OrthoATI™

Autologous Tenocyte Implantation

What is in this leaflet

This leaflet answers some common questions about the OrthoATI™ treatment. Please read this leaflet carefully and keep it for future reference. It does not contain all the available information about OrthoATI™ and it does not take the place of talking to your clinician who has assessed the risks and benefits of this treatment for you.

Follow your clinician's advice, even if it differs from this leaflet.

What OrthoATI™ is used for

OrthoATI™ is a cellular therapy used to treat tendons damaged by tendinopathy.

A small sample (biopsy) is collected from your healthy tendon. The laboratory extracts the tendon cells, called tenocytes, and grows them over a period of approximately 6 weeks.

When sufficient cells have grown, they will be injected using ultrasound guidance.

Before you are given OrthoATI™

You will be asked to complete a questionnaire about your health. Your answers are necessary to help your clinician determine your suitability for treatment. It will also identify any factors which may affect the likelihood of treatment success or increase the risk of side effects. Please answer these questions to the best of your ability.

OrthoATI™ may not be suitable if you:

- Are outside the recommended age range (18-65 years)
- Have a history of allergy to any of the following:
  - » Gentamicin or other aminoglycoside antibiotics (including Kanamycin, Tobramycin, Neomycin, Streptomycin)
  - » Materials of bovine (cow) origin
- Are pregnant or breast-feeding
- Have a current medical condition that affects your immune system, such as:
  - » Autoimmunity
  - » Low immune system response (immunocompromised)
- Have a medical condition that affects your bones or joints (other than tendinopathy), including:
  - » Pain or swelling not consistent with your tendinopathy
  - » Connective tissue disorders
- Have diabetes
- Have had cancer in your bones, cartilage, tendons, muscles or fat
- Are routinely taking medications, including those purchased over the counter (OTC). These should be discussed with your clinician as some may affect tendon healing (i.e corticosteroids, diclofenac and fluoroquinolone antibiotics are known to affect connective tissues).
- Have been diagnosed with a full thickness tendon tear which has not been repaired

If any of the above apply to you, please discuss these with your clinician prior to your OrthoATI™ injection.

How to use OrthoATI™

OrthoATI™ is provided directly to your clinician for injection. Your clinician will determine the dose to be injected at the site of tendon damage. Your clinician will use ultrasound to guide the injection.

Side effects

Like all medicines, cell therapies sometimes cause unwanted side effects, although not everybody gets them.

The most common side effects are temporary mild pain at the biopsy collection site and also where OrthoATI™ is injected. Tell your clinician if you experience severe or long-lasting pain (>6 months). OrthoATI™ has no known impact upon personal behaviour.

You will be provided with a *Patient Card* which includes Orthocell contact information. Please ask your clinician for this information if you have not yet received it.

Contact your clinician if you experience a significant side effect or adverse outcome.

As with all medications, success of treatment cannot be guaranteed, although clinical evidence for OrthoATI™ indicates a high level of success including in patients whom have failed other treatments for tendinopathy. OrthoATI™ is not currently included on the ARTG and each treatment requires regulatory approval.

Overdose

OrthoATI™ is used only for local application by trained clinicians, so the chance of receiving an overdose is very unlikely.

In the event of severely worsening pain or other concerns, advice should be sought directly from your clinician.

Storing OrthoATI™

OrthoATI™ is provided directly to your clinician and will be stored at 18-25°C in the original packaging until used.

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

After you are given OrthoATI™

It is important that you follow your clinician's guidance after the procedure. Follow clinician advice when resuming physical activities and increase your activity level gradually. Orthocell can provide a rehabilitation guide upon request. Failure to follow the provided instructions may affect the outcome of your treatment.

If you experience pain, decrease your activity to the previous level until it resolves.

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

Further information

OrthoATI™ can only be obtained through consultation with a trained clinician. If you want more information about OrthoATI™, your treatment in general, or if you have any questions or are not sure about something in this leaflet, please ask your clinician.

Orthocell may follow up with patients in the form of post-market surveillance surveys sent out a minimum of six months after your treatment. You may opt out of receiving these.

Product description

What it looks like

OrthoATI™ 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 OrthoATI™ contains 2-5 million tenocyte cells in a solution supplemented with 10% autologous serum (made from your blood sample), vitamin C (preservative), gentamicin (antibiotic) and a standardised cell nutrient fluid.

Manufacturer

OrthoATI™ is made by:
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