



## WHAT IS AKEEGA® NIRAPARIB/ABIRATERONE?

- A combination targeted therapy and antihormonal drug used in association with a corticosteroid (prednisone or prednisolone) used to treat some prostate cancers.
- Prescribed and renewed by your oncologist or cancer specialist.
- Available from hospital pharmacies on presentation of your prescription.




Oval shaped, film-coated tablet, two dosages available:

- **50 mg/500 mg:** orange-brown tablet with "N 50A" on one side
- **100 mg/500 mg:** orange tablet with "N 100 A" on one side



- Do not store above 25°C, and keep out of the sight and reach of children.
- Do not take the tablets out of the blister pack to put them in a pillbox.
- Wash your hands carefully before and after handling the tablets.
- Do not throw away opened boxes, please return them to your pharmacist.

## HOW TO TAKE THIS MEDICINE

<b>When?</b>	.....:.....	<b>= 1 dose per day at a set time, not at mealtimes</b> (At least one hour before or two hours after a meal)
<b>How?</b>		Swallow the tablets whole, with water, one after another, at the same time every day. Do not chew, cut, crush or dissolve them.

You can use your **medical diary**\* and a **calendar** to note doses.

Do not stop taking or change how you take your treatment without consulting your doctor.

*This leaflet is not a prescription, please refer to your most recent prescription.*

## IF YOU FORGET TO TAKE YOUR MEDICINE OR VOMIT



- **If you forget to take your medicine and remember the same day**, take the missed dose as soon as possible on the same day. Continue your treatment at the usual time and dose the following day (do not take a double dose). Keep a record in your medical diary\*.
- **If it has been more than one day since your dose was due** do not take the missed dose. Take your next dose at the usual time, do not take a double dose. Keep a record in your medical diary\*.
- **If you throw up**, do not take another dose. Take your next dose at the usual time, do not take a double dose. Keep a record in your medical diary\*.

## INTERACTION WITH OTHER MEDICINES AND OTHER INTERACTIONS

Check with your doctor or pharmacist that the medicines (prescribed or over-the-counter), other substances (foods, spices and plants, including **St. John's Wort**, probiotics, essential oils, food supplements, etc.) and derivative products you use are **compatible with your treatment**. The molecules they contain, their dose and how often they are taken can interact with your treatment and affect its effectiveness and the occurrence of side effects










- You and your partner must use effective methods of contraception (condoms and another method) throughout treatment **and for 4 months after the last dose**.

\*Patient diary available (in French) at [www.omedit-fiches-cancer.fr](http://www.omedit-fiches-cancer.fr)

# WHAT SIDE EFFECTS CAN OCCUR WITH AKEEGA® NIRAPARIB/ABIRATERONE?

Like all medicines, the combination of niraparib and abiraterone may cause side effects, although not everybody gets them.

Side effects	Prevention
 Rashes, sensitivity to light	Use soap-free gel or a dermatological bar. Avoid hot water. Pat dry. Use moisturiser (cream or milk). Avoid sun exposure, particularly between noon and 4pm. Wear protective clothing, even under a parasol (UVA reflection). Use SPF 50+ sun cream, applied 30 minutes before exposure and reapplied every 2 hours.
 Digestive effects: constipation, nausea, vomiting, loss of appetite	Monitor your weight and remember to hydrate (1.5 to 2 L water per day). <b>In case of constipation</b> , eat foods rich in fibre (bran, grains, wholemeal bread, green vegetables, fruit and nuts) and exercise regularly. <b>In case of nausea/vomiting</b> , divide your meals into several small meals and eat slowly. Avoid fatty, fried or spicy foods, and foods that smell strongly. Avoid having an empty stomach (can worsen nausea). Drink between, rather than with, meals. Use your prescribed antiemetics if applicable.
 Low red blood cells, white blood cells and platelets	<b>Low red blood cells:</b> contact your doctor in case of paleness, shortness of breath on exertion or when resting, persistent tiredness, palpitations, dizziness or headaches. <b>Low white blood cells:</b> contact your doctor in case of temperature > 38°C, chills, sweating, cough, shortness of breath/pain when breathing, a burning sensation when urinating, diarrhoea accompanied by fever or any other signs suggesting infection. <b>Low platelets:</b> contact your doctor in case of small red dots on your skin, bruising, nosebleeds, bleeding eyes or gums, or blood in your urine or faeces.
 Joint pain and osteoporosis	Exercise regularly (suitable activities include walking and swimming). Use a walking stick to support your joints. Avoid repetitive movements and strenuous physical effort. Eat foods rich in calcium and vitamin D (dairy products, oily fish, eggs, etc.).
 High blood pressure	Headaches, dizziness, and tinnitus are the first warning signs of high blood pressure. Measure your blood pressure (resting and sitting down, in the morning before breakfast and in the evening before going to bed; take three measurements two minutes apart); keep a record of your results. Exercise regularly (suitable activities) (30 minutes 3 times per week). Limit salt (max. 5 g per day) and alcohol. Eat a diet low in saturated fats (animal fats) and high in fibre.
 Risk of infection (UTI, lung infection)	Limit contact with people with infections. Wash your hands regularly. Disinfect all wounds thoroughly. Contact your doctor in case of temperature > 38°C, cough, shortness of breath/pain on breathing, pain when urinating/foul-smelling urine, change in type/frequency of bowel movements (diarrhoea, constipation), or in case of redness, pain or discharge around your central line, feeding tube or urinary catheter.
 Tiredness, dizziness	Eat a balanced diet. Avoid using psychostimulants (e.g. coffee, tobacco, alcohol). Take care when driving. Rest during the day, while maintaining up to moderate levels of activity. Go to bed at a regular time and get sufficient sleep at night.

Only the most common side effects are listed here. For more information, read the Patient Leaflet included with your medicine or ask your doctor or pharmacist.

You can also ask your [Regional Pharmacovigilance Centre](#) and report any side effects online: [signalement-sante-gouv-fr](https://signalement-sante.gouv.fr)



Remember to go for the lab tests prescribed by your doctor.

## WHAT TO DO IF YOU EXPERIENCE SIDE EFFECTS

- Take the medicine prescribed to counteract the side effects, as prescribed.
- Follow the preventive measures.

Useful contacts:

Contact your doctor rapidly in case of:

- Fever, unusual and/or significant bleeding
- Irregular or rapid heart rate, shortness of breath, rapid weight gain, swollen feet, ankles or legs
- Any persistent or worsening side effect



Note: