EMA/315758/2020
EMEA/H/C/002736

Spherox (*spheroids of human autologous matrix-associated chondrocytes*)

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

What is Spherox and what is it used for?

Spherox is a medicine used to repair defects to the cartilage in the knee in adults who are experiencing symptoms (such as pain and problems moving the knee). It is used where the affected area is no larger than 10 cm^2.

Spherox contains spheroids (spherical aggregates) of chondrocytes, cells found in healthy cartilage, that have been prepared from the patient's own tissues.

How is Spherox used?

Spherox is available as a suspension for implantation into the knee joint. The medicine is prepared specifically for each individual patient and must be given by a qualified doctor in a medical facility.

To prepare the medicine, a small sample is taken by arthroscopy (a type of keyhole surgery) from the patient's cartilage in the knee. The cartilage cells are then grown in the laboratory to prepare a suspension of chondrocyte spheroids. During arthroscopy, the medicine is placed into the damaged area of the patient's cartilage. The chondrocyte spheroids attach to the cartilage within 20 minutes. Patients treated with Spherox should follow a specific rehabilitation programme, including physiotherapy. This allows the chondrocyte spheroids to fill in the cartilage defect.

The medicine can only be obtained with a prescription.

How does Spherox work?

Cartilage in the knee can be damaged because of an accident, such as a fall or a sport injury. Spherox contains spheroids made from the patient's own healthy cartilage cells. When the spheroids are implanted into the patient's cartilage, they attach to the area of the defect and produce new tissue, thereby repairing the defects in the knee.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

What benefits of Spherox have been shown in studies?

Spherox has been shown to improve patients' symptoms and knee function in two studies in adults between 18 and 50 years of age. The main measure of effectiveness was the KOOS (knee injury and osteoarthritis outcome score), which is graded on a scale of 0 to 100 (where 0 means severest symptoms and 100 means no symptoms). The KOOS was self-measured by patients rating the severity of their symptoms such as pain, impact on daily living, sport and recreational activities, and quality of life.

In the first study involving 102 patients, Spherox was compared with microfracture (a type of surgery used to treat defects in cartilage). The knee cartilage defects were between 1 and 4 cm^2 in size. Preliminary data from this study after one year show that Spherox improved the outcome score by 22 points and was as effective as microfracture.

The second study looked at 73 patients with large cartilage defects of the knee from 4 to 10 cm^2. All these patients received treatment with Spherox, as microfracture is not recommended to repair large defects. In this study, patients' outcome scores with Spherox improved by 16 points in the first year and further improvements were seen up to three years after treatment.

What are the risks associated with Spherox?

The most common side effects with Spherox (seen in more than 1 patient in 10) are arthralgia (joint pain) and joint effusion (accumulation of liquid in the knee), which can cause swelling of the joint. For the full list of side effects reported with Spherox, see the package leaflet.

Spherox must not be used in patients with primary generalised osteoarthritis or with advanced osteoarthritis of the knee (conditions causing swelling and pain in the joints) and in patients whose bones in the knee joint are still growing. It must also not be used in patients infected with hepatitis B, C and/or HIV.

Why is Spherox authorised in the EU?

Spherox has been shown to be effective at treating defects in the knee cartilage between 1 and 10 cm^2 in size. Using chondrocyte spheroids that attach to the knee cartilage allows for a less invasive surgery (i.e. arthroscopy). The safety profile was considered acceptable; most side effects expected can be due to the surgery. The European Medicines Agency therefore decided that Spherox's benefits are greater than its risks and it can be authorised in the EU. However, knowledge on the long-term effects of the medicine is still awaited.

What measures are being taken to ensure the safe and effective use of Spherox?

The company that markets Spherox will ensure that all surgeons and other healthcare professionals handling or using the medicine receive training materials on how to use and store it, and that systems are in place to trace the medicine and identify the correct patient when it is prepared and given. The training materials will include guidance on how to safely collect and handle the cartilage sample from patients, implant Spherox and inform and follow up patients.

The company will also provide more information about the long-term safety and effectiveness of Spherox from a follow-up study.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Spherox have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Spherox are continuously monitored. Side effects reported with Spherox are carefully evaluated and any necessary action taken to protect patients.

Other information about Spherox

Spherox received a marketing authorisation valid throughout the EU on 10 July 2017.

Further information on Spherox can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/spherox.

This overview was last updated in 07-2020.