

NIGFAST SACHETS 50mg Powder for Oral Solution

Diclofenac Potassium

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 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.

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1 What Nigfast is and what it is used for

Nigfast belongs to a group of medicines called “non-steroidal anti-inflammatory drugs” (NSAIDs), which are used to treat pain and inflammation.

Nigfast relieves the symptoms of inflammation, such as pain and swelling, and also reduces fever. It has no effect on the causes of inflammation or fever.

In migraine attacks, Nigfast is effective in relieving the headache as well as in improving the accompanying symptoms such as nausea and vomiting.

Nigfast can be used for short-term treatment of the following conditions:

- Sprains, strains, or other injuries.
- Pain and swelling after surgery.
- Painful menstrual periods.
- Migraine attacks.
- Back pain, frozen shoulder, tennis elbow, and other forms of soft-tissue rheumatism.
- Infections of the ear, nose or throat.

If you have any questions about how Nigfast works or why this medicine has been prescribed to you, ask your doctor.

2 What you need to know before you take Nigfast

Tell your doctor if you recently had or you are going to have a surgery of the stomach or intestinal tract before receiving/taking/using Nigfast, as Nigfast can sometimes worsen wound healing in your gut after surgery.

Follow all instructions given to you by your doctor or pharmacist carefully, even if they differ from the general information contained in this leaflet.

Do not take Nigfast

- **If you are** allergic to diclofenac or to any of the other ingredients of Nigfast listed in Section 6 of this leaflet.
- **If you have** ever had an allergic reaction after taking medicines to treat inflammation or pain (e.g. acetylsalicylic acid/aspirin, (diclofenac or ibuprofen). Reactions may include asthma, chest pain, runny nose, skin rash, swelling of the face, lips, tongue, throat, and/or extremities (signs of angioedema). If you think you may be allergic, ask your doctor for advice.
- **If you have** stomach or intestinal ulcer.
- **If you have or previously had** gastrointestinal bleeding, symptoms of which may include blood in your stools or black stools.
- **If you suffer** from severe kidney or liver disease.
- **If you are** in the last three months of pregnancy.
- you have heart disease (e.g. if you have had a heart attack, have angina or blockages in the arteries of your heart)
- you have cerebrovascular disease (e.g. if you have had a stroke, mini-stroke or have blockages of the arteries to the brain)
- you have peripheral arterial disease (e.g. poor circulation or blockages of the arteries to the legs and feet)
- you have severe heart failure

If any of these apply to you, tell your doctor and do not take Nigfast. Your doctor will decide whether this medicine is suitable for you.

Warnings and Precautions

Talk to your doctor or pharmacist before taking your medicine if:

- if you have diabetes
- if you smoke
- If you have angina, blood clots, high blood pressure, raised cholesterol or raised triglycerides
- **If you are taking** Nigfast simultaneously with other anti-inflammatory medicines including acetylsalicylic acid/aspirin, corticosteroids, “blood thinners” or SSRIs (see “Taking other medicines”).

- If you have ever had asthma, other breathing problems (such as COPD) or often get chest infections
- If you have ever had hay fever or nasal polyps
- If you have any allergies
- **If you have** ever had any gastrointestinal problems such as stomach ulcer, bleeding or black stools, or have experienced stomach discomfort or heartburn after taking anti-inflammatory medicines in the past.
- **If you have** an inflammation of the colon (ulcerative colitis) or intestinal tract (Crohn's disease).
- **If you have or have had** heart problems or high blood pressure.
- **If you have** liver or kidney problems.
- **If you could** be dehydrated (e.g. by sickness, diarrhoea, before or after major surgery).
- **If you have** swollen feet.
- **If you have** a bleeding disorder or other blood disorders
- **If you have a** condition called porphyria.

If you have significant risk factors for cardiovascular disease such as high blood pressure, abnormally high levels of fat (cholesterol, triglycerides) in your blood, diabetes, or if you smoke, and your doctor decides to prescribe Nigfast, you must use the lowest effective dosage for the shortest duration necessary.

Look out for serious side effects

Nigfast can cause some serious side effects. These are listed at the beginning of Section 4. You will need to look out for these while you are taking Nigfast. If you get a serious side effect you need to stop taking Nigfast and talk to your doctor straight away. Side effects may be minimized by using the lowest effective dose for the shortest duration necessary.

Risk of heart attack or stroke with Nigfast

Medicines such as Nigfast may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment. If, at any time while taking Nigfast you experience any signs or symptoms of problems with your heart or blood vessels such as chest pain, shortness of breath, weakness, or slurring of speech, contact your doctor immediately.

If you have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

Nigfast may reduce the symptoms of an infection (e.g. headache, high temperature) and may therefore make the infection more difficult to detect and to treat adequately. If you feel unwell and need to see a doctor, remember to mention that you are taking Nigfast.

In very rare cases, Nigfast, like other anti-inflammatory medicines, may cause severe allergic skin reactions (e.g. rash). Therefore, inform your doctor immediately if you experience such reactions.

Monitoring during your treatment with Nigfast

If you have significant risks for heart disease, your doctor will periodically re-evaluate whether you should continue treatment with Nigfast

If you have any liver impairment, kidney impairment or blood impairment, you will have blood tests during treatment. These will monitor either your liver function (level of transaminases) or your kidney function (level of creatinine) or your blood count (level of white and red blood cells and platelets). Your doctor will take these blood tests into consideration to decide if Nigfast needs to be discontinued or if the dose needs to be changed.

Children/adolescents

Nigfast must not be given to children and adolescents below 14 years of age. For paediatric use, other forms of diclofenac can be used.

Older people

Elderly patients may be more sensitive to the effects of Nigfast than other adults. Therefore, they should follow the doctor's instructions particularly carefully and take the minimum number of sachets that provides relief of symptoms. It is especially important for elderly patients to report undesirable effects promptly to their doctor.

The use of Nigfast in migraine has not been established in children and adolescents.

Other medicines and Nigfast

Tell your doctor or pharmacist if you are taking have recently taken or might take any other medicines.

Remember also those not prescribed by a doctor.

It is particularly important to tell your doctor if you are taking any of the following medicines:

- Lithium or selective serotonin-reuptake inhibitors (SSRIs); (medicines used to treat some type of depression).
- Digoxin (a medicine used for heart problems).
- Diuretics (medicines used to increase the amount of urine).
- ACE inhibitors or beta-blockers (classes of medicines used to treat high blood pressure and heart failure).
- Other anti-inflammatory medicines such as acetylsalicylic acid/aspirin or ibuprofen.
- Corticosteroids (medicines used to provide relief for inflamed areas of the body).
- Anticoagulants (blood thinning tablets like warfarin)
- Medicines used to treat diabetes, except insulin.
- Methotrexate (a medicine used to treat some kinds of cancer or arthritis).
- Ciclosporin, Tacrolimus (medicines primarily used in patients who have received organ transplants).

- Trimethoprim (a medicine used to prevent or treat urinary tract infections)
- Quinolone antibacterials (medicines used to treat infection).
- Voriconazole (a medicine used to treat fungal infections).
- Phenytoin (a medicine used to treat seizures).

Pregnancy and breastfeeding

If you are pregnant or think that you may be pregnant, **tell your doctor**.

You should not take Nigfast during the first six months of pregnancy unless absolutely necessary.

As with other anti-inflammatory medicines, you must not take Nigfast during the last 3 months of pregnancy, as it could harm your unborn child or cause problems at delivery.

Nigfast may make it more difficult to become pregnant. You should not take Nigfast unless necessary if you are planning to become pregnant or if you have problems to become pregnant.

You should tell your doctor if you are breast-feeding.

You should not breast-feed if you are taking Nigfast, as it might be harmful for your infant.

Driving and using machines

In rare cases, patients using Nigfast may experience side effects such as vision disorders, dizziness or drowsiness. If you notice such effects, you should not drive, use machines, or carry out other activities that need careful attention. Tell your doctor as soon as possible if you experience such effects.

Nigfast Sachets contain phenylalanine

Nigfast contains aspartame, a source of phenylalanine which may be harmful for patients with phenylketonuria.

3 How to take Nigfast

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

Do not exceed the recommended dose. It is important that you use the lowest dose that controls your pain and that you do not take Nigfast for longer than necessary.

Your doctor will tell you exactly how many sachets of Nigfast to take. Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

Adults

For adults, the recommended dose to start the treatment is generally 100 to 150 mg daily (to be taken in 2 to 3 doses). In milder cases, 50 to 100 mg daily are usually sufficient (to be taken in 1 to 2 doses). Do not exceed 150 mg per day.

In painful menstrual periods, start treatment with a single dose of 50 to 100 mg as soon as you feel the first symptoms. Continue with 50 mg up to three times a day for a few days, as needed. If 150 mg a day does not provide sufficient pain relief over 2 to 3 menstrual periods,

your doctor may recommend you to take up to 200 mg a day during your next menstrual periods. Do not exceed 200 mg per day.

In migraine, take Nigfast at the first symptoms of a migraine attack. The initial dose is 50 mg. If relief is not obtained within 2 hours, take a further dose of 50 mg. This may be repeated at intervals of 4 to 6 hours, but you should not take more than 200 mg per day.

Children and adolescents

Nigfast is not recommended for use in children and adolescents below 14 years of age. For adolescents aged 14 years and over, 50 to 100 mg daily are usually sufficient given as 1 to 2 divided doses. Do not exceed 150 mg per day.

The use of Nigfast in migraine attacks has not been established in children and adolescents.

The contents of the sachet should be dissolved by stirring in a glass of non-carbonated water. The solution may remain slightly cloudy, but this should not influence the efficacy of the medicine. The solution should be swallowed preferably before a meal.

If you take more Nigfast than you should

If you have accidentally taken more Nigfast than prescribed, **tell your doctor or pharmacist or go to the hospital emergency unit at once.**

You may require medical attention.

If you forget to take Nigfast

Do not take a double dose to make up for forgotten individual doses.

4 Possible side effects

Like all medicines, Nigfast can cause side effects, although not everybody gets them. The following side effects may happen with this medicine.

Some side effects could be serious. Stop taking Nigfast and see a doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

- Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome
- Chest pain or tightness with shortness of breath (*may affect between 1 and 10 in every 1000 patients*)
- Breathlessness, difficulty of breathing when lying down, swelling of the feet or legs (*may affect between 1 and 10 in every 1000 patients*)
- Vomiting of blood, bleeding from the bowel (*may affect from less than 1 to 10 in every 10,000 patients*)
- Sudden slurred speech, facial drooping, weakness, disorientation, or speech problems (*may affect from less than 1 to 10 in every 10,000 patients*)
- allergic reactions which can include skin rash, itching, bruising, painful red areas, peeling or blistering, wheezing or shortness of breath (“bronchospasm”), swollen face, lips hands

or fingers, hypotension (low blood pressure) and fainting (*may affect from less than 1 to 10 in every 10,000 patients*)

- Mild cramping and tenderness of the abdomen, starting shortly after the start of the treatment with Nigfast and followed by rectal bleeding or bloody diarrhoea usually within 24 hours of the onset of abdominal pain (frequency not known, cannot be estimated from the available data)

The following side effects have also been reported in patients taking Nigfast

These rare or very rare side effects may affect from less than 1 to 10 in every 10,000 patients

- allergic reactions which can include skin rash, itching, bruising, painful red areas, peeling or blistering, wheezing or shortness of breath (“bronchospasm”), swollen face, lips hands or fingers, hypotension (low blood pressure) and fainting
- stomach pain, indigestion, heartburn, wind, feeling sick (nausea), or being sick (vomiting)
- any sign of bleeding in your stomach or intestine, for example, when emptying your bowels, blood in vomit, or black tarry faeces
- yellowing of your skin or the whites of your eyes
- pain in your abdomen and lower back, with feeling or being sick or loss of appetite (possible signs of pancreatitis)
- persistent sore throat or high temperature
- an unexpected change in the amount of urine produced and/or its appearance
- bruising more easily than usual
- frequent sore throats or infections
- fits, headaches together with a dislike of bright lights, fever and a stiff neck
- headache and dizziness (signs of high blood pressure, hypertension)
- serious skin rashes including Stevens-Johnson syndrome and Lyell’s syndrome
- sudden severe headache, nausea, dizziness, numbness, inability or difficulty to speak, paralysis (possible signs of stroke)
- chest pain (possible sign of heart attack).

Stop taking Nigfast and see a doctor straight away if you notice any of the side effects above.

Other side effects

Common (may affect up to 1 in 10 people)

- stomach pain, heartburn, nausea, vomiting, diarrhoea, indigestion, wind, loss of appetite
- headache, dizziness, vertigo
- skin rash or spots
- raised levels of liver enzymes in the blood.

Rare (may affect up to 1 in 1,000 people)

- stomach ulcers or bleeding (there have been very rarely reported cases resulting in death, particularly in the elderly)
- drowsiness, tiredness
- skin rash and itching
- fluid retention, symptoms of which include swollen ankles.

Very rare (may affect up to 1 in 10,000 people)

Effects on the nervous system:

Tingling or numbness in the fingers, tremor, blurred or double vision, hearing loss or impairment, tinnitus (ringing in the ears), sleeplessness, nightmares, mood changes, depression, anxiety, mental health disorders, disorientation and loss of memory.

Effects on the stomach and digestive system:

Constipation, inflammation of the tongue, taste changes, mouth ulcers, problems with your food pipe, lower gut disorders (including inflammation of the colon).

Effects on the heart, chest or blood:

Palpitations (fast or irregular heart beat), inflammation of blood vessels (vasculitis), inflammation of the lung (pneumonitis), congestive heart failure, blood disorders (including anemia).

Effects on the liver or kidneys:

Kidney or liver disorders, presence of blood or protein in the urine.

Effects on skin or hair:

Skin rashes which may be made worse by exposure to sunlight, hair loss.

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

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. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.
imbpharmacovigilance@imb.ie.

5 How to store Nigfast

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. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package, to protect from moisture.

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

6 Contents of the pack and further information

What Nigfast contains

- The **active substance** in Nigfast powder for oral solution is **diclofenac potassium**. Each sachet contains 50 mg of diclofenac potassium.
- The **other ingredients** are potassium hydrogen carbonate, mannitol, aspartame, saccharin sodium, glyceryl dibehenate, mint flavour, anise flavour.

What Nigfast looks like and contents of the pack

Nigfast is a white to light yellow powder for oral solution. It is available in sachets. Three sets of serrated triplet sachets are packaged in one carton.

Marketing Authorisation Holder

Wisdom Pharmaceutical Technology Co Limited
Wilton Park House, Wilton Place, Dublin 2, Ireland

Manufacturer

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