

Package leaflet: Information for the patient

Wakix 4.5 mg film-coated tablets

Wakix 18 mg film-coated tablets

pitolisant

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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. See section 4.

What is in this leaflet?

1. What Wakix is and what it is used for
2. What you need to know before you take Wakix
3. How to take Wakix
4. Possible side effects
5. How to store Wakix
6. Contents of the pack and other information

1. What Wakix is and what it is used for

Wakix contains the active ingredient pitolisant. It is a medicine used to treat adult patients with:

- Narcolepsy, with or without cataplexy
- Obstructive sleep apnoea to treat excessive daytime sleepiness. It is used when sleepiness occurs despite treatment with continuous positive airway pressure (CPAP) or in patients who have not tolerated CPAP.

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

Obstructive sleep apnoea is a condition that causes you to stop breathing for at least 10 seconds during sleep. This can lead to excessive daytime sleepiness and a tendency to suddenly fall asleep in inappropriate situations (sleep attacks).

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

2. What you need to know before you take Wakix

Do not take Wakix if you

- Are allergic to pitolisant or any of the other ingredients of this medicine (listed in section 6).
- Have severe liver problems, as pitolisant is normally broken down in the liver and excess levels may build up in patients whose liver function is severely reduced.
- Are breastfeeding.

Warnings and precautions

Talk to your doctor before taking Wakix if any of the situations mentioned below apply to you:

- You ever had anxiety or depression with suicidal thoughts.
- You have liver or kidney problems, as your dose may need to be adjusted.

- You have a gastric ulcer or you take medicines that can irritate your stomach such as medicines against inflammations, since gastric reactions have been reported with Wakix.
- You are obese or anorexic, as you may have change of your body weight (increase or decrease) while taking Wakix.
- You have heart problems. Your doctor will need to check this regularly while you are taking Wakix.
- You have severe epilepsy.

If any of these apply to you, talk to your doctor or pharmacist before taking Wakix.

Other things to talk to your doctor or pharmacist about:

Some people with history of psychiatric disorders have reported having suicidal thoughts while taking this medicine. Tell your doctor straight away if you notice that you are becoming depressed or have suicidal thoughts (see section 4). You may want to consider asking a family member or close friend to help you look out for signs of depression or other changes in your behaviour.

Children and adolescents

Wakix should not be taken by children or adolescents.

Other medicines and Wakix

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Wakix can affect the way other medicines work and other medicines can affect the way Wakix works. Your doctor may need to adjust your doses.

In particular, you should be cautious if you take Wakix together with some antidepressants (e.g. imipramine, clomipramine and mirtazapine) and some medicines to treat allergic conditions (anti-histamines, e.g. pheniramine maleate, chlorpheniramine, diphenhydramine, promethazine, mepyramine, doxylamine).

Tell your doctor or pharmacist if you are taking any of the following medicines: rifampicin (an antibiotic), phenytoin, carbamazepine and phenobarbital (mainly used to control seizures), quinidine, digoxin (used to treat 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 (used to treat fungal infections), metformin, repaglinide (used to treat diabetes), docetaxel, irinotecan (used to treat cancer), cisapride (used to treat gastric reflux), pimozide (used to treat some mental disorders), halofantrine (to treat malaria), efavirenz (antiviral medicine to treat HIV), morphine, paracetamol (used to treat pain), dabigatran (used to treat problems of the veins), warfarin (used to treat heart diseases), probenecid (used to treat gout and gouty arthritis). Pitolisant can be used with modafinil or sodium oxybate.

Wakix may reduce the effectiveness of hormonal contraceptives, an alternative method of effective contraception has to be used (see section "Pregnancy").

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Wakix should not be used during pregnancy unless your doctor says so. There is not enough information available to know whether any particular risk is associated with the use of Wakix during pregnancy. If you are a woman, you have to take a contraceptive during your treatment with Wakix and at least up to 21 days after treatment discontinuation. As Wakix may reduce the effectiveness of hormonal contraceptive, an alternative method of effective contraception has to be used.

Breast-feeding

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

Driving and using machines

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

3. How to take Wakix

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Narcolepsy

Treatment is normally started with a dose of 9 mg once per day, and gradually increased over three weeks to the most appropriate dose.

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.

Excessive daytime sleepiness in patients with obstructive sleep apnoea

Treatment is normally started with a dose of 4.5 mg once per day, and gradually increased over three weeks to the most appropriate dose. The maximum daily dose is 18 mg.

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.

At any time, your doctor can increase or decrease your dose depending on how well the medicine works for you and how well you tolerate it.

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

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

Take Wakix once a day by mouth, in the morning upon waking.

If you take more Wakix than you should

If you take too many tablets of Wakix, contact your nearest hospital casualty department or tell your doctor or pharmacist immediately. You may experience headaches, stomach pain, feeling sick or irritable. You may also have difficulty sleeping. Take this leaflet and any remaining tablets with you.

If you forget to take Wakix

If you forget to take your medicine take the next dose at the usual time, do not take a double dose to make up for the forgotten one.

If you stop taking Wakix

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

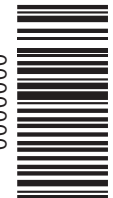
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you notice any side effects, contact your doctor.

You should seek immediate medical attention if you experience any of these serious side effects:

- Sudden and transient episode of muscle weakness, uncontrollable muscle spasms or movement of one leg
- Epilepsy



- Slow or fast heart rate, heart block or rhythm disorders (symptoms include chest pain, lightheadedness, fainting, shortness of breath), abnormal reading (ECG) of the heart
- Loss of consciousness
- Feeling, seeing or hearing things that are not really there when you are awake or during sleep
- Suicidal thoughts, feelings of emotional or mental discomfort
- Inflammation of the digestive tract (symptoms include diarrhoea, swelling, fever, bloody stools)
- Infection of the skin
- Spontaneous abortion

Other side effects

Common side effects (may affect up to 1 in 10 people):

- Difficulty in sleeping, feeling anxious, feeling depressed, sleeping problems, tiredness (fatigue)
- Feeling of “spinning” (vertigo), loss of balance, trembling
- Feeling sick, vomiting, indigestion

Uncommon side effects (may affect up to 1 in 100 people):

- Decrease or increase of appetite, increase or decrease in weight
- Oedema, tension
- Feeling jittery, nervousness, feeling restless and unable to keep still, disturbance in attention
- Changing emotions, state of indifference with lack of emotion, panic reaction, fear
- Abnormal dreams, nightmare
- Difficulty in falling asleep at the beginning of the night or in the middle of the night or at the end of the night, difficulty in staying asleep, sleep paralysis, excessive sleepiness, somnolence, trouble with sleep rhythm
- Migraine
- Altered or increased sexual interest
- Movement disturbance, slow body movement, sudden and unpredictable phases of mobility and immobility, feeling unsteady, muscle rigidity, muscle weakness, spasms of muscles
- Sensation of tingling, tickling, pricking, or burning of the skin
- Reduced visual acuity, abnormal contraction or twitch of the eyelid, dry eye, presence of flashes of light or floaters in the vision
- Hearing of sound when no external sound is present
- Abnormal heart beat, palpitations, decrease blood pressure, abnormal heart rate, hot flush
- Yawning, cough, shortness of breath at night, chest pain
- Dry mouth, odour of the breath, changes in taste, high secretion of saliva, thirst
- Constipation, discoloration of the faeces
- Heartburn, stomach pain and discomfort, gastritis, excessive acidity of the gastrointestinal tract, rectal bleeding
 - Itching, skin condition of the face where the nose and cheeks are unusually red, sweating or excessive sweating, fever
 - Joint pain, back pain, pain of the muscle and the bones, pain in the toes and in the fingers, discomfort of arms and legs, pain of the tendons
 - Abnormal urination
 - Irregular uterine bleeding
 - Weakness, loss of strength or extreme tiredness, malaise
- Abnormal blood values related to the function of the liver, change in bleeding analyses, increase of cholesterol levels or other fats in the blood seen in tests
- Viral upper respiratory tract infection (common cold), cold sores
- Alcohol intolerance, low blood sugar level
- Withdrawal syndrome

Rare side effects (may affect up to 1 in 1000 people):

- Loss or increased appetite, abdominal discomfort, difficulty or pain in swallowing
- Abnormal behaviour, excitability, abnormal general physical condition
- Tension headache, trouble with memory, poor sleep quality
- Neck pain, pain around the chest area, sense of oppression
- High blood level of the enzyme creatinine phosphokinase

If you are being treated for obstructive sleep apnoea, some of the following side effects may also occur:

Very common side effects (may affect more than 1 in 10 people): Headache

Common side effects (may affect up to 1 in 10 people): Raised blood pressure, diarrhoea, abdominal pain, discomfort or pain in the belly (abdomen), pain and discomfort, night sweats

Uncommon side effects (may affect up to 1 in 100 people): Flatulence, abnormally high sensitivity of the skin to sunlight, depressed mood, irritability, confusional state

If you are being treated for narcolepsy, some of the following side effects may also occur:

Common side effects (may affect up to 1 in 10 people): Headache, feeling irritable, dizziness

Uncommon side effects (may affect up to 1 in 100 people):

Raised blood pressure, diarrhoea, abdominal pain, discomfort or pain in the belly (abdomen)

Rare side effects (may affect up to 1 in 1000 people): Pain, flatulence, night sweats, abnormally high sensitivity of the skin to sunlight, confusional state, depressed mood.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Wakix

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions

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

6. Contents of the pack and other information

What Wakix contains

The active substance is pitolisant.

Wakix 4.5 mg tablet

Each tablet contains pitolisant hydrochloride, equivalent to 4.45 mg of pitolisant

Wakix 18 mg tablet

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

The other ingredients are microcrystalline cellulose, crospovidone Type A, talc, magnesium stearate, colloidal anhydrous silica, poly(vinyl alcohol), titanium dioxide (E 171), macrogol 3350.

What Wakix looks like and contents of the pack

Wakix 4.5 mg comes in a white, round, film-coated tablet of 3.7 mm, biconvex marked with “5” on one side.

Wakix 18 mg comes in a white, round, film-coated tablet of 7.5 mm, biconvex marked with “20” on one side.

Wakix is available in a bottle of 30 tablets or 90 tablets.

Wakix 4.5 mg: Available in packs containing 1 bottle of 30 tablets.

Wakix 18 mg: Available in packs containing 1 bottle of 30 tablets or packs containing 1 bottle of 90 tablets or multi-packs containing 90 (3 bottles of 30) tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Wakix 18 mg

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