York and Scarborough Teaching Hospitals
NHS Foundation Trust

Bisphosphonate use in patients with early breast cancer

Information for patients, relatives and carers

ⓘ For more information, please contact:

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Why have I been given this leaflet?

You have been given this leaflet because you have been offered treatment with a bisphosphonate medicine (zoledronic acid or ibandronic acid) as part of your breast cancer management.

In post-menopausal and male patients with early breast cancer, these treatments have been shown to reduce the risk of cancer recurrence and the risk of death from breast cancer (overall survival).

How is the treatment given?

The treatment will usually be given as an intravenous (IV) dose of zoledronic acid every six months for three years.

If you do not tolerate zoledronic acid or who wish to have an oral alternative can take an oral bisphosphonate called ibandronic acid (one 50mg tablet taken daily).

How long will I need to take the treatment for?

Provided you do not experience any unwanted side effects, treatment will be for three years. If you switch bisphosphonate formulations, you will still complete three years of treatment in total (oral and IV combined).

Who will prescribe the medication?

If you are commenced on zoledronic acid, this will be prescribed by your oncology team. This can be administered at the medical elective service (MES) in York, Scarborough, Bridlington or Selby hospitals or the mobile chemotherapy unit in Malton. You will have had a blood test within three weeks of the intravenous treatment to ensure your calcium level and kidney function are adequate. You will be given or sent a blood form before your first dose and the treatment team will give you a blood form for the next treatment after each dose.

If you are prescribed ibandronic acid, your first prescription will usually be prescribed by your breast cancer team. Your GP will then take over prescribing. We advise an annual blood test to check the calcium level and kidney function.

What if I am already on bisphosphonate treatment?

Bisphosphonates can be prescribed for a number of different reasons. They are commonly used to prevent or treat osteoporosis (thinning of the bones). Oral alendronate and risedronate are bisphosphonates usually prescribed for osteoporosis.

If you are already taking alendronate or risedronate, your breast cancer team will suggest you switch to zoledronic acid or ibandronic acid.

Both of these drugs have been shown to have a beneficial impact on breast cancer outcomes.
These drugs will also continue to help with the problem that you were being treated for previously.

Are there any side effects?

All drugs can potentially cause side effects. You should read this leaflet alongside the manufacturer's patient information leaflet you will get when the tablets are dispensed or the information that you are given before starting intravenous treatment.
Bisphosphonates may affect the way some bones work and can occasionally cause problems such as:

- Osteonecrosis of the jaw.
- Osteonecrosis of the external auditory canal.
- Unusual fractures of the thigh bone.

More information on these particular side effects is provided in the next section. **These complications of bisphosphonate use are rare.**

Oral bisphosphonates can also sometimes cause inflammation of the oesophagus (gullet) which is why it is important to take the tablet with a full glass of water whilst sitting or standing (see instructions for taking oral ibandronic acid).

What is osteonecrosis?

Osteonecrosis occurs when the blood supply to an area of bone is reduced causing damage to the bone. It is more common when infection is also present.

Osteonecrosis of the jaw can occur in up to one in every 100 patients treated with bisphosphonates. This condition can also develop after treatment has stopped.

There have been a small number of reported cases of patients on a bisphosphonate who have experienced problems of the external ear canal (less than one in every 10,000 patients treated).

Are there any signs and symptoms I should look out for during treatment?

You should contact your doctor, pharmacist, nurse or dentist (for mouth related problems) immediately if you notice any of the following symptoms:

The following may be signs of osteonecrosis of the jaw:

- Feeling of numbness, heaviness or other unusual sensations in your jaw.
- Pain or swelling in your jaw.
- Sores in your mouth which do not heal.
- Any discharge or unpleasant taste in your mouth.
- Loose teeth.

The following may be signs of osteonecrosis of the ear:

- Any ear pain, discharge from the ear or ear infections during treatment.

The following may be signs of fractures of the thigh bone:

- Thigh, hip or groin pain.

The following may be signs of oesophageal reactions (inflammation of the gullet) if you are taking the oral ibandronic acid:

- Difficulty or pain on swallowing.
- Chest pain.
- New or worsening heartburn.
- Nausea and poor appetite

If you experience any other side effects, including those not listed in this leaflet, make an appointment to discuss these with your GP or cancer team.

Side effects should also be reported via the United Kingdom Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard. If you do not have access to the internet, ask your doctor, pharmacist or nurse to report for you. This information helps to inform healthcare teams elsewhere about possible problems.

How can I decrease the risk of developing osteonecrosis of the jaw?

There are several things you can do to reduce your risk.

- Visit your dentist for regular dental check-ups (we recommend having them at least annually).
- If you wear dentures make sure that they fit properly.
- Tell your dentist about all of the medications you are taking.
- Maintain good oral hygiene. Your dentist can advise you on how best to do this.
- Reduce the quantity of sugary snacks and drinks that you consume.
- Reduce the amount of alcohol that you drink.
- Stop smoking (https://www.nhs.uk/live-well/quit-smoking/nhs-stop-smoking-services-help-you-quit/).

What do I need to do before starting treatment?

- You should have a dental review, and any necessary dental work should be performed before starting bisphosphonate treatment. If this is not possible, then it should be undertaken as soon as possible afterwards.
- If for any reason you struggle to get a dental appointment, let your breast cancer team know.
- You must tell your doctor or oncology team if you have any problems with your mouth or teeth.

If you are having **dental treatment** or are due to undergo dental surgery, you should always tell your dentist that you are being treated with a bisphosphonate.

Will I require any monitoring, or blood tests?

You will have a blood test before starting the treatment to check the kidney function, vitamin D and calcium levels. If the Vitamin D is low, it will need to be corrected with oral supplements before starting treatment. We may ask your GP to arrange this.

If you are having the intravenous zoledronic acid, you will have regular blood tests to check your calcium and kidney function up to three weeks before your dose is due. The treating team will send you blood forms before your treatment is due unless you have been given a form at the previous appointment.

If you are taking the oral ibandronic acid you should have an annual blood test to check your calcium and kidney function. Your GP will arrange for this to be done.

We will ask you to visit your dentist for a dental check-up before starting your treatment. We will then ask you to have at least annual dental check-ups.

Will I need supplements?

Bisphosphonates can reduce the level of calcium in your blood. Because of this you will be prescribed a tablet which contains calcium and vitamin D. This will initially be prescribed by your breast cancer team. You will be given one tablet to take daily, however this may change depending on your calcium levels.

Will I need a DEXA (bone density) measurement?

Bone density measurement can be used to help assess your risk of osteoporosis. If you are offered bisphosphonates as part of your breast cancer treatment you will not require a routine bone density measurement.

In patients who are advised to take aromatase inhibitors for more than five years, bone health should be discussed after five years of treatment, even if three years of bisphosphonates have been given.

Should I stop taking the bisphosphonate?

The medical benefits of taking a bisphosphonate outweigh the risks, but you should always discuss any potential side effects with your breast cancer team or GP so that you can be advised what to do.

Bisphosphonates are not licensed for reducing the risk of breast cancer recurrence. What does this mean?

Pharmaceutical companies must hold a license for each medicine that they sell in the United Kingdom.
The Medicines and Healthcare products Regulatory Agency (MHRA) issue these licenses only after they have assessed information on the quality and safety of the medicine. The license states what conditions or symptoms the medicine has been approved to treat.

The manufacturer's information leaflet that you will receive with the tablets will state that the tablets are used to prevent complications to the bones.
This includes fractures in women whose breast cancer has spread to the bones. This is the use the manufacturer has asked the MHRA to be approved for.

Do not be alarmed; we have no reason to believe that your breast cancer has spread to your bones.
In early breast cancer we use bisphosphonates for a different reason, which is to reduce the risk of your breast cancer coming back. This is not a licensed use, because the manufacturer has not asked the MHRA to approve the treatment for this use. However, available evidence suggests they are beneficial in this respect.

Ibandronic acid:

Ibandronic acid tablets must be taken as instructed below:

- Take on an empty stomach first thing in the morning before your other medicines and before any food or drink (other than water). Leave at least 30 minutes after swallowing the tablet before you eat, drink or take any other medicines.
- Take with a full glass of water only (not less than 200ml).
- The tablet should not be taken with water which contains a high concentration of minerals such as calcium and magnesium. This is because the minerals can interfere with the absorption of the tablet if they are in your stomach at the same time. If your tap water is classed as hard water, it will contain high mineral levels. In this case it is advised that you take the tablets with bottled water which has a low mineral content.
  - To find out more about water hardness where you live you can contact Yorkshire Water or look on the internet at https://www.yorkshirewater.com/
- Take the tablet whole; do not crush or chew.
- Take the tablet when sitting or standing. Remain upright (do not lie down) for 60 minutes after taking.

Whilst you are taking bisphosphonates adequate calcium and vitamin D are also required. You will usually also be prescribed a tablet containing calcium and vitamin D which you should take regularly. Calcium supplements should not however be taken at the same time of day as ibandronic acid as they can interfere with its absorption.

Can I take other medicines at the same time?

Supplements containing calcium, magnesium, aluminium, iron are likely to interfere with the way ibandronic acid tablets get absorbed. Food and milk are also likely to interfere. As already discussed food, supplements, medicines and drinks (other than water) should not be taken for at least 30 minutes after taking the tablet.

Aspirin and anti-inflammatory drugs such as ibuprofen, naproxen and diclofenac should be avoided. They can cause irritation of the stomach lining which may make gastric side effects with oral ibandronic acid more likely. Some of these medicines can be purchased over the counter as a pain killer. They should only be taken if you have discussed it with your GP or hospital specialist.

Tell us what you think of this leaflet

We hope that you found this leaflet helpful. If you would like to tell us what you think, please contact Mr Michal Sladkowski, Advanced Pharmacist - Oncology and Dr Andrew Proctor, Consultant Medical Oncologist, by contacting yhs-tr.yorkbreastcarenurses@nhs.net.

Teaching, training and research

Our Trust is committed to teaching, training and research to support the development of health and healthcare in our community. Healthcare students may observe consultations for this purpose. You can opt out if you do not want students to observe. We may also ask you if you would like to be involved in our research.

Patient Advice and Liaison Service (PALS)

PALS offers impartial advice and assistance to patients, their relatives, friends and carers. We can listen to feedback (positive or negative), answer questions and help resolve any concerns about Trust services.

PALS can be contacted on 01904 726262, or email yhs-tr.patientexperienceteam@nhs.net.

An answer phone is available out of hours.

Leaflets in alternative languages or formats

If you would like this information in a different format, including braille or easy read, or translated into a different language, please speak to a member of staff in the ward or department providing your care.

Patient Information Leaflets can be accessed via the Trust's Patient Information Leaflet website: www.yorkhospitals.nhs.uk/your-visit/patient-information-leaflets/

Owner	Michal Sladkowski, Advanced Pharmacist – Oncology
Date first issued	February 2018
Review Date	November 2028
Version	5 (issued November 2025)
Approved by	SACT Development Group
Document Reference	PIL1188 v5

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