LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Palsiva
(palbociclib)

SE/H/2705/001-003/DC

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Summary Public Assessment Report

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palbociclib

Film-coated tablet, 75 mg, 100 mg, 125 mg

This is a summary of the public assessment report (PAR) for Palsiva. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Palsiva and what is it used for?

The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Ibrance.

Palsiva is used to treat patients with certain types of breast cancer (hormone receptor-positive, human epidermal growth factor receptor 2-negative) which have spread beyond the original tumour and/or to other organs. It is given together with aromatase inhibitors or fulvestrant, which are used as hormonal anticancer therapies.

How does Palsiva work?

Palsiva is an anticancer medicine containing the active substance palbociclib.

Palbociclib works by blocking proteins called cyclin-dependent kinase 4 and 6, which regulate cell growth and division. Blocking these proteins can slow down growth of cancer cells and delay the progression of your cancer.

How is Palsiva used?

The pharmaceutical form is film-coated tablet for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Palsiva have been shown in studies?

Because the product is a generic medicine, studies have been limited to tests to determine that it is bioequivalent to the reference medicine, Ibrance. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Palsiva?

Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Palsiva approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Ibrance, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Palsiva?

A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

For more details, please see the full PAR for Palsiva on the following website: MRI - Home.

Other information about Palsiva

The full PAR for Palsiva can be found on the following website: MRI - Home. For more information about treatment with Palsiva, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2026-04.