# ARTHOSAMID INJECTION

*Information sheet*

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bringing health to you

LivingCare works in partnership with Leeds Teaching Hospitals. This may mean that there are trainees involved in your care. All trainees have the appropriate level of training and will always supervised by a trainer. You will be informed of their involvement (if applicable) on arrival to the department where further information will be provided. You have the right to decline care from a trainee and this will also be discussed with you on arrival.

## Introduction

**This procedure requires your formal consent.**

If you are unable to keep your appointment, please notify the booking office on 0113 249 4655 as soon as possible. This will enable the staff to give your appointment to someone else and they will be able to arrange another date and time for you.

This booklet has been written to enable you to make an informed decision in relation to agreeing to any investigations. The consent form is a legal document therefore please read it carefully. Once you have read and understood all the information, including the possibility of complications, and you agree to undergo the investigation.

## Arthosamid Patient Information

The purpose of this document is to provide written information regarding the risks, benefits and alternatives of/to Arthosamid injections for knee Osteoarthritis. This is supplementary to the discussion you have had with the doctor. It is important you fully understand this information so please read this document carefully.

## What is a knee injection?

Knee injections are often recommended for the treatment of pain and inflammation in and around the knee joint.

## Proposed Intervention

Arthosamid is a hydrogel injection administered by ultrasound guidance for symptomatic knee osteoarthirits. The hydrogel itself does not degrade and therefore it provides long-lasting relief, improving your quality of life. In clinical trials, patients reported significant reduction in their pain symptoms by week 4 after their injection and, unlike other injectable treatments, the level of reduction was maintained at the year follow up period.

## Disclosure

Before undergoing one of these procedures, understanding the associated risks is essential. No procedure is risk-free. The following risks are well recognised, but there may also be risks not included in this list that are unforeseen by the doctors.

This is a new treatment with early promising results. Arthrosamid is a device and not a medicine. It has received the appropriate CE marking.

As this procedure has not yet been fully assessed by the National Institute for Health and Care Excellence (NICE). Your surgical team will therefore ask you to complete a short questionnaire prior to and following your treatment to monitor your response.

## Intended Benefits

Arthrosamid® is approved for the symptomatic treatment of knee osteoarthritis so any patient with this condition may be suitable. Over the last 10 years many patients have benefitted from treatment with the hydrogel in Arthrosamid®. Typical Symptoms include pain, stiffness, swelling and physical function.

## Alternative Treatment Options

Given that this is a novel treatment we wish to confirm that all appropriate treatments have been explored. These may include:

- Physiotherapy course
- Activity modification
- Weight management
- Analgesia
- Steroid/hyaluronic acid injection/platelet rich plasma (PRP) injection
- Mechanical aids such as bracing

Surgery may be an alternative and may remain a possible option should the hydrogel injection not help.

## No Intervention

Not having the injection is a reasonable option, and if you are in any doubt then you are advised not undergo this treatment.

## Before the Procedure

As Arthrosamid is a device and not a medicine and given the injection is permanent it is therefore important that 1-2 hours before the injection oral antibiotics must be taken to reduce the risk of developing an infection.

- Please inform the doctor of any known allergies.
- Please bring a list of your current medications with you.
- You should take your medication as normal. If you are taking anticoagulant medication, you may be given special instructions;
- You may eat and drink as normal.
- Your doctor will discuss the procedure with you and ask you to sign a consent form;
- If there is any possibility that you may be pregnant, please inform the doctor or nurse.

## The Procedure

- The procedure is carried out in one of the clinic treatment rooms;
- You will be asked to sit or lie on a hospital couch.
- The doctor will clean your skin with an antiseptic solution which may feel cold;
- A local anaesthetic will be injected with a fine needle. This may sting initially before the skin goes numb.
- If a small dressing has been placed over the needle insertion site. This can be removed in the evening.

## Can everyone have this treatment?

Arthrosamid® may not be suitable for everyone. Your doctor is the best person to advise you, but situations where you should not use Arthrosamid® (contraindications) include:

- If you have an infection at or near the injection site
- You have a temperature.
- If you have haemophilia or take anticoagulant treatment
- If you have had a knee arthroscopy within the past 6 months

Additionally, your doctor may advise you not to have treatment with Arthrosamid® if your diabetes is poorly controlled, you are having major dental work, or you have been diagnosed with an autoimmune disorder, (such as Multiple Sclerosis, Addison's, or Coeliac disease). If you are under 18, pregnant, breastfeeding, or have a foreign body in your knee, your doctor may advise against the injection.

PLEASE TELL THE DOCTOR IF YOU HAVE ANY ALLERGIES OR HAVE EVER HAD A REACTION TO A MEDICATION.

## Risks

No procedure is risk free. Sterile techniques are always used, which helps to reduce this risk.

Summary Key risks include:

- Non-efficacy (the treatment may not work)
- Short lived efficacy (the treatment may work for a limited time)
- Joint infection
- Allergic reaction to Antibiotics, local anaesthetic, preservatives or to the hydrogel itself.
- Injection-related mild to moderate pain and/or mild swelling during the first weeks to months following the injection may occur.
- Swelling of Baker's cyst may also occur.

Please feel free to discuss these with your treating doctor.

## After the Procedure

ou should avoid any strenuous weight-bearing activities (e.g. running, tennis or long walks) during the first few days after your injection. Your doctor will be able to advise you on how to slowly introduce more activity.

- After the procedure you may need to rest for 20-30 minutes.
- You are advised to avoid driving after the injection, on the day of treatment.
- The injected knee can feel uncomfortable once the local anaesthetic has worn off.
- Take your regular medication and pain killers as normal.
- If after the injection your knee becomes red, hot, swollen or more painful please call the clinic.

Most patient start to notice a gradual improvement in symptoms after about 10 days. Pain levels and function should continue to improve for up to 12 weeks and should last multiple years.

Please note if in the future you require a major surgical or dental procedure, you should tell your treating physician that you have an Arthrosamid® implant in your knee to ensure an accurate medical assessment.

## Further Information

If you have any questions or would like further information, please contact the clinic on 0113 245 4655, Option 2 then 1.

## Confirmation of Reflection

It is important before undergoing any non-emergency treatment that you have time to:

- Reflect upon the information provided
- Consider other treatment options
- Speak to friends and family
- Ask any follow up questions you may have

## Follow up

We are very keen to monitor your progress, and understand how you respond to the treatment. For this reason, we will contact you at time points after the injection to find out how you are doing. This may involve follow up appointments, video consultation of possible telephone assessments, and online questionnaires. There is no obligation to take part, but we would encourage your participation.

**Patient Name:** .....

**Date of Birth:** .....

**Diagnosis:** .....

**Type of injection:** Arthrosamid

**Patient information leaflet given and read by patient:** YES/NO

| CONTRADICTIONS: | PRECAUTIONS: | SIDE EFFECTS: |
|---|---|---|
| Reluctant Patient | Immunosuppressed | Infection |
| Very unstable joint | Oral Steroids | Anaphylaxis |
| Early Trauma | Cytotoxins | Facial Flushing |
| Infection | Anticoagulants | Glycaemic Control |
| Allergic Reaction | Bleeding Disorder | Fat atrophy/depigmentation |
| Prosthetic Joint | Diabetes | Uterine bleed |
| Hemarthrosis | Anxiety | Post infection flare of pain |
| Children | MRSA | Bleeding/Bruising |
| | Pregnancy | No response to treatment |
| | | Worsening of symptoms |

## Consent

My consent and authorization for this elective procedure is strictly voluntary. By signing this informed consent form, I hereby grant authority to the practitioner to perform injections to area(s) discussed during our consultation. I have read this informed consent and certify I understand its contents in full. All my questions have been answered to my satisfaction and I consent to the terms of this agreement. I agree to adhere to all safety precautions and instructions after the treatment. I have been instructed in and understand post treatment instructions. I understand and acknowledge that no guarantee has been given or implied by anyone as to the results that may be obtained by this treatment. I also understand this procedure is "elective" and not covered by insurance and that payment is my responsibility. Payment is expected in full at the time of treatment and is non-refundable.

I have been informed of the possibility of complications as detailed above. If you are happy to proceed and have no further questions, please sign and date below.

I understand that any procedure in addition to those described on the form will only be carried out if its necessary to save my life or prevent serious harm to my health.

I agree that LivingCare may contact me for feedback about this procedure after 3 months.

**Patient name:** **Date of birth:**

**Signature & Date :**

**Consultant/ Surgeon name:**

**Signature & Date:**

NHS
The Mid Yorkshire Hospitals
NHS Trust

NHS
The Leeds
Teaching Hospitals
NHS Trust


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