Summary Public Assessment Report

Generics

Thiamazole Uni-Pharma
Tabletter 5mg

THIAMAZOLE

DK/H/2614/001/DC

Date: 28-04-2017
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thiamazole, tablets 5mg

This is a summary of the public assessment report (PAR) for Thiamazole Uni-Pharma. It explains how Thiamazole Uni-Pharma was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Thiamazole Uni-Pharma.

For practical information about using Thiamazole Uni-Pharma, patients should read the package leaflet or contact their doctor or pharmacist.

What is Thiamazole Uni-Pharma and what is it used for?
The medicine contains thiamazole. It controls the overproduction of thyroid hormones in the thyroid gland regardless of the cause.

How is Thiamazole Uni-Pharma used?
The pharmaceutical form of Thiamazole Uni-Pharma is tablets and the route of administration is oral.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The recommended dose:
Depending on how serious your condition is, your doctor will decide on your individual dose. The following doses are usually recommended:

Use in adults

Severe cases:
Initial dose: 6 to 8 tablets (30-40 mg) daily administered in several doses. Follow the doctor’s instructions.

Mild cases:
Initial dose: 2 to 4 tablets (10-20 mg) daily administered in two doses. Follow the doctor’s instructions.

Maintenance dose:
1 to 2 tablets (5-10 mg) daily.

If you have an enlarged thyroid gland, or you have been in treatment with iodine, your doctor may prescribe very large doses at the beginning of the treatment.
Your doctor may reduce your dose according to your individual needs. Thiamazole Uni-Pharma may be used in combination with thyroid hormones to control your condition.

You should take the tablets with a glass of water.

**Use in children and adolescents**

*Children and adolescents (3–17 years):*

The dose depends on the child’s weight. The doctor can tell you what the dose is and how long the treatment lasts.

The medicine can only be obtained with a prescription.

**What benefits of Thiamazole Uni-Pharma have been shown in studies?**

Because Thiamazole Uni-Pharma is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Thiamazol Hexal. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

The company provided data from the published literature on thiamazole.

**What are the possible side effects of Thiamazole Uni-Pharma?**

Because Thiamazole Uni-Pharma is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of restrictions, see the package leaflet.

**Why is Thiamazole Uni-Pharma approved?**

It was concluded that, in accordance with EU requirements, Thiamazole Uni-Pharma has been shown to have comparable quality and to be comparable to Thiamazol Hexal. Therefore, the Danish Health and Medicines Authority decided that, as for Thiamazol Hexal, the benefits are greater than its risk and recommended that it can be approved for use.

**What measures are being taken to ensure the safe and effective use of Thiamazole Uni-Pharma?**

A risk management plan has been developed to ensure that Thiamazole Uni-Pharma is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Thiamazole Uni-Pharma, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

**Other information about Thiamazole Uni-Pharma**

The marketing authorisation for Thiamazole Uni-Pharma was granted on 26-04-2017.

The full PAR and the package leaflet for Thiamazole Uni-Pharma can be found on the website [http://mri.medagencies.org/Human/](http://mri.medagencies.org/Human/). For more information about treatment with Thiamazole Uni-Pharma, read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 04-2017.