

**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.

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.

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).

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), pimozone (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 animal. 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.

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

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 your breakfast. Do not take a dose of Wakix in the afternoon since you may have difficulty sleeping.

### 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.

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

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

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

- Sweating
- Decrease or increase of appetite
- Oedema
- Feeling jittery, nervousness, seeing or hearing things that are not really there
- Changing emotions
- Abnormal dreams
- Tension
- 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, excessive sleepiness, somnolence
- State of indifference with lack of emotion
- Nightmare
- Feeling restless and unable to keep still
- Panic reaction
- Suicidal thoughts
- Altered or increased 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 phases of mobility and immobility
- Feeling unsteady
- Reduced visual acuity, abnormal contraction or twitch of the eyelid
- Hearing of sound when no external sound is present
- Abnormal heart beat, slow or fast heart rate, raised or decrease blood pressure, hot flush
- Yawning
- Dry mouth
- Diarrhoea, abdominal pain, discomfort or pain in the belly (abdomen), constipation, heartburn, stomach pain and discomfort, gastritis, excessive acidity of the gastrointestinal tract
- Itching, skin condition of the face where the nose and cheeks are unusually red, excessive sweating
- Joint pain, back pain, muscle rigidity, muscle weakness, pain of the muscle and the bones, pain in the toes and in the fingers
- Abnormal urination
- Irregular uterine bleeding
- Loss of strength or extreme tiredness, chest pain, malaise, oedema
- Weight increase, weight decrease, abnormal reading (ECG) of the heart, abnormal blood values related to the function of the liver.

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

- Loss of appetite, increased appetite
- Abnormal behaviour, confusional state, depressed mood, excitability, feelings of emotional and mental discomfort, feeling of seeing or hearing things that are not really there when you sleep
- Loss of consciousness, tension headache, trouble of the memory, poor sleep quality
- Abdominal discomfort, difficulty or pain in swallowing, flatulence, inflammation of the digestive tract
- Infection of the skin, abnormally high sensitivity to sunlight

- Neck pain, chest pain
- Spontaneous abortion
- Pain, night sweats, sense of oppression
- High blood level of the enzyme creatinine phosphokinase, abnormal general physical condition, modification of the electrical registration of the heart (ECG)

## 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](http://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 5 mg of pitolisant hydrochloride, equivalent to 4.45 mg of pitolisant

#### Wakix 18 mg tablet

Each tablet contains 20 mg of pitolisant hydrochloride, equivalent to 17.8 mg of pitolisant.

The other ingredients are microcrystalline cellulose, crospovidone, talc, magnesium stearate, colloidal anhydrous silica, polyvinyl alcohol, titanium dioxide, 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

Bioprojet Pharma

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### Manufacturer

Wakix 18 mg

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Wakix 4.5 mg

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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### Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:

<http://www.ema.europa.eu>.

This leaflet is available in all EU/EEA languages on the European Medicines Agency website.