



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 June 2015
EMA/386551/2015

EMA recommends measures to ensure safe and effective use of Strensiq

Colour coding of different presentations and booklet for patients to ensure correct use and avoid medication errors

Several measures have been put in place to ensure the safe and effective use of Strensiq (asfotase alfa) and to reduce the risk of medication errors. Strensiq is used for the treatment of a rare inherited bone disease called hypophosphatasia. It is given by injection under the skin either six times a week or three times a week and will be available in vials of different strengths and volumes. Before Strensiq is given the required dose needs to be drawn up into a syringe. As the medicine is for use in growing children and the dose depends on the child's bodyweight, the doctor will need to adjust the dose frequently. Medicines such as Strensiq that require frequent dose adjustments and are available in different strengths and volumes are more likely to lead to medication errors. These could be due to mistakes in calculating the dose and confusion between the different presentations, which could lead to over- or under-dosing. The medicine's carton and label will therefore be colour-coded to better distinguish between presentations. In addition, booklets and animated injection guides with detailed information on the correct use of the medicine will be available to patients and carers.

Further information on the measures that have been introduced to ensure the safe use of Strensiq are described below.

Information for patients and carers

- Strensiq's dose depends on bodyweight. As the child grows and gains weight, the dose will need to be adjusted.
- To facilitate adjustment, Strensiq is available in different strengths and volumes.
- To help differentiate between them, the carton and the labels on the vials are colour-coded as follows:

12mg/0.3ml **18mg/0.45ml** **28mg/0.7ml** **40mg/1ml**

80mg/0.8ml

- Unless your doctor changes your dose, you should always use the same coloured presentation (or combination of presentations).



- If you give the medicine to yourself or to your child, your doctor will tell you which vial (or combination of vials) to use and train you on how to withdraw and inject the correct dose from the vial(s).
- You will be given a patient information booklet, which you should read carefully. An animated injection guide will also be available.
- If you have any questions about the treatment, speak to your doctor or pharmacist.

Information for healthcare professionals

- Strensiq is available in vials in two strengths and five volumes to meet the different dosing requirements:
 - The 40 mg/ml strength is available in the following volumes: 0.3 ml (containing 12 mg asfotase alfa); 0.45 ml (18 mg); 0.7 ml (28 mg) and 1 ml (40 mg);
 - The 100 mg/ml strength is available in one volume: 0.8 ml (containing 80 mg asfotase alfa).
- To help differentiate between the different presentations, the cartons and the labels on the vials will be colour-coded as follows:



- Always ensure that the prescription includes the dose in milligrams. Prescribing the dose in millilitres only may lead to medication errors as two different strengths are available.
- The product information contains a dosing chart that should be used when converting the dose into the volume needed to be injected.
- Before patients and carers can administer the medicine at home, you need to explain to them how many millilitres they need to withdraw from the vial(s), how to withdraw the dose from the vial(s) and how to inject it.
- A booklet and an animated injection guide will also be available to facilitate the training.

More about the medicine

Strensiq is a medicine used to treat patients with hypophosphatasia that started in childhood. Hypophosphatasia is a rare inherited disease caused by defects in the gene responsible for producing 'alkaline phosphatase (ALP)', an enzyme that plays a key role in creating and maintaining healthy bones, and managing calcium and phosphate in the body. Patients with hypophosphatasia do not have enough normal functioning ALP, which leads to weak bones. Asfotase alfa, the active substance of Strensiq, is a modified copy of the human enzyme ALP and serves as a replacement for the defective enzyme, thereby increasing blood levels of normal functioning ALP.

More information on Strensiq can be found on the Agency's website: ema.europa.eu/Find_medicine/