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EPAR summary for the public

ChondroCelect

characterised viable autologous cartilage cells expanded ex vivo expressing specific marker proteins

This is a summary of the European public assessment report (EPAR) for ChondroCelect. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for ChondroCelect.

What is ChondroCelect?

ChondroCelect is a suspension for implantation that contains cartilage cells.

ChondoCelect is a type of advanced therapy medicine called a 'tissue engineered product'. This is a type of medicine containing cells or tissues that have been manipulated so that they can be used to repair, regenerate or replace tissue.

What is ChondroCelect used for?

ChondroCelect is used in adults to repair damage to the cartilage in the knee. It is used when there is a single defect in the cartilage of the femoral condyle (the bottom end of the thighbone) that is causing symptoms.

The medicine can only be obtained with a prescription.

How is ChondroCelect used?

ChondroCelect is a medicine that is prepared specially for each individual patient and can only be used to treat the particular patient it was prepared for.

ChondroCelect must be administered by a qualified surgeon in a hospital. First, a biopsy (a small sample) is taken from the patient's cartilage in the knee. The cartilage cells are then grown and

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expanded in the laboratory to provide enough cells to make up a suspension of cells that can be used to treat the cartilage defect. During surgery on the knee, the suspension is placed into the defect in the patient's cartilage. A biological membrane is then used as a seal to keep the cells in place while the cartilage repairs.

Patients treated with ChondroCelect should follow specific rehabilitation programme, including physiotherapy. This helps the patients to recover from the operation but also leaves enough time for the cartilage cells to implant themselves and for the knee to heal. The programme may last up to approximately a year.

How does ChondroCelect work?

Cartilage in the knee can be damaged because of an accident, such as a fall, or because they wear off. The active substance in ChondroCelect is the patient's own cartilage cells. These cells are 'characterised viable autologous cartilage cells expanded *ex vivo* expressing specific marker proteins'. This means that they are cells taken from the patient, grown outside the body and can be used for implantation into the patient's cartilage. These cells repair the defects in the knee by producing new cartilage.

How has ChondroCelect been studied?

ChondroCelect was compared with microfracture (a type of surgery used to treat defects in cartilage) in one main study involving 118 adult patients with symptoms caused by defects in their knee cartilage. The defects were on the femoral condyle and were between 1 and 5 cm^2 in size. The main measures of effectiveness were how well the defects had healed after one year and the change in the patients' Knee Injury and Osteoarthritis Outcome Score (KOOS) after one and three years of treatment. The KOOS was measured by patients rating the severity of their symptoms.

What benefit has ChondroCelect shown during the studies?

ChondroCelect was more effective than microfracture at healing the defects in the cartilage. After one year, when scans were performed and samples of cartilage were examined, patients who were treated with ChondroCelect showed better structural repair of their cartilage than patients treated with microfracture. ChondroCelect was also as effective as microfracture at improving symptoms. There was no clear evidence of a difference in the change of KOOS in patients treated with ChondroCelect and those treated with microfracture.

What is the risk associated with ChondroCelect?

The most common side effects with ChondroCelect (seen in more than 1 patient in 10) are arthralgia (joint pain), cartilage hypertrophy (overgrowth), joint crepitation (unusual crackling sounds) and swelling of the joint. For the full list of all side effects reported with ChondroCelect, see the package leaflet.

ChondroCelect must not be used in people who are hypersensitive (allergic) to any of the other ingredients or to bovine serum (cow's blood). It must also not be used in patients with advanced osteoarthritis of the knee (a disease causing swelling and pain in the knee) and those with the femoral growth plate (the end part of the thighbone) that is not fully closed.

Why has ChondroCelect been approved?

Because ChondroCelect is an advanced therapy medicine, it was assessed by the Committee for Advanced Therapies (CAT). Based on the assessment performed by the CAT, the CHMP decided that ChondroCelect's benefits are greater than its risks and recommended that it be given marketing authorisation.

The CHMP considered that ChondroCelect was shown to be effective at treating defects in the knee cartilage between 1 and 5 cm^2 in size, and that the safety profile was considered acceptable. However, knowledge on the long-term effect of the medicine is limited.

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

A risk management plan has been developed to ensure that ChondroCelect is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for ChondroCelect, including the appropriate precautions to be followed by healthcare professionals and patients.

In addition, the company that makes ChondroCelect will ensure that all surgeons and other healthcare professionals involved in the handling or use of ChondroCelect receive training materials on how to use the product. The training materials for surgeons will include information on how to collect the cartilage biopsy from patients, perform the operation and follow patients up. The materials for other healthcare professionals will include information on how to handle the collected biopsy and prepare ChondroCelect for implantation, and how to follow patients up and plan the recommended physiotherapy. The company is also performing an observational study to obtain more information about the safety and effectiveness of ChondroCelect.

Other information about ChondroCelect

The European Commission granted a marketing authorisation valid throughout the European Union for ChondroCelect on 5 October 2009.

The full EPAR for ChondroCelect can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with ChondroCelect, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 07-2014.