NOVARTIS

Pivito®
(alpelisib)

50, 150 and 200 mg film-coated tablets

Patient Information Leaflet

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PIVIKTO® 50 mg film-coated tablets

PIVIKTO® 150 mg film-coated tablets

PIVIKTO® 200 mg film-coated tablets

Alpelisib

Sugar-free

Read all of this leaflet carefully before you start taking PIVIKTO

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- PIVIKTO has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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1. What PIVIKTO is and what it is used for

What PIVIKTO is

PIVIKTO film-coated tablets contain the active substance alpelisib, which belongs to a group of medicines called phosphatidylinositol-3-kinase (PIK3CA) inhibitors and is used to treat certain types of breast cancer.

What PIVIKTO is used for

PIVIKTO is a prescription only medicine that is used for the treatment of patients with advanced hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer whose disease progressed following an endocrine based regimen. PIVIKTO is to be used in combination with fulvestrant, a hormonal anticancer therapy.

Your blood or tumour tissue sample will first be tested for certain changes (mutations) in a gene called PIK3CA, and if the result is positive your cancer is likely to respond to treatment with PIVIKTO.

How PIVIKTO works

PIVIKTO works by blocking the effects of enzymes called phosphatidylinositol-3-kinases (PI3K) which signal cancer cells to grow and multiply. By blocking these enzymes, PIVIKTO can reduce cancer cell growth and the ability to make new cancer cells and can destroy cancer cells.

PIVIKTO has to be used together with another medicine called fulvestrant.

If you have any questions about how PIVIKTO works or why this medicine has been prescribed for you, ask your doctor, pharmacist or healthcare provider.

2. What you need to know before you take PIVIKTO

Follow all of your doctor's instructions carefully, as they may differ from the general information contained in this leaflet.

Do not take PIVIKTO

If you are allergic (hypersensitive) to alpelisib or to any of the other ingredients of PIVIKTO listed in section 6, do not take PIVIKTO.

If you think you may be allergic, ask your doctor for advice.

If you are pregnant.

Tell your doctor or health care provider if you have or ever had any of these before taking PIVIKTO:

- If you have or ever had high levels of sugar in your blood (or signs of an increased sugar levels, such as excessive thirst and dry mouth, urinating more often than usual or higher amounts of urine than usual, tiredness or feeling sick, increased appetite with weight loss).

  Before you start treatment with PIVIKTO your doctor may tell you to also start a prescription medicine to reduce the likelihood of getting high levels of sugar and to reduce the severity of the potential side effect. Follow your healthcare provider's instructions on how to use this prescription medicine.

- If you have or ever have experienced rash, red skin, blistering of the lips, eyes or mouth, skin peeling, with or without fever, which may be possible signs of Stevens-Johnson syndrome (SJS), erythema multiforme (EM) [symmetrical, red, raised skin areas that can appear all over the body], toxic epidermal necrolysis (TEN) [extensive exfoliation of the epidermis and mucous membrane], or drug reaction with eosinophilia and systemic symptoms (DRESS) [an extensive mucocutaneous rash, accompanied by fever, lymphadenopathy, hepatitis, haematologic abnormalities with eosinophilia and atypical lymphocytes].

Tell your doctor or pharmacist immediately if you get any of these symptoms after initiating treatment with PIVIKTO:

- If you notice rash or itching, or experience hives (itchy, raised, red or skin-coloured welts/ wheals on the skin's surface), breathlessness or difficult breathing, wheezing or coughing, light-headedness, dizziness, changes in levels of consciousness, hypotension, skin reddening, facial/throat swelling, or blue discoloration of the lips, tongue or skin (possible signs of severe hypersensitivity reactions).
- If you experience new or changing respiratory problems including difficult or painful breathing, cough, rapid breathing, pain in chest while breathing, blue discolouration of the lips, tongue or skin, or hiccups, which may be signs of non-infectious pneumonitis and pneumonia.
- If you experience signs of increased blood sugar levels, like increased thirst and dry mouth, needing to pass urine frequently, tiredness or feeling sick, increased appetite with weight loss.
- If you experience rash, red skin, blistering of the lips, eyes or mouth, skin peeling, with or without fever, which may be possible signs of Stevens-Johnson syndrome (SJS), erythema multiforme (EM), toxic epidermal necrolysis (TEN), or drug reaction with eosinophilia and systemic symptoms (DRESS).
- If you experience diarrhoea, or if you experience severe abdominal pain or stools with mucus or

blood, which may be signs of inflammation of your intestine (colitis).

Your doctor may need to temporarily interrupt your treatment, reduce your dose or permanently stop your treatment with PIVIKTO.

Monitoring during your treatment with PIVIKTO

You will have regular blood tests before and during treatment with PIVIKTO to monitor the blood sugar level in your body. This sugar level can be affected by PIVIKTO. If necessary, your doctor may decide to temporarily interrupt your treatment or reduce your PIVIKTO dose to allow your blood sugar to recover. Your doctor may also decide to stop treatment permanently. You may also have other blood tests, such as for electrolytes (potassium, calcium) during PIVIKTO treatment.

Older people (65 years of age and older)

You can use PIVIKTO if you are aged 65 years or over at the same dose as for other adults.

Children and adolescents (under 18 years of age)

PIVIKTO is not to be used in children and adolescents under 18 years of age.

Taking other medicines (interactions with other medicinal products)

Always tell your health care provider if you are taking or have recently taken or might take any other medicines, including medicines or supplements obtained without a prescription, because these might interact with PIVIKTO. This includes in particular:

- eltrombopag, a medicine used to treat low platelet count
- medicines used to treat certain types of breast cancers, such as lapatinib, ribociclib
- everolimus, apalutamide, enzalutamide and mitotane, medicines used to treat certain types of cancers
- pantoprazole, a medicine used to reduce the amount of acid produced in your stomach, or heart burn
- midazolam, a medicine used to make you sleepy or to put you to sleep
- rifampicin, a medicine used to treat tuberculosis
- encorafenib, a medicine used to treat a certain type of skin cancer
- warfarin, a medicine used to reduce the clotting ability of the blood
- carbamazepine and phenytoin, medicines used to treat seizures or convulsions
- St. John's Wort, a herbal product used to treat depression and other conditions

PIVIKTO may increase or decrease your blood levels of some other medicines including medicines or supplements obtained without a prescription and/or herbal medicines. Make sure you inform your doctor of all medicines and supplements including herbal medicines you are taking before taking PIVIKTO.

While taking PIVIKTO you should also tell your doctor if you are prescribed any new medicine that you have not taken previously during PIVIKTO treatment.

Ask your doctor or pharmacist if you are not sure whether your medicine is one of the medicines listed above.

Taking PIVIKTO with food and drink (interaction with food and drink)

You should take PIVIKTO every day at the same time, immediately following food.

Female patients who are able to become pregnant and male patients

PIVIKTO may harm your unborn baby. PIVIKTO should not be used during pregnancy. If you are a woman of child-bearing age, your doctor will check with you if you are pregnant and may perform a pregnancy test if necessary before starting treatment with PIVIKTO.

If you may become pregnant, you should use effective birth control during treatment and for at least 1 week after stopping PIVIKTO. Ask your doctor about options of effective birth control.

If you or your female partner become pregnant or think you or she are pregnant after starting treatment with PIVIKTO, immediately tell your doctor.

Male patients should use a condom for intercourse with female partners who are or may become pregnant during treatment, and for at least 1 week after stopping PIVIKTO.

PIVIKTO may reduce fertility in male and female patients.

Pregnancy and breastfeeding

PIVIKTO should not be used during breastfeeding. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine. Your doctor will discuss with you the potential risks of taking PIVIKTO during pregnancy or breastfeeding.

Driving and using machines

Patients are advised to be cautious when driving or using machines in case they experience fatigue or blurred vision during treatment.

3. How to take PIVIKTO

Do not share medicines prescribed for you with any other person.

Always take PIVIKTO exactly as your doctor (or pharmacist) has told you. Your doctor (or pharmacist) will tell you exactly how many tablets to take and which days to take them on. Check with your doctor (or pharmacist) if you are not sure. Do not change the PIVIKTO dose or schedule without first talking to your doctor.

Do not exceed the recommended dose prescribed by your doctor.

How much PIVIKTO to take

- The usual starting dose of PIVIKTO is 300 mg (2 tablets of 150 mg) once daily. Your doctor will tell you exactly how many tablets of PIVIKTO to take.
- Take PIVIKTO once a day, immediately after food.
- If you vomit after you swallow the PIVIKTO tablets, do not take any more tablets until your next scheduled dose.
- Your doctor will tell you the dose of fulvestrant you should take and when you should take it.

Depending on how your body responds to the treatment with PIVIKTO, your doctor may ask you to adjust your dosage. It is very important to follow your doctor's recommendations. If you have certain side effects your doctor may ask you to change to a lower dose or ask you to skip the dose or to discontinue treatment.

When to take PIVIKTO

Taking PIVIKTO at the same time each day will help you to remember when to take your medicine.

How to take PIVIKTO

PIVIKTO tablets should be swallowed whole (tablets should not be chewed, crushed or split prior to swallowing). No tablet should be ingested if it is broken, cracked, or otherwise not intact.

How long to take PIVIKTO

Take PIVIKTO for as long as your doctor tells you to do so.

This is a long-term treatment, possibly lasting for months or years. Your doctor will regularly monitor your condition to check that the treatment is having the desired effect.

If you have questions about how long to take PIVIKTO for, talk to your doctor or to your pharmacist.

If you take more PIVIKTO than you should

If you accidentally take too many tablets, or if someone else accidentally takes your medicine, consult your doctor or pharmacist immediately. If neither is available, contact the nearest hospital or poison centre. Show the PIVIKTO packet. Medical treatment may be necessary.

If you forget to take PIVIKTO

If you forget to take PIVIKTO, you may still take it, immediately following food, up to 9 hours after the time you normally take it. If you remember more than 9 hours after you normally take your PIVIKTO, skip the dose for that day. The next day, take the dose at your usual time. Do not take a double dose to make up for the one that you missed.

If you stop taking PIVIKTO

Stopping your treatment with PIVIKTO may cause your condition to become worse. Do not stop taking PIVIKTO unless your doctor tells you to stop.

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

4. Possible side effects

PIVIKTO can have side effects.

Not all side effects reported for PIVIKTO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PIVIKTO, please consult your health care provider for advice.

Some side effects could be serious

If you experience any serious side effects, **stop taking this medicine and tell your doctor immediately.**

Frequent

- If you feel very thirsty, urinate more often than usual or urinate higher amounts than usual, and/or have increased appetite with weight loss (possible symptoms of hyperglycaemia, glycosylated haemoglobin increased).
- Rash, itching, hives, skin reddening, blue discolouration of the lips, tongue or skin wheezing or coughing, light-headedness, dizziness, changes in levels of consciousness, hypotension, with or without mild generalised itching, breathlessness or difficult breathing, facial/throat swelling (possible symptoms of hypersensitivity).
- Respiratory problems including difficult or painful breathing, cough, rapid breathing, pain in chest while breathing, blue discolouration of the lips, tongue or skin, or hiccups (possible symptoms of pneumonitis).
- Fever; cough; runny nose; enlarged lymph nodes; painful joints; rash; night sweats; weight loss (possible symptoms of low level of lymphocytes, a type of white blood cells).
- Urinating less than usual or a lower amount of urine than usual, swelling in the legs, ankles, and around the eyes, tiredness, confusion, nausea, seizure, chest pain (possible symptoms of acute kidney injury).
- Pain, swelling or numbness of the jaw, a feeling of heaviness in the jaw or loosening of a tooth (possible symptoms of osteonecrosis of the jaw).
- Rash, skin reddening, blistering of lips, eyes or mouth, skin peeling (possible symptoms of erythema multiforme).

Less frequent

- Difficulty breathing, headache, nausea, vomiting (possible symptoms of high level of acids in the blood, ketoacidosis).

- Severe upper stomach pain (possible symptoms of pancreatitis).
- Rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever (possible symptoms of Stevens-Johnson syndrome [SJS]).

Frequency not known: *frequency cannot be estimated from the available data*

- Rash, fever (possible symptoms of drug reaction with eosinophilia and systemic symptoms [DRESS]).
- Facial/throat swelling and difficult breathing (possible symptoms of angioedema, a type of hypersensitivity reaction).
- Diarrhoea, severe abdominal pain, stool with mucus or blood (possible symptoms of colitis).
- Confusion, dry mouth, dry or flushed skin, nausea, vomiting, tiredness, need to pass urine frequently, thirst (possible symptoms of hyperglycaemic hyperosmolar nonketotic syndrome [HHNKS]).
- Redness of the eye, eye pain, sensitivity to light, dark floaters in your field of vision, blurred vision, decrease in vision, small pupil (possible symptoms of uveitis).

Other possible side effects

Other side effects include the following listed below. If these side effects become severe, tell your doctor, pharmacist or healthcare provider.

Frequent

- Painful and frequent urination (possible symptoms of urinary tract infection)
- Tiredness, fatigue, pale skin (possible symptoms of low level of blood cells) (anaemia)

- Loss of appetite
- Headache
- Strange taste in the mouth (dysgeusia)
- Diarrhoea
- Nausea
- Vomiting
- Mouth sores or ulcers with gum inflammation (stomatitis)
- Abdominal pain
- Upset stomach, indigestion (dyspepsia)
- Rash
- Hair loss or hair thinning (alopecia)
- Itching (pruritus)
- Dry skin
- Tiredness (fatigue)
- Pain, redness and swelling of airways or food pipe or genital mucosa (mucosal inflammation)
- Swollen hands, ankles or feet (peripheral oedema)
- Fever (pyrexia)
- Mucosal dryness
- Weight decreased
- Abnormal kidney blood test result (indicated by a high level of creatinine in the blood)

- Gum bleeding, tender or enlarged gums (signs of inflammation of the gums)
- Spontaneous bleeding or bruising (signs of low level of thrombocytes, also called platelets)
- Vision blurred
- Generalised swelling (oedema)
- Dry eye
- Reduced level of calcium in the blood, which may sometimes lead to cramps (hypocalcaemia)
- Reduced level of potassium in the blood, associated with signs of muscle weakness, muscle spasms, abnormal heart rhythm
- Reddening and/or swelling and possibly peeling on the palms and soles of the feet which may be accompanied by tingling sensation and burning pain (signs of hand-foot syndrome)
- Dehydration
- Headache, dizziness (possible symptoms of high blood pressure)
- Swelling of a part (or) all of your arm including fingers, or leg including toes, feeling of heaviness, restricted movement, discomfort, thickening of the skin and recurring infections (possible symptoms of lymphoedema)
- Muscle spasms
- Muscle pain (myalgia)
- Toothache
- Cracked, chapped lips (cheilitis)
- Gingival pain
- Erythema

- Skin inflammation with rash (dermatitis)
- Problems to fall asleep (insomnia)

During PIVIKTO treatment, you may also have side effects of abnormal blood test results which can give your doctor information on the functioning of some parts of your body:

Frequent

- High levels of the following enzymes: gamma glutamyl transferase, alanine aminotransferase (liver enzymes), lipase (pancreatic enzyme)
- High levels of creatinine (chemical compound left over from energy producing processes in your muscles), sugar in blood
- Low levels of lymphocyte (type of white blood cell) and platelet (small cell fragments in our blood that form clots) count in blood
- Low levels of sugar, calcium, potassium, magnesium, haemoglobin, albumin in blood
- Activated partial thromboplastin time (aPTTT: a blood test that characterises coagulation of the blood) increased.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website. By reporting side effects, you can help provide more information on the safety of PIVIKTO.

5. How to store PIVIKTO

- Keep this medicine out of the sight and reach of children.
- Do not take this medicine after the expiry date, which is stated on the box.
- Do not store above 30 °C.
- Store the container in the outer carton to protect the contents from moisture.
- Do not take this medicine if you notice any damage to the packaging or if there are any signs of tampering.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Ask your pharmacist how to dispose of medicines you no longer use.

6. Contents of the pack and other information

What PIVIKTO contains

The **active substance** of PIVIKTO is alpelisib.

The **other ingredients** of PIVIKTO are:

Tablet core: Microcrystalline cellulose, mannitol, sodium starch glycolate, hypromellose, and magnesium stearate.

Coating material: Hypromellose, titanium dioxide, macrogol/polyethylene glycol (PEG), talc, iron oxide red, and iron oxide black.

What PIVIKTO looks like and contents of the pack

PIVIKTO is supplied as film-coated tablets in aluminum blisters, in the following pack sizes:

Packs containing 50 mg and 200 mg film-coated tablets (Multipacks): 28 film-coated tablets (14 of 50 mg and 14 of 200 mg) or 56 film-coated tablets (28 of 50 mg and 28 of 200 mg).

Packs containing 50 mg film-coated tablets: 28 or 56 film-coated tablets.

Packs containing 150 mg film-coated tablets: 28 or 56 film-coated tablets.

Packs containing 200 mg film-coated tablets: 14 or 28 film-coated tablets.

Film-coated tablets: 50 mg, 150 mg and 200 mg alpelisib.

- 50 mg: Light pink, unscored, round, curved film-coated tablet with bevelled edges, imprinted with “L7” on one side and “NVR” on the other side. Each film-coated tablet contains 50 mg of alpelisib.
- 150 mg: Pale red, unscored, ovaloid, curved film-coated tablet with bevelled edges, imprinted with “UL7” on one side and “NVR” on the other side. Each film-coated tablet contains 150 mg of alpelisib.
- 200 mg: Light red, unscored, ovaloid, curved film-coated tablet with bevelled edges, imprinted with “YL7” on one side and “NVR” on the other side. Each film-coated tablet contains 200 mg of alpelisib.

Holder of the Certificate of Registration

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