Package leaflet: Information for the patient

ALLDONE 100 mg effervescent tablets (nimezulide)

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 your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet:

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

1. What AllDone is and what it is used for

AllDone belongs to the group of non-steroidal anti-inflammatory drugs with analgesic (pain relievers) and antipyretic (lowering the temperature) properties. The basis of its action is the inhibition of the cyclooxygenase enzyme, which catalyzes the synthesis of prostaglandins.
This drug is also prescribed for painful menstruation.

Before prescribing AllDone, your doctor will assess the benefits this medicine may give you against your risks of developing side effects.

2. What you need to know before you use AllDone

Do not take AllDone

- if you are allergic to nimesulide or any of the other ingredients of of this medicine (listed in point 6);
- if you have had an allergic reaction (eg bronchospasm, rhinitis, urticaria) after using acetylsalicylic acid (aspirin) or other non-steroidal anti-inflammatory drugs (diclofenac, ibuprofen, indomethacin, ketoprofen, meloxicam, naproxen);
- if you have ever developed fixed drug eruption (round or oval patches of redness and swelling of the skin, blistering, hives and itching) after taking nimesulide;
- if you have had or have any of the following conditions:
  - hepatis impaiment or elevated liver enzymes;
  - active gastritis or ulcer of the duodenum and stomach, gastrointestinal bleeding, cerebrovascular bleeding or other active bleeding or changes in the blood picture;
  - severe blood clotting disorders;
  - severe heart failure;
  - severe renal impairment;
  - if you are taking other medicines that are known to affect the liver, e.g. paracetamol or other painkillers, or treatment with NSAIDs;

- if you are taking drugs or have developed a habit that makes you addicted to drugs or other substances;
- if you are a regular heavy drinker alcohol;
- if you are suffering from fever or flu (feeling generally achy, unwell, chills or shivering or have a temperature);
- if you are pregnant, planning a pregnancy or breast-feeding;
- for children under 12 years.

Medicines such as AllDone may be associated with a small increased risk of heart attack ("myocardial infarction" or stroke).
Any risk is more likely with high doses AllDone and prolonged treatment. Do not exceed the recommended dose or duration of treatment.
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.

Other medicines and AllDone
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Patients are advised not to take other analgesics (analgin, paracetamol, etc.) while using AllDone.
Concomitant use of different non-steroidal anti-inflammatory drugs (diclofenac, ibuprofen, indomethacin, ketoprofen, meloxicam, naproxen) is not recommended.

AllDone is not a substitute for acetylsalicylic acid for the prevention of disorders of the cardiovascular system.

Elderly people are particularly susceptible to the side effects of non-steroidal anti-inflammatory drugs. Therefore, they require appropriate clinical monitoring of cardiac, renal and hepatic function. In case of such injuries or bleeding from the gastrointestinal tract, treatment should be discontinued.

AllDone with food and drinks
Excessive alcohol consumption should be avoided while taking AllDone, as the risk of liver complications increases.

Pregnancy and breastfeeding
Ask your doctor or pharmacist for advice before taking any medicine.

The use of AllDone is contraindicated in the third trimester of pregnancy. It is contraindicated during breastfeeding.
In women who intend to become pregnant or undergo an infertility test, discontinuation of AllDone should be considered due to reversible suppression of fertility.

Driving and using machines
There are no studies on the effects on the ability to drive and use machines.
If you experience any of the described side effects (drowsiness, dizziness, lightheadedness), you should refrain from driving or using machines.

3. How to take AllDone

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

AllDone should be used for the shortest possible period of time, depending on the specific situation and no more than 15 days for each course of treatment.

Adults
Unless otherwise prescribed by your doctor, the usual dose is one tablet AllDone twice a day, dissolved in a glass of water, after a meal.

Adolescents (12-18 years)
There is no need to adjust the recommended adult dose (one tablet AllDone twice a day).

Children (under 12 years)
AllDone is contraindicated for use in children under 12 years.

Patients with impaired renal function:
Based on the pharmacokinetics of nimesulide, no dose reduction is required in patients with mild to moderate renal impairment, whereas in severe renal impairment the use of AllDonen is contraindicated.

Hepatic impairment
AllDone is contraindicated in patients with hepatic impairment.

If you experience fever and/or flu-like symptoms (general feeling of pain, malaise, chills or tremors) during treatment with AllDone, you should stop taking the product and tell your doctor.

If you take more AllDone than you should
In case of overdose of this drug, seek medical attention.

If you forget to take AllDone
Do not take a double dose to make up for a forgotten dose.

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

4. Possible side effects

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

The following side effects have been reported while taking AllDone. According to the frequency, they are classified as very common (>1/10), common (>1/100, <1/10), uncommon (>1/1000, <1/100), rare (>1/10000, <1/1000), very rare (<1/10000), not known (no estimate can be made from the available data).

Blood and lymphatic system disorders	Rare	Anaemia
	Very rare	Hematopoietic disorders, red spots due to subcutaneous bleeding
Immune system disorders	Very rare	Acute allergic reaction/Anaphylactic shock
Mental disorders	Rare	Sleep disorders, nightmares
Nervous system disorders	Very rare	Headache, drowsiness, encephalopathy (severe brain disease)
Eye disorders	Very rare	Visual disturbances
Vestibular disorders	Very rare	Dizziness

Cardiac disorders	Rare	Increased pulse rate
Vascular disorders	Uncommon	High blood pressure
Respiratory, thoracic and mediastinal disorders	Very rare	Asthma, bronchospasm
Gastrointestinal disorders	Very rare	Abdominal pain, indigestion, inflammation of the oral mucosa, black stools, gastrointestinal bleeding, gastric and duodenal ulcers and perforation.
	Uncommon	Bleeding from the stomach or intestines; duodenal or gastric ulcer and rupture of the ulcer.
Hepato-biliary disorders (see section 4.4)	Very rare	Rapidly developing hepatitis/jaundice, biliary disorders
Skin and tissue disorders	Very rare	Urticaria (acute allergic disease), swelling of the face, limbs, tongue and/or throat. Severe skin reactions/erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis
	Uncommon	Fixed drug eruption (may look like round or oval patches of redness and swelling of the skin), blistering (hives), itching
Kidney and urinary tract disorders	Rare	Urinary incontinence/urinary retention; blood in the urine
	Very rare	Renal failure, renal inflammation and decreased urine output
General disorders	Very rare	Hypothermia/lowering of body temperature
Deviations in laboratory studies	Common	Increase in liver enzymes

The risk of side effects can be reduced if AllDone is used for the shortest possible time.
If gastrointestinal bleeding (black stools) occurs or an ulcer develops, AllDone should be discontinued.
AllDone treatment should be discontinued if no improvement or relief of pain is observed.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 national reporting system:

Bulgarian Drug Agency
8 Damyan Gruev Str., 1303 Sofia
Tel.: +359 2 8903417 website:
www.bda.bg

By reporting side affects you can help provide more information on the safety of this medicine.

5. How to store AllDone

Keep out of the reach and sight of children.

AllDone should be stored below 25 °C in a place protected from moisture. After

each use, close the tube tightly.

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

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

6. Contents of the pack and other information

What AllDone contains

- The active substance is: Nimesulide
- The other ingredients are: citric acid, sodium bicarbonate, sorbitol, potassium carbonate, orange flavor, simethicone, saccharin sodium, macrogol-6-glycerol caprylocaprate, sodium lauryl sulfate.

What AllDone looks like and contents of the pack

Each pack contains a box of 2 tubes of 10 effervescent tablets.

Marketing Authorisation Holder and manufacturer

Tchaikapharma High Quality Medicines Inc.
1 G. M. Dimitrov Blvd, Sofia 1172, Bulgaria Tel.: 02/
962 54 54 FAX:
02/ 960 37 03 e-mail:
info@tchaikapharma.com

This leaflet was last approved

Sempember 2022