PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only.

Wakix 4.5 mg, Wakix 18 mg

Film-coated Tablets

The active ingredient and its quantity:

Wakix 4.5 mg

Each tablet contains pitolisant hydrochloride, which is equivalent to 4.45 mg of pitolisant.

Wakix 18 mg

Each tablet contains pitolisant hydrochloride, which is equivalent to 17.8 mg of pitolisant.

Inactive and allergenic ingredients in the preparation: see section 6 "Further Information".

- **Read this leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Wakix is intended for the treatment of adult patients with narcolepsy, with or without cataplexy.

Therapeutic group: Other nervous system medicines.

What is narcolepsy and what is cataplexy

Narcolepsy is a condition that causes excessive daytime sleepiness and a tendency to suddenly fall asleep in inappropriate situations (sleep attacks). Cataplexy is sudden muscle weakness or paralysis without losing consciousness, in response to sudden excitement, such as anger, fear, joy, laughter or surprise.

How Wakix works

The active ingredient, pitolisant, attaches to receptors on brain cells that are involved in stimulating alertness. This helps to combat daytime sleepiness and cataplexy and promote wakefulness.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to the active ingredient pitolisant or any of the additional ingredients contained in the medicine (see list of inactive ingredients in section 6).
- you suffer from severely impaired liver function, as pitolisant is broken down in the liver, and excessively high levels may build up in the body in patients with severely impaired liver function.
- you are a breastfeeding woman.

Special warnings regarding use of this medicine

Before treatment with Wakix, tell the doctor if

- you have suffered in the past from conditions of anxiety or depression with suicidal thoughts.
- there have been reports of suicidal thoughts during treatment with Wakix, in patients with a history of psychiatric disorders. Inform your doctor immediately if you have signs of depression or suicidal thoughts (see section 4). Consider consulting a friend or relative who will help you identify these signs.
- you suffer from impairments of liver or kidney function, as the dose may need to be adjusted in these conditions.
- you suffer from a gastric ulcer or you take medicines that can irritate your stomach, such as medicines against inflammation, since gastric reactions have been reported with respect to Wakix.
- you suffer from obesity or anorexia, as your weight may change (increase or decrease) during treatment with Wakix.
- you suffer from heart problems. Your doctor will need to monitor heart function regularly while you are taking Wakix.
- you suffer from severe epilepsy.

Children and adolescents

Do not give Wakix to children or adolescents.

Drug interactions:

If you are taking, or have recently taken, other medicines, including non-prescription medicines or nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:

- Certain antidepressants (e.g., imipramine, clomipramine and mirtazapine).
- Certain medicines to treat allergic conditions (anti-histamines, e.g., pheniramine maleate, chlorpheniramine, diphenhydramine, promethazine, mepyramine, doxylamine).
- Rifampicin (an antibiotic), phenytoin, carbamazepine and phenobarbital (mainly against seizures), quinidine, digoxin (for treatment of abnormal heart rhythms), paroxetine, fluoxetine, venlafaxine, duloxetine (antidepressants), St. John's Wort (*Hypericum perforatum*) – a herbal remedy for depression, bupropion (antidepressant or aid to smoking cessation), cinacalcet (for treatment of disorders of the parathyroid gland), terbinafine (against fungal infections), metformin, repaglinide (for treatment of diabetes), docetaxel, irinotecan (for treatment of cancer), cisapride (for treatment of gastric reflux), pimozide (treatment of certain mental disorders), halofantrine (against malaria), efavirenz (antiviral medicine to treat AIDS), morphine, paracetamol (pain killers), dabigatran (for treatment of problems of the veins), warfarin (for treatment of heart illnesses), probenecid (against gout and gouty arthritis).
- Pitolisant can be used with modafinil or with sodium oxybate.
- Wakix may reduce the effectiveness of contraceptive pills; therefore, it is recommended to use another effective method of contraception (see below "Pregnancy, breastfeeding and fertility").

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you are pregnant or are planning to become pregnant, consult with a doctor or pharmacist before taking this medicine.

Pregnancy

Do not use Wakix during pregnancy, unless otherwise instructed by the doctor. There is not enough information available to know whether any particular risk is associated with the use of Wakix during pregnancy. Every woman must use a contraceptive for as long as she is taking Wakix and for at least 21 days after treatment discontinuation. As Wakix may reduce the effectiveness of contraceptive pills, an alternative effective method of contraception must be used.

Breastfeeding

Wakix passes into breast milk in animals. Patients taking Wakix must stop breastfeeding.

Driving and operating machinery

You should be cautious with activities that require concentration, such as driving and operating machinery. If you are unsure whether your condition has a negative effect on your fitness to drive, talk to your doctor.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen with the medicine. The dosage and treatment regimen will be determined by the doctor only. The usual dose is generally:

Treatment is normally started with a dose of 9 mg once a day, and gradually increased over three weeks to the appropriate dose. At any time, your doctor can increase or decrease the dose depending on how the medicine affects you and how well you tolerate it.

It might take a few days before you feel the benefit that the medicine provides, and the maximum benefit is usually felt after a few weeks.

Do not change the dose of Wakix on your own. Any change in dosage must be prescribed and monitored by a doctor.

For a dose of 4.5 mg, take one 4.5 mg tablet.

For a dose of 9 mg, take two 4.5 mg tablets.

For a dose of 18 mg, take one 18 mg tablet.

For a dose of 36 mg, take two 18 mg tablets.

Take Wakix once a day by mouth, in the morning with breakfast. Do not take Wakix in the afternoon, since this could cause difficulties falling asleep.

Do not exceed the recommended dose.

There is no information regarding crushing/ halving/chewing.

If you accidentally take too high a dose of Wakix

In case an excessively large quantity of Wakix tablets is taken, contact the nearest hospital emergency room or inform your doctor or pharmacist of this immediately. You may experience headaches, abdominal pain, nausea or irritability, as well as sleeping difficulties. Take this leaflet and all the remaining tablets with you. If a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the medicine package with you.

If you forget to take Wakix

If you forgot to take your medicine, take the next dose at the scheduled time. Do not take a double dose to make up for the forgotten dose.

Adhere to the treatment regimen recommended by the doctor.

If you stop taking the medicine

You should continue to take the medicine for as long as instructed by your doctor. Do not stop taking Wakix suddenly on your own.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Wakix may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Common side effects (may occur in up to 1 in 10 patients):

- Sleeping difficulties, feeling anxious, irritability, feeling depression, sleeping problems
- Headaches, feeling of spinning (vertigo), balance disturbances, trembling
- Nausea, vomiting, indigestion
- Tiredness (fatigue)

Uncommon side effects (may occur in up to 1 in 100 patients):

- Sweating
- Decrease or increase of appetite
- Edema
- Irritability, feeling jittery, seeing or hearing things that are not really there
- Changing emotions
- Abnormal dreams
- Tension
- Difficulty in falling asleep at the beginning, in the middle or at the end of the night, difficulty in staying asleep, excessive sleepiness, somnolence
- State of indifference and lack of emotion
- Nightmares
- Feeling restless and unable to sit still
- Panic reaction
- Suicidal thoughts
- Increased or altered sexual interest
- Sudden and transient episode of muscle weakness, uncontrollable muscle spasms or movement of one leg
- Disturbance in attention
- Migraine
- Epilepsy
- Weakness
- Movement disturbance, slow body movement
- Sensation of tingling, tickling, pricking, or burning of the skin
- Sudden and unpredictable incidents of mobility and immobility
- Feeling unsteady
- Reduced visual acuity, abnormal contraction or twitching of the eyelids
- Hearing sounds when no external sound is present
- Irregular pulse, slow or fast heart rate, raised or decreased blood pressure, hot flushes
- Yawning
- Dry mouth
- Diarrhea, abdominal pain, a feeling of discomfort in the abdomen, constipation, heartburn, pain and discomfort in the area of the stomach, gastritis, excessive acidity of the gastrointestinal tract
- Itching, abnormal redness of the nose and cheeks, excessive sweating
- Joint pain, back pain, muscle rigidity, muscle weakness, pain of the muscles and the bones, pain in the toes and in the fingers
- Abnormal urination
- Irregular uterine bleeding
- Lack of strength or extreme tiredness, chest pain, malaise, edema
- Weight increase, weight decrease, abnormal heart function recording (ECG), abnormal blood test results related to the liver function

Rare side effects (may occur in up to 1 in 1,000 patients):

- Loss of appetite, increased appetite
- Abnormal behavior, confusional states, depressed mood, overexcitement, feelings of emotional and mental discomfort, feeling of hearing and seeing things that are not really there during sleep
- Loss of consciousness, tension headaches, memory disturbances, poor sleep quality
- Abdominal discomfort, difficulty or pain in swallowing, flatulence, inflammation of the digestive tract
- Infections of the skin, abnormally high sensitivity to sunlight
- Neck pain, chest pain
- Spontaneous abortion
- Pain, night sweats, sense of oppression
- High blood levels of the enzyme creatinine phosphokinase, abnormal general physical condition, modifications of the electrical recording of the heart (ECG)

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects of drug treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

Storage conditions:

Store below 30°C. After first opening, it may be used for 40 days, at a temperature that is no higher than 30°C.

Do not throw away any medicines via household waste or wastewater. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Microcrystalline cellulose, Crospovidone, Talc, Opadry II HP85F18422 white (containing polyvinyl alcohol, titanium dioxide, macrogol 3350, talc), Magnesium stearate, Colloidal anhydrous silica

What the medicine looks like and contents of the package:

Wakix 4.5 mg is a white, round, biconvex, film-coated tablet, 3.7 mm in diameter, marked on one side with the number "5".

Wakix 18 mg is a white, round, biconvex, film-coated tablet, 7.5 mm in diameter, marked on one side with the number "20".

Wakix is available in bottles of 30 tablets.

Registration Holder and address: Truemed Ltd., 10 Beni Gaon St., Netanya 4250499.

Manufacturer and address: Bioprojet Pharma, Paris, France.

This leaflet was revised in December 2021 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

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