OrthoACI™

Autologous Chondrocyte Implantation

What is in this leaflet

This leaflet answers some common questions about the OrthoACI™ treatment. It does not contain all the available information about OrthoACI™ and it does not take the place of talking to your doctor.

All treatments have risks and benefits. Your doctor will have assessed the risks and benefits for you associated with the use of this treatment.

If you have any concerns about this treatment, ask your doctor. Follow your doctor's advice, even if it is different from what this leaflet says.

Please read this leaflet carefully and keep it for future reference.

The information in this leaflet is subject to change. Please check with your doctor whether there is any new information about this treatment that you should know.

What OrthoACI™ is used for

OrthoACI™ is a cell therapy product and is known as a biologic. It is used to help repair damaged articular cartilage in joints such as the knee.

A small sample (biopsy) of your healthy joint cartilage will be sent to a laboratory where the cartilage cells, called chondrocytes, will be extracted and grown over a period of approximately 6 weeks.

Once there are enough cells, they will be implanted in your joint with a collagen scaffold. The implanted cartilage cells help to repair the damaged cartilage.

Before you are given OrthoACI™

As part of your treatment you will be asked to complete a questionnaire with questions about your health. Your answers are necessary to help your doctor make sure that you are suitable for this procedure. It will also identify any conditions/factors which may affect the likelihood of treatment success or may make you more susceptible to adverse events. Please answer these questions to the best of your ability.

OrthoACI™ may not be suitable if you:

Please advise your doctor if any of the following may apply to you or if you have concerns regarding any allergies or adverse reactions to medications or treatments.

- Are outside the recommended age range (18-65 years)
- Have a history of allergy to any of the following:
  - » Antibiotics (specifically Gentamicin).
  - » Materials of bovine (cow) or porcine (pig) origin
- Are pregnant or breast-feeding
- Have a current medical condition that affects your immune system, such as:
  - » Autoimmunity
  - » Low/deficient immune system response (immuno-compromised)
- Have a medical condition that affects your bones or joints (other than the condition that you are receiving OrthoACI™ for), including:
  - » Pain or swelling not consistent with your pre-existing condition
  - » Inflammatory arthritis
  - » Dysplasia (abnormal bone/tissue growth)
  - » Connective tissue disorders (e.g. Marfan, Ehlers-Danlos Syndromes)
  - » Issues with joint alignment and loading (e.g. knock-knees, bowed legs, neuromuscular disorders)
- Have diabetes
- Have haemophilia or other blood clotting disorders
- Have had cancer in your bones, cartilage, tendons, muscles or fat
- Are taking or using any other medicines, including those bought from pharmacies, supermarkets and health food stores. This includes non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen.

If you have not told your doctor about any of the above, please tell them before you receive OrthoACI™.

How to use OrthoACI™

The OrthoACI™ product is provided directly to your surgeon for implantation under general anaesthetic. Your doctor will determine the dose of OrthoACI™ that you will receive. OrthoACI™ will be applied to a collagen scaffold, which is then implanted at the site(s) of cartilage damage.

Side effects

Medicines and therapies sometimes cause unwanted side effects, although not everybody gets them.

The most common side effects of OrthoACI™ are temporary mild pain and discomfort in the area where the biopsy sample is collected and also following implantation. Tell your doctor if you experience severe or long-lasting pain. Although rare, the use of OrthoACI™ may result in adverse outcomes such as graft overgrowth (hypertrophy) or loss of the graft (delamination), both of which may result in pain and restriction of function or movement.

Contact your doctor if you experience a side effect that is not mentioned in this leaflet. Adverse outcomes of treatment can also be communicated directly to Orthocell using the information on the provided Patient Card (IFU-0000119). Please ask your doctor if you have not yet received it.

As with all therapies, success of treatment cannot be guaranteed, although clinical data demonstrates a high rate of safety and efficacy of cellular therapy treatments of cartilage damage.

Overdose

OrthoACI™ is used only for local application by trained practitioners and the likelihood of receiving an overdose is very small.

In the event of an adverse reaction, advice may be sought from your doctor or directly from Orthocell.

Storing OrthoACI™

OrthoACI™ is provided directly to your doctor prior to your surgery and will be stored at 15-25°C in the original packaging until used.

The OrthoACI™ should not be used after the expiry time and date indicated on the packaging.

After you are given OrthoACI™

It is important that you follow your doctor's guidance after the procedure, which includes completion of rehabilitation. Rehabilitation guides are available following treatment in the ankle (IFU-0000121) or knee (IFU-0000122).

Follow your doctor's advice when resuming physical activities and increase your activity level gradually. If you experience pain, decrease your activity to the previous level until it resolves.

If you experience swelling after physical activity, you can use an ice pack to reduce it.

If you experience severe pain during or after your rehabilitation, contact your doctor for advice.

Further information

OrthoACI™ can only be obtained through consultation with a medical practitioner trained in the delivery of OrthoACI™. This leaflet does not contain all the available information about OrthoACI™. If you would like further information about OrthoACI™ or your treatment, please ask your doctor.

Orthocell may contact you in the form of surveys after your treatment. You can opt out of receiving these.

Product description

What it looks like

OrthoACI™ is a clear liquid with an off-white layer (cells) in the bottom of the glass vial which is mixed prior to treatment.

Ingredients

Each vial of OrthoACI™ contains 2-5 million cells in a solution supplemented with serum (a component of your own blood), vitamin C (preservative), gentamicin (antibiotic) and a cell culture solution.

Manufacturer

OrthoACI™ is made and supplied in Australia by:
Orthocell Ltd
ABN 57 118 897 135
Building 191, Murdoch Uni, Murdoch Western Australia 6150
Phone: 08 9360 2888
Fax: 08 9360 2899