EMA/410964/2018
EMEA/V/C/004727

# Arti-Cell Forte (*chondrogenic induced equine allogeneic peripheral blood-derived mesenchymal stem cells*)

An overview of Arti-Cell Forte and why it is authorised in the EU

## What is Arti-Cell Forte and what is it used for?

Arti-Cell Forte is a veterinary medicine used to treat mild to moderate lameness linked to non-infective joint inflammation in horses. It contains stem cells which are obtained from equine blood. Stem cells can develop into other types of cells. The stem cells in the active substance (mesenchymal stem cells) are treated so that they develop into cartilage cells.

## How is Arti-Cell Forte used?

The medicine is available as an injection and can only be obtained with a prescription. It consists of two vials which are supplied frozen: one vial contains the active substance and a second vial contains equine allogeneic plasma (EAP) which is the liquid part of blood. In order to prepare the injection, the content of both vials, once thawed, are mixed and then injected only by a veterinarian directly into the affected joint.

For more information about using Arti-Cell Forte, see the package leaflet or contact your veterinarian or pharmacist.

## How does Arti-Cell Forte work?

This product contains chondrogenic induced equine mesenchymal stem cells and EAP. The stem cells have been prepared by being taken from blood from donor horses and grown in the laboratory to increase their numbers; they are treated so that they develop into cartilage cells which help to protect cartilage. The addition of the EAP to the stem cells after thawing and just before injection of the medicine increases the viability (ability to live) of the stem cells.

## What benefits of Arti-Cell Forte have been shown in studies?

In a field study involving horses with a history of lameness lasting 2 to 6 months, 50 horses were treated with Arti-Cell Forte and 25 received a placebo (dummy injection) of saline in one fetlock joint. All horses received intravenous ketoprofen, a medicine to relieve pain and inflammation, at the time of treatment. Six weeks after treatment 68% of the horses treated with Arti-Cell Forte had a lameness score reduction by 2 or 3 lameness grades compared to none of the horses in the control group. The

**Official address** Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
**Address for visits and deliveries** Refer to www.ema.europa.eu/how-to-find-us
**Send us a question** Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

improvement in lameness was considered relevant and positive effects lasted over a period of one year.

## What are the risks associated with Arti-Cell Forte?

The most common side effects with Arti-Cell Forte (which may affect more than 1 in 10 horses) are mild increases in lameness, injection site reactions such as swelling and mild increases in temperature at the injection site. The side effects were seen in the first week after use of the medicine.

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

The vials containing equine mesenchymal stem cells and equine allogeneic plasma can be stored and transported either frozen or in liquid nitrogen containers. Liquid nitrogen containers should be handled by properly trained personnel only. The handling of liquid nitrogen should take place in a well-ventilated area. Before withdrawing the vials from the liquid nitrogen canister, protective equipment consisting of gloves, long sleeves and a facemask or goggles should be worn.

In case of accidental self-injection, medical advice should be sought immediately and the package leaflet or label shown to the doctor. Accidental self-injection can cause pain, local inflammatory reactions and swelling at the injection site which may last for several weeks and possibly cause fever.

## 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 Arti-Cell Forte is ‘zero’ days, which means that there is no mandatory waiting time.

## Why is Arti-Cell Forte authorised in the EU?

The European Medicines Agency decided that Arti-Cell Forte’s benefits are greater than its risks and it can be authorised for use in the EU.

## Other information about Arti-Cell Forte

Arti-Cell Forte received a marketing authorisation valid throughout the EU on 29 March 2019.

Further information on Arti-Cell Forte can be found on the Agency’s website: ema.europa.eu/Find medicine/Veterinary medicines/European public assessment reports.

This overview was last updated in June 2018.