Ortho-ATI™

Autologous Tenocyte Implantation

What is in this leaflet

This leaflet answers some common questions about the Ortho-ATI™ treatment. It does not contain all the available information about Ortho-ATI™ 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.

Ask your doctor if you have any questions about why Ortho-ATI™ has been prescribed for you.

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 Ortho-ATI™ is used for

Ortho-ATI™ belongs to a group of medicines called cell therapies. It is used to help repair damaged tendons.

A small sample (biopsy) from one of your healthy tendons will be sent to a laboratory where the tendon cells, called tenocytes, will be extracted and grown over a period of approximately 6 weeks.

Once there are enough cells, they will be injected into your injured tendon using ultrasound guidance. The injected tendon cells (tenocytes) will help repair the damaged areas by increasing in number and producing key tendon proteins.

Before you are given Ortho-ATI™

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 able to undergo the 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.

Ortho-ATI™ 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, Tobraemycin, Neomycin, Streptomycin). Please inform your doctor if you have previously had a reaction to any antibiotic
  - Materials of bovine (cow) origin
  - Please tell your doctor if you have allergies to any medicines, foods or dyes, or if you have ever had an adverse reaction to an injection
- Are pregnant or breastfeeding
- Have a current medical condition that affects your immune system, such as:
  - Autoimmunity
  - Low/deficient immune system response [immunocompromised]
- Have a medical condition that affects your bones or joints (other than the condition that you are receiving Ortho-ATI™ for), including:
  - Pain or swelling not consistent with your pre-existing condition
  - Connective tissue disorders (e.g. Marfan’s, Ehlers-Danlos Syndromes)
  - Issues with joint alignment and loading (e.g. knock-knees, bowed legs, neuromuscular disorders)
- Have diabetes
- 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 agents (NSAIDs) such as ibuprofen and treatment with corticosteroids and fluorquinolone antibiotics (ciprofloxacin, Noroxin (norflaxin), Floxin (ofloxacin) within the last 3 months
- Have been diagnosed with a full thickness tendon tear and have not received surgery to repair this
- Have had a full thickness tendon tear and have not received surgery to repair this

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

How to use Ortho-ATI™

The Ortho-ATI™ product is provided directly to your doctor for injection. Your doctor will determine the dose of Ortho-ATI™ that you will receive. Ortho-ATI™ will be given to you as an injection into one or more areas where your tendon is damaged. Your doctor
will use ultrasound to guide the injection of the treatment.

**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 and discomfort in the area where the biopsy is collected and also where the Ortho-ATI™ is injected. Tell your doctor if you experience severe or long lasting pain (>6 months).

You will be provided with a Patient Card (10-IFU-13) which includes important additional information about your procedure, potential side-effects and Orthocell contact information. Please ask your doctor for this information if you have not yet received it.

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.

As with all medications, success of treatment cannot be guaranteed, although clinical evidence for Ortho-ATI™ indicates a high level of success including in patients whom have failed other treatments for tendinopathy.

**Overdose**

Ortho-ATI™ is used only for local application by trained doctors, so the chance of receiving an overdose is very unlikely.

In the event of severely worsening pain or other concerns, advice may be sought directly from your doctor, Orthocell or the Poisons Information Centre at 13 11 26.

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### Storing Ortho-ATI™

Ortho-ATI™ is provided directly to your doctor prior to your injection, and will be stored at 18-25°C in the original packaging until used.

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

### After you are given Ortho-ATI™

It is important that you follow your doctor’s guidance after the procedure, which includes completion of rehabilitation. Orthocell has guidance documents to assist in this (Ortho-ATI™ Rehabilitation Guide, 10-IFU-15). Failure to follow the instructions of your doctor may affect the outcome of your treatment.

The patient card provides additional information including the requirement to avoid the use of non-steroidal anti-inflammatory medications. Please ask your medical practitioner for additional information.

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

Ortho-ATI™ can only be obtained through consultation with a medical practitioner trained in the delivery of Ortho-ATI™. This leaflet does not contain complete information about Ortho-ATI™. If you want more information about Ortho-ATI™, your treatment in general, or not sure about something in this leaflet, please ask your doctor.

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

### Product description

### What it looks like

Ortho-ATI™ 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 Ortho-ATI™ 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

Ortho-ATI™ is made and supplied in Australia by:

Orthocell Ltd
ABN 57 118 897 135
Cnr Murdoch Dve & Discovery Way, Murdoch Western Australia 6150
Phone: 08 9360 2888
Fax: 08 9360 2899

Ortho-ATI™ is a trademark registered in Australia by Orthocell Ltd.