



York and Scarborough
Teaching Hospitals
NHS Foundation Trust

Bisphosphonate use in patients with breast cancer

Information for patients, relatives and carers

① For more information, please contact:

Medicines Information

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York Hospital Medicines Information

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Contents	Page
Why have I been given this leaflet?	4
How is the treatment given?	4
How long will I need to take the treatment for?	6
Can I take other medicines at the same time?	6
Who will prescribe the medication?	7
What if I am already on bisphosphonate treatment?	7
Bisphosphonates are not licensed for reducing the risk of breast cancer recurrence. What does this mean?	8
Are there any side effects?	9
What is osteonecrosis?	10
Are there any signs and symptoms I should look out for during treatment?	11
How can I decrease the risk of developing osteonecrosis of the jaw?	12
What do I need to do before starting treatment?	13
Will I require any monitoring, or blood tests?	14
Should I stop taking the bisphosphonate?	14
Tell us what you think of this leaflet	15
Teaching, training and research	15
Patient Advice and Liaison Service (PALS)	15

Why have I been given this leaflet?

You have been given this leaflet because you are going to be treated with a bisphosphonate medicine (zoledronic acid and/or ibandronic acid).

In post-menopausal women, with early breast cancer, these drugs have been shown to reduce the risk of the disease recurring and increase length of life.

How is the treatment given?

The treatment will usually be provided as an oral tablet of ibandronic acid (one 50mg tablet taken once daily).

Women who need to have chemotherapy will initially be given zoledronic acid. This is administered as an intravenous infusion (drip into a vein) every six weeks at the same time as the chemotherapy. After three infusions, the treatment will be changed to oral ibandronic acid 50mg as above.

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/your-water/water-hardness/>

Take the tablet whole; do not crush or chew.

- Take the tablet when sitting / 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. Follow the advice given earlier and take the ibandronic acid at least 30 minutes before your other medicines.

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. Women who only have the oral treatment will take the ibandronic acid tablets for 36 months. Women who have intravenous treatment with zoledronic acid first will take the ibandronic acid tablets for 30 months.

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.

Who will prescribe the medication?

Your first supply of oral ibandronic acid will probably be prescribed by your hospital specialist (as long as your calcium level is normal). Your GP will then take over prescribing.

If, however, the amount of calcium in your blood is low, your GP will be asked to prescribe some supplements to correct this **before** you start oral ibandronic acid. In this case your first supply and ongoing supplies of ibandronic acid will be prescribed by your GP.

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 alendronic acid and risedronate are bisphosphonates usually prescribed for osteoporosis.

If you are already taking alendronic acid or risedronate, your doctor will suggest you switch to ibandronic acid. This drug has better published information for its use in reducing the risk of breast cancer recurring.

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/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 the tablets 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 yet asked the MHRA to approve the tablets for this use. However, available evidence suggests they are beneficial in this respect.

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.

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.

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.

What is osteonecrosis?

Osteonecrosis occurs when the blood supply to an area of bone is reduced causing damage to the bone.

Osteonecrosis of the jaw bone 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.
- Any other abnormality of your mouth.

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):

- Difficulty or pain on swallowing.
- Chest pain.
- New or worsening heartburn.

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

Side effects should also be reported via the United Kingdom Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard. If you don't 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.
- If you wear dentures make sure that they fit properly.
- Tell your dentist about all 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 (call the NHS Stop Smoking Helpline on 0300 123 1044, or go to www.smokefree.nhs.uk for help).

What do I need to do before starting treatment?

- All patients should have a dental check-up 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.
- You must tell your doctor/nurse 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 at the hospital before starting treatment to check the calcium level in your blood. If this is low it will need to be corrected with oral supplements before starting treatment. We will ask your GP do this.

You should have an annual blood test to check kidney function and the calcium level in your blood. Your GP will arrange for this to be done.

You should visit your dentist for regular dental check-ups.

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 GP so that you can be advised what to do.

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:

Medicines Information, Pharmacy Department, The York Hospital, Wigginton Road, York, YO31 8HE .

Telephone 01904 725960 or via e-mail
medicines.information@york.nhs.uk

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
pals@york.nhs.uk.

An answer phone is available out of hours.

Leaflets in alternative languages or formats

Please telephone or email if you require this information in a different language or format, for example Braille, large print or audio.

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或發電

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