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# Xospata® (active substance: gilteritinib)

First authorisation in Switzerland: 24.09.2020

## Medicinal product for the treatment of relapsed or refractory acute myeloid leukaemia with a certain genetic mutation

## About the medicine

The medicinal product Xospata, containing the active substance gilteritinib, is a film-coated tablet.

Xospata, taken alone, has been authorised for the treatment of adult patients whose acute myeloid leukaemia, with a certain genetic alteration known as the FMS-like tyrosine kinase 3 mutation, or FLT3 mutation for short, has either relapsed or has not responded to other treatments.

The FLT3 gene gives instructions for a protein with the same name that sits on the cell's outer surface. Other proteins can bind to it, acting like an "on" switch telling the cell to grow and make more copies of itself.

Acute myeloid leukaemia is a type of blood cancer that originates in the bone marrow. It is rapidly fatal if left untreated. This particular genetic mutation, found in 25 to 30 % of patients, has been linked to a higher risk of relapse.

## Mode of action

The active ingredient in Xospata, gilteritinib, blocks the action of the FLT3 protein. FLT3 is a member of a family of proteins known as tyrosine kinases that act like on-off switches in cells. In this case, the FLT3 protein targeted by gilteritinib is responsible for the growth of white blood cells. In patients with a mutation in this protein, the body goes into overdrive and produces too many white blood cells. Gilteritinib works by blocking these proteins and slowing cancer progression.

## Use

Xospata is available by prescription only. Treatment with this medicine must be started and monitored by a physician experienced in cancer therapy.
The medicine comes as a 40 mg tablet. The recommended dose of Xospata is 120 mg, or 3 tablets, per day taken with or without food.

Certain tests, including blood tests and electrocardiograms, should be performed both before the start of and during treatment.

Xospata is appropriate for use in adults with a confirmed genetic alteration known as the FMS-like tyrosine kinase 3 mutation.

It may take up to 6 months for patients to see a response to the treatment. The dose may be adjusted depending on a patient's tolerance of the medication.

## Efficacy

The efficacy of Xospata, with the active substance gilteritinib, was investigated in a trial involving 371 patients, 247 of whom received gilteritinib and 124 chemotherapy.

Study participants were adults with acute myeloid leukaemia who had an FMS-like tyrosine kinase 3 mutation and who either relapsed after one prior line of treatment, or whose disease had not responded to initial treatment.

The medicine gilteritinib was compared to standard chemotherapy. Patients treated with the active ingredient gilteritinib lived for about 3.7 months longer than patients who received standard chemotherapy (median 9.3 months compared with 5.6 months). Additionally, 35 % of patients who had previously needed regular blood transfusions no longer needed them, and 59 % of patients who had not needed transfusions remained without a need for them while being treated with gilteritinib.

## Precautions, undesirable effects & risks

Xospata may not be used if the patient has a hypersensitivity to the active ingredient gilteritinib or any other substance in the medicine.

The most common side effects, occurring in at least 1 in 10 patients, were diarrhoea, fatigue, nausea, constipation, cough, swelling of arms and/or legs, difficulty breathing, low blood pressure, dizziness, joint stiffness and muscle aches and pains, as well as abnormal liver enzyme test results.
Gilteritinib, the active ingredient in Xospata, has been linked to a life-threatening complication called differentiation syndrome. Symptoms include fever, difficulty breathing, excess fluid around the heart or lungs, low blood pressure, rapid weight gain, and rash.

Other complications linked to this medicine include swelling in the brain, known as posterior reversible encephalopathy syndrome, and abnormal heart rhythms.

All precautions, risks and other possible undesirable effects are listed in the Information for healthcare professionals.

## Why the medicine has been authorised

Acute myeloid leukaemia is a form of blood cancer that is quickly fatal if left untreated.
The studies showed that patients treated with Xospata survived longer.
Comparing the side effects between gilteritinib and chemotherapy was challenging because fewer participants received chemotherapy and four different chemotherapy regimens were administered (two high-dose and two low-dose regimens).
Patients treated with gilteritinib reported more side effects than those treated with low-dose chemotherapy. Side effects were similar when comparing gilteritinib with high-dose chemotherapy.

Taking into account all the available data, the benefits of Xospata outweigh the risks. Swissmedic has therefore authorised the medicine Xospata with the active ingredient gilteritinib for use in Switzerland.

## Further information on the medicinal product

Information for healthcare professionals:
Information for healthcare professionals Xospata®

Healthcare professionals (doctors, pharmacists and others) can answer any further questions.

This information is correct as at the date above. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

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