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# Sprycel (*dasatinib*)

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

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

Sprycel is a cancer medicine. It is used to treat adults with the following types of leukaemia (cancer of the white blood cells):

- chronic myeloid leukaemia (CML) in the 'chronic' phase in newly diagnosed patients who are 'Philadelphia chromosome positive' (Ph+). In CML, granulocytes (a type of white blood cell) start growing out of control. Ph+ means that some of the patient's genes have rearranged themselves to form a special chromosome called the Philadelphia chromosome which produces an enzyme, Bcr-Abl kinase that leads to the development of leukaemia.
- CML in 'chronic', 'accelerated' and 'blast' phases. Sprycel is used when other treatments including imatinib (another cancer medicine) do not work or cause troublesome side effects;
- Ph+ acute lymphoblastic leukaemia (ALL), where lymphocytes (another type of white blood cell) multiply too quickly, or in 'lymphoid blast' CML. Sprycel is used when other treatments do not work or cause troublesome side effects.

Sprycel is also used in children to treat:

- newly diagnosed Ph+ CML in the 'chronic' phase, or Ph+ CML when other treatments including imatinib cannot be given or have not worked;
- newly diagnosed Ph+ ALL in combination with chemotherapy (cancer medicines).

Sprycel contains the active substance dasatinib.

## How is Sprycel used?

Sprycel can only be obtained with a prescription and treatment should be started by a doctor who has experience in the diagnosis and treatment of leukaemia.

Sprycel is available as tablets (20, 50, 70, 80, 100 and 140 mg) and a powder to make up a suspension (10 mg/ml) to be taken by mouth. It is taken once a day, consistently either in the morning or in the evening. The doses for Sprycel tablets and suspension are not the same.

The starting dose depends on the condition being treated and, for children, their body weight. The dose is then gradually increased until the disease is controlled well enough. In children with ALL who

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are also receiving other cancer medicines, a fixed dose of Sprycel is used throughout their treatment. The doctor may reduce the dose or interrupt treatment if blood cell counts are too low or certain side effects occur. Treatment is stopped if the medicine no longer controls the condition or if the patient cannot take the medicine because of side effects.

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

## How does Sprycel work?

The active substance in Sprycel, dasatinib, belongs to a group of medicines that block enzymes known as protein kinases. Dasatinib acts mainly by blocking the Bcr-Abl protein kinase. This enzyme is produced by leukaemia cells, and causes them to multiply uncontrollably. By blocking Bcr-Abl kinase, as well as other kinases, Sprycel helps to reduce the number of leukaemia cells.

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

The five main studies of Sprycel in adults involved 515 patients, all of whom had received treatment with imatinib, which had not worked or had stopped working. None of these studies compared Sprycel with another medicine. Most of these studies assessed how well the leukaemia responded to treatment by measuring the levels of white cells and platelets in the blood, to see if they were returning to within normal levels, and by measuring the number of white blood cells that contained the Philadelphia chromosome, to see if it was decreasing.

Two studies were in patients with chronic CML (198 and 36 patients), one was in accelerated CML (120 patients), one was in myeloid blast CML (80 patients), and one was in Ph+ ALL and lymphoid blast CML (81 patients).

In the larger main study of patients with chronic phase CML, blood levels of platelets and white blood cells returned to within normal values in 90% of the patients. In patients with CML in other phases (accelerated, myeloid blast and lymphoid blast) and in ALL, around 25 to 33% of the patients had complete response. In addition, the number of white blood cells containing the Philadelphia chromosome was reduced in around 33 to 66% of treated patients in the five main studies.

Two further studies compared the effects of Sprycel taken once or twice a day, one in 670 patients with chronic phase CML and the other in 611 patients with advanced phase CML or Ph+ ALL. Once- and twice-daily Sprycel had similar effectiveness, but the once-daily dose caused fewer side effects.

A further study involving 519 patients compared Sprycel with imatinib in treating newly diagnosed Ph+ patients with chronic phase CML who had not received any previous treatment. Sprycel was more effective than imatinib: within one year, 77% of patients receiving Sprycel no longer had the Philadelphia chromosome in their blood cells, compared with 66% of patients receiving imatinib.

Another main study looked at the effectiveness of Sprycel in 113 children with Ph+ chronic phase CML, including 29 patients who could not use imatinib or it had not worked, as well as 84 newly diagnosed children who had not been previously treated. A response was seen in around 90% of patients who could not use imatinib or it had not worked, and in 94% of newly diagnosed patients.

In a study involving 106 children and adolescents with newly diagnosed Ph+ ALL, patients were treated with Sprycel and chemotherapy. The main measure of effectiveness was the proportion of patients who did not have an unwanted event within 3 years of treatment. Such events were: any sign of the disease in bone marrow, return of the disease anywhere in the body, a second cancer or death. Among patients treated with Sprycel and chemotherapy, 66% did not have an unwanted event. In

comparison, using results of previous studies, the figure was 49% in patients who had received chemotherapy alone and 59% in patients who had received imatinib and chemotherapy.

## What are the risks associated with Sprycel?

The most common side effects with Sprycel (seen in more than 1 patient in 10) are infection, suppression of the bone marrow (decreasing numbers of blood cells), headache, haemorrhage (bleeding), pleural effusion (fluid around the lungs), dyspnoea (difficulty breathing), diarrhoea, vomiting, nausea (feeling sick), abdominal pain (belly ache), skin rash, musculoskeletal pain, tiredness, swelling in the legs and arms and in the face, fever. For the full list of side effects and restrictions with Sprycel, see the package leaflet.

## Why is Sprycel authorised in the EU?

The European Medicines Agency decided that Sprycel'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 Sprycel?

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

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

## Other information about Sprycel

Sprycel received a marketing authorisation valid throughout the European Union on 20 November 2006.

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

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