



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/224390/2018 Rev. 1  
EMA/H/C/004309

**Update of 27 April 2018:**

The applicant for Dexxience has requested a re-examination of the CHMP's March 2018 opinion. Upon receipt of the grounds of the request, the CHMP will re-examine its opinion and issue a final recommendation.

23 March 2018

## Refusal of the marketing authorisation for Dexxience (betrixaban)

On 22 March 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a negative opinion, recommending the refusal of the marketing authorisation for the medicinal product Dexxience, intended for the prevention of venous thromboembolism.

The company that applied for authorisation is Portola Pharma UK Limited. It may request a re-examination of the opinion within 15 days of receipt of notification of this negative opinion.

### What is Dexxience?

Dexxience is a medicine that contains the active substance betrixaban. It was to be available as capsules.

### What was Dexxience expected to be used for?

Dexxience was expected to be used to prevent venous thromboembolism (formation of blood clots in veins). It was to be used in adults admitted to hospital for the treatment of a recent medical illness. These patients may be at high risk of blood clots because of reduced mobility during their hospital treatment as well as other underlying conditions that increase the risk.



## **How does Dextience work?**

Blood clots that start off in the veins can move to another part of the body such as the lungs and the brain where they can cause severe problems with breathing or stroke.

The active substance in Dextience, betrixaban, is a 'factor Xa inhibitor'. This means that it blocks factor Xa, a protein which is involved in the production of thrombin. Thrombin is needed for blood to clot. By blocking factor Xa, the medicine reduces the levels of thrombin in the blood and this reduces the risk of blood clots forming in blood vessels.

## **What did the company present to support its application?**

The company presented the results of one main study involving over 7,500 adults who had been admitted to hospital for a recent medical illness. The patients were at high risk of venous thromboembolism because of their age, presence of a protein indicating a blood clot, previous blood clots, cancer and lack of mobility during hospital treatment. Treatment with Dextience was compared with enoxaparin, another medicine for preventing blood clots. The main measure of effectiveness was the occurrence of deep vein thrombosis (blood clot in a deep vein, usually in the leg), or of pulmonary embolism (blood clot in the lung), or death from a blood clot.

## **What were the CHMP's main concerns that led to the refusal?**

The CHMP considered that the main study did not satisfactorily show that Dextience's benefits outweighed its risk when used for preventing blood clots in patients admitted to hospital for recent medical illness. Moreover, the results of the study were not considered reliable because some results of tests for blood clots were not available. Patients treated with Dextience had more episodes of bleeding than those treated with the comparator medicine. This was considered an important concern given that the medicine was expected to be used in patients with serious underlying conditions. Therefore, the CHMP concluded that the benefits of Dextience did not outweigh its risks and recommended that it be refused marketing authorisation.

## **What consequences does this refusal have for patients in clinical trials?**

The company informed the CHMP that there are no consequences for patients currently included in clinical trials with Dextience.

If you are in a clinical trial and need more information about your treatment, contact the doctor who is treating you in the clinical trial.