7 December 2015
EMA/677776/2015

Measures to avoid medication errors with Blincyto

Educational materials to help use the medicine correctly

Educational materials will be provided to patients, their carers and healthcare professionals to ensure that the cancer medicine Blincyto (blinatumomab) is used in a safe and effective way, and to prevent the risk of medication errors.

Blincyto is used for the treatment of adults with a rare type of blood cancer, 'acute lymphoblastic leukaemia'. It is available as a powder that is made into a solution and then given to the patient as an infusion (drip) into a vein. Blincyto is infused continuously for 4 weeks (one treatment cycle) using a pump device. The pump contains an infusion bag with the medicine; this bag will be changed periodically. The doctor will determine how often to change the infusion bag and this will make the infusion go faster or slower.

Medication errors have been reported in 3.2% (6 out of 189) of patients in the main study that led to the approval of Blincyto in the EU. Most of these errors occurred either during the preparation of Blincyto's solution for infusion or during the use of the infusion pump. In most cases errors resulted in an overdose that did not cause side effects and when side effects did occur they were mostly mild in severity and resolved. However, it was considered necessary to provide educational materials to ensure that the medicine will be used correctly in clinical practice.

Information for patients and carers

- Blincyto is given as an infusion (drip) into a vein continuously for the 4 weeks of each treatment cycle using an infusion pump. It is usually given for two treatment cycles. The pump is connected to the patient 24 hours a day for 4 weeks. For the first 4-week treatment cycle, patients should remain in hospital for at least 9 days, and for the second cycle for at least 2 days. The doctor will decide if treatment can be continued at home after the initial stay in hospital.
- Patients and carers are advised to be very careful with the pump and tubing:
  - Patients/carers should ensure the tubing stays connected to the pump at all times and that the tubing does not become tangled, twisted or blocked (e.g. by lying on them) at any time. If blood is found in the tubing, patients should contact the doctor or nurse immediately.
  - Patients/carers should never unlock the pump or change the pump settings.

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  - If the pump alarm goes off at any time, if the pump stops working unexpectedly or if the infusion bag empties too quickly, patients/carers should contact the doctor or nurse immediately.
  - Patients/carers should keep the pump, the tubing, and area where it is inserted into the vein dry at all times.
- In case of any concern regarding how the pump is working or patients/carers should contact the doctor or nurse.

Information for healthcare professionals

- In the pivotal clinical study medication errors were observed in 3.2% (6 out of 189) of subjects. The majority of these errors were reported as overdoses and occurred primarily due to errors with the infusion pump or the preparation of Blincyto. Most errors of overdose did not result in an adverse event. When adverse events occurred they were consistent with the known safety profile, mild in severity, and resolved.
- Doctors should advise patients not to unlock the pump, modify the pump's settings or try to fix the pump if it seems to be working incorrectly, and to contact the doctor or nurse immediately in case of any problem with the pump.
- Pharmacists should follow the recommendations in the product information and in the educational materials regarding how to prepare the correct dose of Blincyto and how to prepare the solution for infusion under aseptic conditions.
- Nurses should follow the recommendations in the product information and in the educational materials regarding how to administer Blincyto safely, programme the pump, change the bag in the pump and clean the area where the drip is inserted into the vein. Nurses should also advise patients/carers not to change the pump settings and on the need to keep the drip area clean.

More about the medicine

Blincyto is a cancer medicine used to treat patients with acute lymphoblastic lymphoma (ALL, a type of blood cancer). Blincyto is used when the ALL has come back or has not responded to previous treatment. It is used when the patients are 'Philadelphia-chromosome-negative' (Ph-). This means that some of their genes are not re-arranged forming a special chromosome called the Philadelphia chromosome, which is often found in patients with ALL. Blincyto contains the active substance blinatumomab.

More information on Blincyto can be found on the Agency's website: Human medicines/European public assessment reports.