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# Copiktra (*duvelisib*)

An overview of Copiktra and why it is authorised in the EU

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

Copiktra is a cancer medicine used to treat chronic lymphocytic leukaemia (CLL, a cancer of a type of white blood cells called B lymphocytes) and follicular lymphoma (another cancer that affects B lymphocytes).

In CLL, Copiktra is used in patients whose disease has either come back or not improved after at least two other treatments. In follicular lymphoma, it is used in patients whose disease has not improved after at least two other treatments.

Copiktra contains the active substance duvelisib.

## How is Copiktra used?

Copiktra can only be obtained with a prescription and it should be prescribed by a doctor experienced in the use of cancer medicines.

Copiktra is available as capsules to be taken by mouth; the recommended dose is 25 mg twice a day. Treatment should be continued for as long as the patient improves or remains stable and the side effects are tolerable. The doctor may reduce the dose or stop treatment temporarily or permanently if certain side effects occur. The dose may also need to be reduced in patients taking other medicines that increase the amount of duvelisib in the body.

Any infection should be treated before starting treatment with Copiktra and patients should also be monitored for infection during Copiktra treatment.

For more information about using Copiktra, see the package leaflet or contact your doctor or pharmacist.

## How does Copiktra work?

The active substance in Copiktra, duvelisib, blocks the effects of certain enzymes (called PI3K-delta and PI3K-gamma) that are overactive in blood cancers. These enzymes enable the growth and survival of the cancer cells. By blocking the effects of the enzymes, duvelisib causes the cancer cells to die, thereby delaying or stopping the progression of the cancer.

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## What benefits of Copiktra have been shown in studies?

A main leukaemia study showed that Copiktra was more effective than another cancer medicine, ofatumumab, in patients with CLL that had not improved or had come back after at least 2 other treatments. Among the 196 such patients in the study, those treated with Copiktra lived on average 16 months before the cancer got worse compared with 9 months in those treated with ofatumumab.

In a second main study of lymphoma, Copiktra was effective in producing a response in patients with follicular lymphoma whose cancer had not improved after 2 previous treatments: 40% of these patients (29 of 73) responded to treatment.

## What are the risks associated with Copiktra?

The most common side effects with Copiktra (which may affect more than 2 in 10 people) are diarrhoea or colitis (inflammation in the large bowel), neutropenia (low levels of neutrophils, a type of white blood cell), rash, tiredness, fever, cough, nausea (feeling sick), upper respiratory tract infection (nose and throat infection), pneumonia (infection of the lungs), musculoskeletal pain (pain in the muscle and bones) and anaemia (low red blood cell count).

The most common serious side effects were pneumonia, colitis and diarrhoea.

For the full list of side effects and restrictions with Copiktra, see the package leaflet.

## Why is Copiktra authorised in the EU?

Copiktra was shown to be effective in delaying worsening of the disease in patients with CLL that had not improved or had come back after at least 2 previous treatments. In addition, the medicine was effective in patients with follicular lymphoma that had not improved after at least 2 previous treatments. The safety of Copiktra was considered acceptable. The European Medicines Agency therefore decided that Copiktra's benefits are greater than its risks and it can be authorised for use in the EU.

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

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

As for all medicines, data on the use of Copiktra are continuously monitored. Side effects reported with Copiktra are carefully evaluated and any necessary action taken to protect patients.

## Other information about Copiktra

Copiktra received a marketing authorisation valid throughout the EU on 19 May 2021.

Further information on Copiktra can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/copiktra.

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