



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## EPAR summary for the public

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# Tookad

## padeliporfin

This is a summary of the European public assessment report (EPAR) for Tookad. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Tookad.

For practical information about using Tookad, patients should read the package leaflet or contact their doctor or pharmacist.

### What is Tookad and what is it used for?

Tookad is a medicine for treating men with low-risk prostate cancer, where the cancer affects only one side of the prostate and patients would normally be expected to survive for at least 10 years.

Tookad contains the active substance padeliporfin.

### How is Tookad used?

Tookad is given as an injection into a vein over 10 minutes and subsequently activated in the prostate by laser light using a procedure known as vascular-targeted photodynamic (VTP) therapy.

During VTP therapy, the patient is put under general anaesthesia so that optical fibres can be inserted into the prostate using hollow needles. Laser light is then shone along the fibres onto the cancer, where it activates the medicine.

Tookad can only be used in a hospital by healthcare professionals trained to carry out VTP therapy. The medicine can only be obtained with a prescription. For further information, see the package leaflet.



## **How does Tookad work?**

Once activated, the active substance in Tookad, padeliporfin, triggers the production of high levels of substances known as oxygen radicals, which cause the destruction of the vessels supplying blood to the cancer followed by rapid death of the cancer cells.

## **What benefits of Tookad have been shown in studies?**

A study of 413 men with low-risk prostate cancer found that Tookad with VTP therapy was effective at clearing signs of prostate cancer in many patients. After 24 months, 49% of patients treated with Tookad had no definitive signs of cancer in their tissues compared with 14% of patients who received no treatment.

In addition, Tookad helped delay the progression from low-risk prostate cancer to a higher risk cancer. On average progression occurred after 28 months in patients treated with Tookad compared with 14 months in those who did not receive treatment.

## **What are the risks associated with Tookad?**

The most common side effects with Tookad, which can affect up to 1 in 4 patients, are problems with urinating (pain, inability to pass urine, strong urge to pass urine, frequent urination and incontinence), sexual problems (erectile dysfunction and ejaculation failure), blood in urine, urinary tract infection, and pain and bleeding around the genital area.

Other side effects include those related to the general anaesthesia (such as brief memory loss and heart rate abnormalities) and mild liver effects (such as raised liver enzymes). For the full list of side effects reported with Tookad, see the package leaflet.

Tookad must not be used in men who have undergone certain procedures on the prostate, men diagnosed with cholestasis (a liver problem) or those with exacerbations (flare-ups) of inflammatory bowel disease. It must also not be used in men who are not suitable for general anaesthesia or invasive procedures, such as VTP therapy. For the full list of restrictions, see the package leaflet.

## **Why is Tookad approved?**

A study found that around half of patients with low-risk prostate cancer treated with Tookad had no definitive signs of the cancer after 2 years. The medicine also doubled the average time it took for a low-risk cancer to progress to a higher risk cancer, which may require more extensive treatment.

The side effects seen with Tookad were mainly caused by the insertion of optical fibres during the VTP therapy. Most were mild, resolving within a few days. It is, however, unclear what effect Tookad treatment will have on future treatments for prostate cancer and more study is needed to find out if such treatments are compromised.

The European Medicines Agency concluded that the benefits seen with Tookad are greater than its risks and recommended that it be approved for use in the EU.

## **What measures are being taken to ensure the safe and effective use of Tookad?**

The company that markets Tookad will make educational material available to patients and healthcare professionals to raise awareness of the medicine's risks and provide them with information about VTP therapy.

In addition, the company will complete new studies to assess the long-term benefits and safety of the medicine, including any effects of Tookad on future treatments.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Tookad have also been included in the summary of product characteristics and the package leaflet.

### **Other information about Tookad**

The European Commission granted a marketing authorisation valid throughout the European Union for Tookad on 10 November 2017.

The full EPAR for Tookad can be found on the Agency's website: [ema.europa.eu/Find\\_medicine/Human\\_medicines/European\\_public\\_assessment\\_reports](http://ema.europa.eu/Find_medicine/Human_medicines/European_public_assessment_reports). For more information about treatment with Tookad, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2017.