RALSIN TABLET Terazosin Hydrochloride (2mg, 5mg)

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What RALSIN TABLET is used for

RALSIN TABLET is used to treat a condition called benign prostatic hyperlapsia (BPH). In this condition there is enlargement of the prostate gland, which leads to difficulty passing urine.

RALSIN TABLET also used to treat high blood pressure.

How RALSIN TABLET works

RALSIN TABLET helps to relieve the obstruction in the prostate gland and improves the flow of urine.

Before you use RALSIN TABLET

- When you must not use it Do not use RALSIN TABLET if you are allergic to Terazosin Hydrochloride or any of the other ingredients listed at the end of the leaflet.

Before you start to use it

taking RALSIN Before TABLET, you must tell your doctor or pharmacist if you have, or have had, any of the following conditions:

- Allergic to any similar • medications such as prozasin, other medicines, foods. dves or preservatives.
- Any heart problems
- Low blood pressure •

If you are not sure if you have, or have had, any of these conditions, you should raise those concerns with your doctor or pharmacist.

Pregnancy

Ask for your doctor's advice if you are pregnant, or likely to become pregnant during your course of medication. **RALSIN TABLET is not** recommended for pregnant women.

Breastfeeding

Ask for your doctor's advice if you are breastfeeding, or likely to breastfeed during your course of medication. Caution should be exercised when RALSIN TABLET is administered to nutrsing women.

Taking other medicines Inform your doctor or pharmacist before taking RALSIN TABLET. Before using RALSIN TABLET, it is important to tell your doctor or pharmacist if you are taking any other medicines, obtained with or without a doctor's prescription.

RALSIN TABLET is not recommended to be use concomitantly with these following medicines:

• Analgesic/ anti-inflammatory (e.g. paracetamol, aspirin,

codeine, ibuprofein, indomethacin)

- Antibiotics (e.g. erythromycin, trimethoprim and sulphamethaxole)
- Anticholinergic/sympathomi metics (e.g. phenylephrine hydrochloride; phenylpropanolamine hydrochloride, pseudoephedrine hydrochloride)
- Antigout (e.g. allopurinol)
- Antihistamine (e.g. chlorpheniramine)
- Cardiovascular agents (e.g. atenolol, hydrochlorothiazide, methyclorothiazide, methylclothiazide, propranolol)
- Corticosteroids
- Gastrointestinal agents (e.g. antacids)
- Hypoglycaemics
- Sedatives and tranquilizer (e.g. diazepam)

RALSIN How to use TABLET

How much to use

instructions Follow the carefully. If you do not understand the instructions on the label, ask your doctor, or pharmacist for help.

Initial Dose: 1 mg at bedtime is the starting dose for all patients, and this dose should not be exceeded.

Subsequent Doses:

Benign Prostatic For Hyperplasia (BPH) treatment: The dose may be slowly increased to achieve the desired clinical response. The usual recommended dose range is 5 to 10 mg administered once a day. Treatment should commence with one tablet of 1 mg taken at bedtime for the first 4 days, then every

morning for the next 3 days. For the next seven days, the dosage is one tablet of 2 mg every morning. In the third week, the dosage is increased to one tablet, 5 mg every morning.

As from the fourth week, a maintenance dosage of 5 - 10 mg is taken daily each morning.

For high blood pressure treatment: The dose may be slowly increased to achieve the desired blood pressure response. The usual recommended dose range is 1 mg to 5 mg administered once a day.

- When to use it

Use as directed by your doctor or pharmacist. RALSIN TABLET is usually taken at bedtime for the first 4 nights to reduce the chance of dizziness. After this the tablets are usually taken once a day, each morning.

- How long to use it

Continue taking RALSIN TABLET as your doctor recommended. If symptoms persist, consult your doctor.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- <u>If you use too much</u> (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too much RALSIN TABLET may cause low blood pressure.

While you are using it

- <u>Things you must do</u>

- Tell all the doctors, dentists and pharmacists treating you that you are taking RALSIN TABLET.
- Tell your doctor immediately if you become pregnant while taking this medication.

- <u>Things you must not do</u>

- Do not take more than the recommended dose unless your pharmacist or doctor tells you.
- Do not take any new medicines without consulting your doctor or pharmacist.
- Do not give RALSIN TABLET to anyone else, even if they have the same symptoms or condition as you.

- <u>Things to be careful of</u> Be careful driving or operating machinery until you know how RALSIN TABLET affects you.

RALSIN TABLET may cause dizziness, lightheadedness or tiredness in some people.

Side effects

Like all medicines, RALSIN TABLET can cause side effects, although not everybody gets them. If side effects persist, do not take the medicine and refer to the doctor.

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

- Dizziness
- Headache

- Asthenia
- Nasal congestion
- Cold symptoms
- Somnolence
- Nausea
- Blurred vision
- Tachycardia
- Palpitations
- Chest pain
- Dyspnoea
- Syncope

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring visiting the website npra.gov.my [Consumers \rightarrow Effects Reporting Side to (ConSERF) Medicines or Vaccines (AEFI)].

Storage and disposal of RALSIN TABLET

<u>Storage</u>

Store below 30°C. Protect from light. Keep out of reach of children.

<u>Disposal</u>

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines. These measures will help to protect the environment.

Product description

- <u>What it looks like</u> RALSIN TABLET 2mg : Blue, round tablet (diameter 7mm) with 'DUOMA/DUOMA' and SCORED marking.

RALSIN TABLET 5mg : Green, round tablet (diameter 7mm) with 'DUOMA/DUOMA' and SCORED marking. - Ingredients

Active ingredient:

• Terazosin hydrochloride

Inactive Ingredients:

- Polyvinylpyrrolidone
- Magnesium Sterate
- Silicone Dioxide
- Quinoline Yellow
- Sodium Starch Glycolate
- Cornstach
- Brilliant Blue
- Lactose

- <u>MAL number(s)</u> RALSIN TABLET 2mg : MAL 20014349AZ RALSIN TABLET 5mg : MAL 20014348AZ

Manufacturer and Product Registration Holder

Duopharma (M) Sdn. Bhd. Lot. 2599, Jalan Seruling 59, Kawasan 3, Taman Klang Jaya, 41200 Klang, Selangor Darul Ehsan, Malaysia

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