

PACKAGE LEAFLET: INFORMATION FOR THE USER

TORECAN

6.5 mg film-coated tablets

THIETHYLPERAZINE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What TORECAN is and what it is used for
2. Before you take TORECAN
3. How to take TORECAN
4. Possible side effects
5. How to store TORECAN
6. Further information

1. WHAT TORECAN IS AND WHAT IT IS USED FOR

Torecan belongs to a group of medicines called phenothiazines. Medicine affects the structure of the medulla oblongata that regulates physiological processes associated with vomiting. This blocks the body's response to stimuli that cause nausea and vomiting. Torecan acts on the centers in the central nervous system to normalize and synchronize stimuli from the organs for balance in the inner ear and apparatus for moving, thereby facilitating various forms of vertigo.

The effect starts after 30 minutes and lasts for about 4 hours.

Medicine is used for the treatment and prevention of vomiting in the following conditions:

- After surgery,
- Chemotherapy of malignant diseases,
- After radiation therapy,
- After taking certain medicines that can cause vomiting,
- With disorders of the digestive system and excretion of bile,
- With untreated severe kidney disease (uremia)
- Some illnesses of the head (migraine, increased intracranial pressure, head injury)

- With travel sickness.

Medicine is used for the treatment and prevention of dizziness in the following conditions:

- Concussion,
- Hardening of the blood vessels of the brain,
- Various disorders in the functioning of organs for balance.

2. BEFORE YOU TAKE TORECAN

Warn your doctor if you are taking other medicines, have a chronic disease, a metabolic disorder, you are hypersensitive to medicines or you have had an allergic reaction to some of them.

Do not take TORECAN in case of

- If you are allergic (hypersensitive) to thiethylperazine, phenothiazines or any ingredients of Torecan,
- With severe disorders of consciousness or other signs of impaired operation of the central nervous system,
- If you have very low blood pressure.

Medicine Torecan should not be taken by children under 15 years of age and children and adolescents with symptoms or signs that are similar to the sudden illness of the brain with concomitant liver damage (Reye's syndrome).

Take special care with TORECAN in

Before starting treatment, tell your doctor:

- If you have problems with low blood pressure,
- If you are pregnant and you have a particular form of high blood pressure with concomitant swelling of the limbs (preeclampsia)
- If you have liver disease,
- If you have ever had problems with disease conditioned by involuntary bodily movements,
- If you are taking medicine bromocriptine.

Like other anti-emetic medicaments, Torecan may mask certain diseases of the gastrointestinal tract and central nervous system or side effects caused by other medicines.

Torecan as a representative of phenothiazines may cause group of lesions • neuroleptic malignant syndrome, which includes high fever, muscle hardening, altered mental state, and fluctuations in blood pressure. In this case, treatment must be discontinued immediately.

Because in the elderly patients can occur involuntary bodily movements after prolonged treatment, the treatment should last a maximum of two months.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. Medicines that should not be used concomitantly with Torecan are the following medicines:

- medicines that act on the central nervous system (tranquilizer, opioid pain medications, soothers, anti-depressant medication),
- medicine that hinders the secretion of certain hormones (bromocriptine)
- medicine for cancer (procarbazine).

Taking food and drink with TORECAN

Food or drinks do not affect the effect of Torecan, with the exception of alcohol, which can cause or grade side effects of the medicine.

Pregnancy and breast-feeding

Due to the lack of data on safety during pregnancy and breastfeeding generally we avoid the medicine.

If you are pregnant, consult your doctor about the treatment with Torecan who will assess the relationship between the benefits for your health and the risks to the fetus, and decide whether you can take the medicine.

If you are breastfeeding, also consult your doctor about the treatment with Torecan.

Driving and using machines

Triangle, the medicine with possible impact on the psychophysical capacities (a warning when driving a car and using machines).

Since Torecan can significantly reduce your ability to manage vehicles and machinery, especially if you take it together with alcohol, a tranquilizer or soporific, caution in the management of motor vehicles or machinery is recommend during treatment.

Other warnings

In case of intolerance to some sugars, contact your doctor before taking this medicine, as it contains lactose and saccharose.

3. HOW TO TAKE TORECAN

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

When taking the medicine Torecan exactly follow doctor's instructions. If you are in any doubt, consult with a doctor or pharmacist.

The usual dose is one tablet a day. Doctor may increase the daily dose to two or three tablets. Swallow the tablet with some liquid. The duration of treatment depends on the course of the causal disease. Your doctor will determine how long you will take the medicine.

If you take more TORECAN than you should

Contact your doctor. If possible, bring a tablet, this instruction or packaging with you to show the doctor what you have taken.

Excessive doses can cause dry mouth, dizziness, confusion, involuntary movements and fainting due to lowering of blood pressure. After taking large quantities of tablets you may additionally experience severe disturbances of consciousness disorders, convulsions and other signs of impaired central nervous system work. If you develop specified signs, tell your doctor or other medical personnel.

If you're unable to see a doctor right away, try to induce vomiting to prevent passage of the medicine in the blood.

If you forget to take Torecan chewable tablets

Do not take a double dose to make up for the forgotten tablet.

If you forget to take your medicine, take the missed dose if you remember in the next 2-3 hours.

If it has been more time, take the missed dose the next day at the appointed time, and be sure to tell your doctor about it.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, TORECAN can cause side effects, although not everybody gets them.

Uncommonly (1 to 10 patients in 1,000 patients) may occur during treatment: drowsiness, dizziness, headache and restlessness.

Rarely (1 to 10 patients in 10,000 patients) can occur during the treatment: cramps and other disorders of the central nervous system (stiff and bent neck, general stiffness, inadvertently turning eyeballs and facial grimaces). In elderly people, after prolonged intake, can occur involuntary bodily movements. These disorders usually disappear after discontinuation of therapy or with dose reduction. There may be a feeling of dry mouth, loss of appetite, water retention in the body with swelling of the limbs and face. After long-term use there may appear blurring of eye lens, blurred vision, or breast enlargement in men.

Very rarely (less than 1 in 10,000 patients) during the treatment may occur: rapid heart rate, lowering of blood pressure, jaundice or pain in the facial (trigeminal) nerve.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE TORECAN

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use TORECAN after the expiry date which is stated on the label.

Expiration date: 5 years.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What TORECAN contains

Active substance: 1 coated tablet contains 6.5 mg of thiethylperazine as 10.3 mg of thiethylperazine dimaleate.

Excipients: lactose, corn starch, talc, stearic acid, and gelatin in the tablet core, as well as sucrose, gum arabic, talc, titanium dioxide (E171) and pharmaceutically waxes (beeswax, carnauba wax, shellac) in the coating.

What TORECAN looks like and contents of the pack

There is a box with 50 coated tablets of 6.5 mg, in a glass bottle.

Coated tablets are white, round, convex.

Regime of dispensing

The medicine is issued on doctor's prescription.

Manufacturer

KRKA tovarna zdravil, d.d.,

Šmarješka cesta 6, Novo mesto, Republika Slovenia