



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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HorStem (*equine umbilical cord mesenchymal stem cells*)

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

What is HorStem and what is it used for?

HorStem is a veterinary medicine used to treat lameness associated with mild to moderate degenerative joint disease (osteoarthritis) in horses. It contains the active substance equine umbilical cord mesenchymal stem cells. These are stem cells taken from the umbilical cord of donor horses when a foal is born and grown in a laboratory to increase their numbers. Stem cells can develop into other types of cells.

How is HorStem used?

The medicine can only be obtained with a prescription. HorStem is given only by a veterinarian as a single injection into the affected joint.

For more information about using HorStem, see the package leaflet or contact your veterinarian or pharmacist.

How does HorStem work?

It is not clear exactly how HorStem works in horses with osteoarthritis. Mesenchymal stem cells can have effects on the immune system as well as anti-inflammatory effects and can possess tissue regenerative properties. These properties are expected to play a role in the effect of HorStem.

What benefits of HorStem have been shown in studies?

In a field study of horses with mild to moderate osteoarthritis, 16 horses received an injection of HorStem into the affected joint and 17 horses received a placebo (dummy) injection. Horses were examined at days 14, 35 and 63. Treatment success was a reduction in lameness to a grade of 1 or less, using an accepted scale for equine lameness measurement (scale from 0 to 5, where 0 is non-lame, and 5 is severely lame). Twelve HorStem treated horses were successfully treated (success rate 75%) at day 63 compared to only 4 of the control group (success rate 25%).

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What are the risks associated with HorStem?

The most common side effect with HorStem (which may affect more than 1 in 10 horses) is short-lived synovitis (inflammation of the joint lining) with severe lameness, joint effusion (increased fluid in the joint) and pain on palpation 24 hours after injection. Substantial improvement occurs in the next 48 hours with complete resolution in the following two weeks. In case of severe inflammation, treatment with an anti-inflammatory medicine (NSAID) might be necessary.

For the full list of side effects and restrictions, see the package leaflet.

What are the precautions for the person who gives the medicine or comes into contact with the animal?

Hands should be washed after handling the medicine.

Care should be taken to avoid accidental self-injection. In case of accidental self-injection, medical advice should be sought immediately and the package leaflet or label shown to the doctor.

What is the withdrawal period in food-producing animals?

The withdrawal period is the time required after administration of a medicine before an animal can be slaughtered and the meat used for human consumption.

The withdrawal period for meat from horses treated with HorStem is 'zero' days, which means that there is no mandatory waiting time.

Why is HorStem authorised in the EU?

The European Medicines Agency decided that HorStem's benefits are greater than its risks and it can be authorised for use in the EU.

Other information about HorStem

HorStem received a marketing authorisation valid throughout the EU on 19 June 2019.

Further information on HorStem can be found on the Agency's website:
ema.europa.eu/medicines/veterinary/EPAR/horstem.

This overview was last updated in February 2019.