

PD-1 inhibitor – Patient information

PD-1 inhibitors are medication that help the immune system fight cancer cells. PD-1 is a molecule in the body that cancer cells can bind to and inhibit the immune system. Pembrolizumab (Keytruda®) and nivolumab (Opdivo®) are antibodies (a type of human protein) that block the cancer cells from binding to and activating PD-1. Nivolumab therefore helps the body to reactivate the immune system and to fight the cancer cells.

Immunotherapy with PD-1 inhibitors pembrolizumab and nivolumab is currently approved in Norway for the treatment of melanoma (melanoma cancer) and several other kinds of cancer.

Who can get the treatment?

Cortisone treatment (Medrol®/prednisolone/dexamethasone®) is immune-inhibiting, and may reduce the effectiveness of ipilimumab and nivolumab. Therefore, there is an upper dose limit corresponding to a maximum of 10 mg of prednisolone per day. The treatment cannot be given to pregnant women. It is best not to give the treatment to patients with HIV, active hepatitis or to patients who have treatment-intensive autoimmune diseases. Patients with brain proliferation can only receive treatment if they are asymptomatic and do not require steroids.

The treatment can be given as an additional treatment after having operated lymph node(s) with metastasis, or in metastatic disease. As an additional treatment, it is given for 1 year, and as a treatment for spreading (metastasis) for up to 2 years. If serious side effects appear or the treatment does not have the desired effect, the treatment will be stopped. In the event of serious side effects, one may decide to postpone the treatment or discontinue it altogether.

How can I prepare?

You should have a relatively new CT scan from the neck to the pelvis (possibly pet-CT). The examination is used as a basis for comparison of further disease evaluations. Some people also do an MRI scan of the head.

How is the treatment executed?

You must arrive the day before the treatment to have blood tests done.

Before the start of the treatment, a needle is inserted into a vein on your arm. The treatment is given as an intravenous infusion for approximately 30 minutes. The treatment is usually well tolerated, and you can return home after the treatment has ended.

Nivolumab is given every 2–4 week, and pembrolizumab every 3–6. The treatment is given for up to 2 years for patients with metastasis, and for 1 year if it is given as an additional treatment after surgery.

Side effects

The side effects of immunotherapy are different from the side effects from chemotherapy. Immune-related side effects may occur from the first treatment with a PD-1 inhibitor, and for about half a year after the last course.

Side effects are experienced by about 50 % of the patients, and are usually mild, but can develop into severe and need intensive treatment. Serious side effects occur in approximately 5 % of the patients.

It is important to get in contact with the hospital as soon as possible if you experience any of these symptoms:

Skin symptoms

The treatment may cause a slight rash or redness on your skin. Your doctor may prescribe an ointment if your skin becomes irritated, and if it itches you can get anti-itching tablets. In case of a stronger rash, consult your doctor.

Some people experience changes in hair and skin pigmentation (vitiligo). This is harmless, and has only cosmetic consequences.

Diarrhea

Signs or symptoms of intestinal inflammation (colitis) that may worsen to bleeding or cause cavities in the intestine

- diarrhea (watery, loose or soft stools), vomiting or nausea
- increase in the number of bowel movements
- blood in the stool or stool of a darker color
- pain or tenderness in the abdomen, fever

Heavy breathing

Heavy breathing may be an expression of pneumonia:

- a newly formed cough
- increased heavy breathing

Other side effects

- fatigue can be experienced on the treatment day, or sometimes a few days later
- tenderness in the muscles or joints
- hormonal disruptions

Rare side effects

- weakness in legs, arms or face
- numbness or tingling sensation in the hands or feet
- red and painful eyes
- impact on liver or kidneys
- increased tendency to bleed or to get bruises

After treatment

The effect of the treatment will be checked every 3 months with CT from the neck to the groin, some must also take MRI of the head.

One to two weeks after the CT/MR examination, you will be given an appointment with a doctor at the outpatient clinic for the results of the CT/MR, clinical examination and blood tests. In the event of stable disease/recovery, you can continue treatment.