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EPAR summary for the public

MACI

matrix applied characterised autologous cultured chondrocytes

This is a summary of the European public assessment report (EPAR) for MACI. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use MACI.

For practical information about using MACI, patients should read the package leaflet or contact their doctor or pharmacist.

What is MACI and what is it used for?

MACI is an implant used to repair cartilage defects at the ends of the bones of the knee joint. It consists of the patient's own cartilage cells on 14.5 cm^2 collagen membranes, which are used by a surgeon to fill in the spaces where cartilage is damaged.

MACI is used to repair full-thickness defects with a surface area of between 3 to 20 cm^2 in adults who are experiencing symptoms (such as pain and problems moving the knee).

MACI is an advanced therapy product 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.

How is MACI used?

In the first stage of treatment, a sample of cartilage cells is taken from the patient's joint and grown in a laboratory. The cells are then placed onto the collagen membrane. Around 6 weeks later, the surgeon shapes the membrane to fit the damaged area in the knee cartilage and then implants it using a surgical procedure. A type of glue known as a fibrin sealant, which is made from blood clotting proteins, is used to hold the implant in place on the cartilage.

MACI should only be used by a surgeon specifically trained and qualified to use it and the product can only be obtained with a prescription.

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How does MACI work?

The active substance in MACI consists of the patient's own cartilage cells, which are implanted into the cartilage defect in the knee. The cells are used to fill in the space where the cartilage has been damaged, thereby regenerating the damaged areas and helping to resolve the patient's symptoms such as pain and problems moving the knee.

What benefits of MACI have been shown in studies?

MACI was compared with microfracture surgery (a surgical procedure commonly used to treat cartilage defects) in a main study which looked at pain relief and improvements in knee function in patients with full thickness cartilage defects in the knee. The study involved 144 adults with defects ranging between 3 and 20 cm^2 in area. A standard scale, known as the 'knee injury and osteoarthritis outcome score' (KOOS), was used to measure pain and knee function, where 0 reflects extreme problems and 100 reflects an absence of problems. The study showed that MACI is more effective than microfracture surgery at relieving pain and improving knee function: two years after surgery, patients treated with MACI had an average score of 82 for pain and 61 for knee function, compared with 71 and 49 respectively for patients treated with microfracture surgery. For both pain and function, improvements of around 45 points were seen in MACI patients compared with around 35 points in patients that underwent microfracture surgery.

What are the risks associated with MACI?

Excess cartilage growth and detachment of the implant may occur in between 1 and 10 patients in 1,000 treated with MACI. The other important risks are those related to the surgical procedure itself, including infection, inflammation, haemoarthrosis (blood in the joints), arthrofibrosis (scar tissue in the joints), and thromboembolic events (blood clots). For the full list of all side effects reported with MACI, see the package leaflet.

MACI must not be used in patients with severe osteoarthritis (swelling and pain) of the knee, inflammatory joint disease, or uncorrected inborn blood clotting disorders. MACI must also not be used in patients whose growth plates in the thigh bone have not fully closed. Growth plates close (or harden) when a child has become skeletally mature and their bones have stopped growing.

Why is MACI approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) noted that the main study had shown that MACI was superior to microfracture surgery in treating patients with cartilage defects of the knee. In addition, patients treated with MACI had fewer side effects compared with microfracture-treated patients.

MACI was evaluated to comply with the EU regulation on advanced therapies, which requires all advanced therapies in EU Member States to undergo an evaluation by the EMA in order to obtain an EU-wide marketing authorisation. The Committee noted that treatments such as MACI are already established in clinical practice and that the results from the main study were consistent with results in the scientific literature.

The CHMP therefore concluded that MACI's benefits are greater than its risks and recommended that it be approved for use in the EU.

As MACI is an advanced therapy product, it was initially assessed by the Committee for Advanced Therapies (CAT). The CHMP's recommendation is based on an initial assessment by the CAT.

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

A risk management plan has been developed to ensure that MACI 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 MACI, including the appropriate precautions to be followed by healthcare professionals and patients.

In addition, surgeons and healthcare professionals who will be involved in treating patients with MACI will receive educational materials providing detailed guidance on how to use MACI as well as information on its risks and the need to follow-up patients treated with MACI.

Other information about MACI

The European Commission granted a marketing authorisation valid throughout the European Union for MACI on 27 June 2013.

The full EPAR for MACI 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 MACI, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 06-2013.