# OSTEOCIS

## PACKAGE LEAFLET: INFORMATION FOR THE PATIENT
## OSTEOCIS 3 mg kit for radiopharmaceutical preparation
## sodium oxidronate

**Read all of this leaflet carefully before you are given this medicine because it contains important information for you.**

- Keep this leaflet.You may need to read it again.
- If you have any further questions, ask your nuclear medicine doctor who will supervise the procedure. .
- If you get any side effects talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet:**


1. What OSTEOCIS is and what it is used for
2. What you need to know before OSTEOCIS is used
3. How OSTEOCIS is used
4. Possible side effects
5. How OSTEOCIS is stored
6. Contents of the pack and other information

# OSTEOCIS

## 1. WHAT OSTEOCIS IS AND WHAT IT IS USED FOR

**Osteocis** is a radiopharmaceutical product for diagnostic use only i.e. a radioactive medicine used for **diagnostic purposes**. Osteocis contains sodium **oxidronate** which is used in combination with a **radioactive solution of technetium ($^{99m}$Tc)** in order to form **a solution of technetium ($^{99m}$Tc)-oxidronate**.

When injected into a vein of your arm, this product temporarily **collects in your bones**. Because of its radioactivity it can be detected outside the body using a special camera, and pictures, known as scans, can be taken. The scan will show exactly the distribution of the radioactivity within the organ and the body. These scans give valuable information about the **structure of your bones**.
Osteocis is used to determine if there is any **bone abnormality**.

The use of OSTEOCIS does involve exposure to small amounts of radioactivity. Your doctor and the nuclear medicine doctor have considered that the clinical benefit that you will obtain from the procedure with the radiopharmaceutical outweighs the risk due to radiation.

## 2. WHAT YOU NEED TO KNOW BEFORE OSTEOCIS IS USED

### OSTEOCIS must not be used

- if you are **allergic** to sodium oxidronate or any of the other ingredients ofthis medicine (listed in section 6).

### Take special care with OSTEOCIS
**Inform the nuclear medicine doctor** in the following cases:

- if you suffer from **allergy**, as a few cases of allergic reactions have been observed after administration of technetium ($^{99m}$Tc),
- If you are **pregnant** or if there is any possibility that you are pregnant (see section “Pregnancy and breast-feeding”).
- If you are **breast-feeding** (see section “Pregnancy and breast-feeding”).
- If you suffer from a high bone uptake and/or a renal impairment
- If you recently have had this kind of examination.

**Before administration of OSTEOCIS you should drink plenty of water** to be well hydrated before the start of the examination in order to urinate as often as possible during the first hours after the study. This will increase the quality of the scan.

### Children and adolescents
Talk to your nuclear medicine doctor, if you are **under 18 years** of age, because damage in growing bones may be observed after radiation exposure.

**Other medicines and OSTEOCIS**

**Tell your nuclear medicine doctor** if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, since they may interfere with the interpretation of the images:

- **(**medicines used to treat metal poisoning)
- **Diphosphonates** (medicines used to treat bones disease)
- **Tetracycline antibiotics** (to treat cancer),
- **Medicines containing iron medicines** (used to treat anaemia)
- **Medicines containing aluminium salts** (used to treat gastric problems).

**Pregnancy and breast-feeding**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your nuclear medicine doctor for advice before you are given this medicine.

**You must inform the nuclear medicine doctor before** the administration of OSTEOCIS **if there is a possibility you might be pregnant, if you have missed your period or if you are breastfeeding.**

When in doubt, it is important to consult your nuclear medicine doctor who will supervise the procedure.

**If you are pregnant,**

The nuclear medicine doctor will only administer this product during pregnancy if a benefit is expected which would outweigh the risks.

**If you are breast-feeding**

**Tell your physician if you are breast-feeding** as she/he may delay the investigation until breast-feeding is completed or ask you to stop breast-feeding for a short while until the radioactivity is no longer in your body. Milk should be banked prior to injection and the subsequent breastfeeding discarded after injection.

**Resuming breast-feeding should be in agreement with the nuclear medicine doctor** who will perform the investigation. Usually breast feeding can be **resumed 4 hours** after injection.

Please ask your nuclear medicine doctor when you can resume breastfeeding.

**Close contact with infants** should be restricted during this period.

**OSTEOCIS contains 6.3 mg/vial of sodium.** Depending on the volume injected, the limit of 1 mmol (23 mg) of sodium per dose administered may be exceeded. This must be taken into account if you are on a low-salt diet.

## 3. HOW OSTEOCIS IS USED ?

There are strict laws on the use, handling and disposal of radiopharmaceutical products. OSTEOCIS will only be used in special controlled areas. This product will only be handled and given to you by people who are trained and qualified to use it safely. These persons will take special care for the safe use of this product and will keep you informed of their actions.

The nuclear medicine doctor supervising the procedure will decide on the quantity necessary to get the desired information.

The quantity to be administered usually recommended for an adult ranges from **300 to 700 MBq** depending on your body mass. (megabecquerel, the unit used to express radioactivity.)

**Use in children and adolescents**
In children and adolescents, the quantity to be administered will be adapted to the child's weight.

**Administration of OSTEOCIS and conduct of the procedure**
This medicine is administered by injection into a vein of your arm.

One injection is sufficient toconduct the test that your doctor needs.

During the administration of medication, you should avoid any movement to prevent inflammation around the injection site due to an administration under the skin.

After injection, you will be offered a drink and asked to urinate immediately preceding the test.

**Duration of the procedure**
Your nuclear medicine doctor will inform you about the usual duration of the procedure. The scans can be taken during a few minutes after the injection in some cases or at 2 or 3 hours after the injection.

**After administration of OSTEOCIS you should:**

- **avoid strenuous exercise** until satisfactory scans have been taken., to ensure the most efficient use of the product. This avoids accumulation of the product in muscles.
- **urinate frequently** in order to eliminate the product from your body.

The nuclear medicine doctor will inform you if you need to take any special precautions after receiving this medicine. Contact your nuclear medicine doctor if you have any questions.

**If you have been given more OSTEOCIS than you should**
An overdose is unlikely because you will only receive a single dose of OSTEOCIS precisely controlled by the nuclear medicine doctor supervising the procedure. However, in the case of overdose, you will receive the appropriate treatment. In particular, the nuclear medicine doctor supervising the procedure may recommend that you drink abundantly in order to facilitate the elimination of OSTEOCIS from your body.

**Should you have any further question on the use of OSTEOCIS, please ask the nuclear medicine doctor who supervises the procedure.**

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following effects have been described with a very rare frequency:
- **allergic type reactions**
- **rash,**
- **feeling sick** (nausea),
- **low blood pressure** (hypotension),
- **pain in joints** (arthralgia).

Onset of these reactions can be **delayed 4 to 24 hours after injection.**
Any of the above could be sign of an allergy (anaphylactic reaction). **Contact a doctor immediately.**

This administered radiopharmaceutical will deliver low amounts of ionising radiation associated with the least risk of cancer and hereditary abnormalities.

**Reporting of side effects**
**If you get any side effects,** , talk to your nuclear medicine doctor or This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Pharmacovigilance Section, Irish Medicines Board, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6767836, Website: www.imb.ie, e-mail: imbpharmacovigilance@imb.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

## 5. HOW OSTEOCIS IS STORED

You will not have to store this medicine. This medicine is stored under the responsibility of the specialist in appropriate premises. Storage of radiopharmaceuticals will be in accordance with national regulation on radioactive materials.

## 6. CONTENTS OF THE PACK AND OTHER INFORMATION

### What OSTEOCIS contains

- **The active substance** is sodium oxidronate.
  Each vial contains 3.0 mg of sodium oxidronate.
- **The other ingredients are**: stannous chloride dihydrate, ascorbic acid, sodium chloride, sodium hydroxide, under nitrogen atmosphere.

### What OSTEOCIS looks like and contents of the pack

You will not have to get this medicine or handle the packaging or the vial. The following data is for your information only.
**OSTEOCIS** is a kit for radioactive preparation. OSTEOCIS is a powder which should be dissolved and labeled with radioactive technetium ($^{99m}$Tc) before use in order to obtain a solution of technetium ($^{99m}$Tc)-oxidronate.This solution is ready to be injected intravenously.

**Pack size:** kit of 5 multidose vials.

### Marketing Authorisation Holder and Manufacturer

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For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

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**The following information is intended for medical or healthcare professionals only:**
The complete Summary of Product Characteristics (SmPC) of OSTEOCIS is provided as a separate document in the product package, with the objective to provide healthcare professionals with other additional scientific and practical information about the administration and use of this radiopharmaceutical.
Please refer to the SmPC.