRIN TABLETS:

- If you have ever had an unusual or allergic reaction to cetirizine or to any of the other ingredients of **TANTRIN TABLETS**.
- If you have ever had an unusual or allergic reaction to hydroxyzine.
- If you are breast feeding.
- If you are pregnant.

Take special care with TANTRIN TABLETS:

- In most patients, **TANTRIN TABLETS** does not cause significant drowsiness. However, there are a small number of patients who may experience drowsiness. If **TANTRIN TABLETS** makes you feel drowsy, do not drive or perform difficult tasks.
- Alcohol or other central nervous system depressants (medicines that slow down the nervous system) can add to the drowsiness and impairment of concentration caused by **TANTRIN TABLETS**.
- Tell your doctor if you have porphyria.
- Tell your doctor if you have kidney or liver disease.

Pregnancy and Breast feeding:

- The safety of **TANTRIN TABLETS** during pregnancy and breast feeding has not been determined.

If you are pregnant or breast feeding your baby while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Driving and using machinery:

TANTRIN TABLETS may cause you to feel drowsy or have difficulty concentrating. Make sure you know how you react to **TANTRIN TABLETS** before you drive, use machines, or do anything else that could be

dangerous if you are not alert.

Taking other medicines with TANTRIN TABLETS:

- Alcohol or other medicines that cause drowsiness should be avoided while taking **TANTRIN TABLETS**.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **[PRODUCT NAME] TABLETS** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

4. HOW TO TAKE TANTRIN TABLETS

- **Dose:**

  Adults and children over 12 years: The usual adult dose is one 10 mg tablet once daily.

  Children aged 6 to 12 years: The usual adult dose is one 10 mg tablet once daily or one 5 mg tablet twice daily.

  Patients with liver or kidney problems – The recommended daily dose should be halved.

Always take **[PRODUCT NAME] TABLETS** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **[PRODUCT NAME] TABLETS** is too strong or too weak, talk to your doctor or pharmacist.

If you take more TANTRIN TABLETS than you should:

An expected symptom of overdose is drowsiness. Overdose symptoms in children may include: Agitation; sleepiness; itching; rash; inability to urinate; tiredness; tremor (shake) and increased rate of heart beat.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take TANTRIN TABLETS:

If you forget to take a tablet, take it as soon as you remember, and then wait at least 24 hours before taking the next tablet.

5. POSSIBLE SIDE EFFECTS

TANTRIN TABLETS can have side effects.

Get emergency medical help if you have any of these signs of an allergic reaction:

- Hives
- Difficulty breathing
- Swelling of your face, lips, tongue, or throat

Call your doctor at once if you have any of these serious side-effects:

- Irregular heart beat, rapid irregular action of heart
- Confusion
- Convulsions (fits)
- Tremor (shake)
- Blurred vision
- Difficult urination

Other side-effects include: Agitation; anxiety; nervousness; drowsiness; dizziness; tiredness; lack of appetite; headache; ringing in the ears; thickening of mucous; nausea (queasiness; feeling that one is about to vomit); increased appetite; dry mouth; abdominal discomfort; skin rash; sensitivity of the skin to sunlight; sweating; hives; itching; lack of well-being; lack of energy.

Tell your doctor if any of the above side-effects are severe, bothersome or do not go away.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF TANTRIN TABLETS

Keep all medicines out of the reach and sight of children.

Store at or below 25 °C. (room temperature).

Keep tablets in a dry place.

Keep the blisters in the carton until required for use. Keep the HDPE containers tightly closed.

KEEP OUT OF REACH OF CHILDREN.

Do not store in the bathroom, near the kitchen sink, or in other damp places. Moisture may cause the medicine to break down.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF TANTRIN TABLETS

TANTRIN TABLETS 5 mg

PVC / PVdC Pack:

Tablets are packed in 250 micron clear PVC coated with 60 gsm PVdC and printed aluminium foil with 7 gsm heat seal lacquer.

Pack size: 10's – Each carton contains 1 blister of 10 tablets each.

30's – Each carton contains 3 blisters of 10 tablets each.

TANTRIN TABLETS 10 mg

PVC / PVdC Pack:

Tablets are packed in 250 micron white opaque PVC coated with 60 gsm PVdC and printed aluminium foil with 7 gsm heat seal lacquer.

Pack size: 10's – Each carton contains 1 blister of 10 tablets each.

30's – Each carton contains 3 blisters of 10 tablets each.

HDPE Container Pack:

Tablets are packed in a 40 ml white opaque HDPE container of 33 neck finish (OFC 51 ml) with 33 mm-400 RS white opaque polypropylene closure with induction seal wad.

Pack size: 30's – One HDPE container of 30 tablets.

8. IDENTIFICATION OF TANTRIN TABLETS

TANTRIN TABLETS 5 mg

White, film-coated, off-rectangular tablets, debossed with "X" on one side with '21' on the other side.

Score line between '2' and '1'.

TANTRIN TABLETS 10 mg

White, film-coated, off-rectangular tablets, debossed with "X" on one side with '20' on the other side.

Score line between '2' and '0'.

9. REGISTRATION NUMBERS

AURO CETIRIZINE TABLETS 5 mg: **43/5.7.1/0643**

AURO CETIRIZINE TABLETS 10 mg: 43/5.7.1/0644

TRANTRIN TABLETS 5 mg: 43/5.7.1/0645

TRANTRIN TABLETS 10 mg: 43/5.7.1/0646

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

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