

The ROYAL MARSDEN

NHS Foundation Trust

Bisphosphonates in early breast cancer

Breast Unit

Patient Information



NHS

What are bisphosphonates?

Bone constantly undergoes a process of renewal. Specialised bone cells break down old bone and replace it with new bone every day. This process helps to repair damage to the skeleton from everyday activities. We call this process bone turnover. However, as we age this process becomes less efficient and the bones become thinner and weaker.

Bisphosphonates are a group of medications that have been used to treat thin bones (osteoporosis) for decades. Bisphosphonates control the cells that break down bone (osteoclasts) and allow the cells that rebuild bone (osteoblasts) to work better. As a result, they increase bone density and strength and therefore reduce the risk of fractures, especially at the wrist, hip and spine.

Why are bisphosphonates being used to treat breast cancer?

Clinical studies have shown that breast cancers can recur in bones, often many years after patients have had an operation to remove the cancer from the breast. Doctors think this could be because the chemicals that control bone turnover could also encourage the growth of breast cancer cells inside bones.

Clinical trials of bisphosphonates in early breast cancer began in the 1990s. These drugs were added to standard treatments after breast surgery, such as chemotherapy and tamoxifen, and compared to these standard treatments alone. These clinical trials found that bisphosphonates reduced the risk of breast cancer coming back in patients' bones and often meant that patients lived longer. Not all patients had the same degree of benefit though. The greatest benefits from bisphosphonates were seen in two groups of women:

- Post-menopausal women
- Pre-menopausal women who were treated with drugs to suppress their ovaries.

In these groups of women, 2 in 3 recurrences of breast cancer in the bone and 1 in 6 deaths from breast cancer at 10 years after diagnosis had been prevented.

Who can take bisphosphonates?

Specialists are prescribing this treatment to the following women:

- Post-menopausal women who have had their breast cancer completely removed
- Pre-menopausal women who are on additional drugs to suppress their ovaries as part of their standard treatment after surgery.

Individuals whose kidneys are not functioning normally will take a reduced dose.

Bisphosphonates are not licensed for use with people who have breast cancer to prevent recurrence of the disease. As a result, they must be started by a specialist in hospital who has the appropriate experience. They will advise your GP on the recommended treatment and for how long you should take the medication for.

How do I take bisphosphonates?

How you take bisphosphonates will depend on whether you are having chemotherapy as part of your treatment plan.

Bisphosphonates will be administered through a drip into a vein using a drug called zoledronic acid (zoledronate, trade name Zometa).

Zoledronic acid

If you are receiving chemotherapy, you may receive your first dose with the last cycle of chemotherapy. This will only add about 15 minutes to the time it takes to give your chemotherapy and should not affect the chemotherapy side effects.

If your doctor has decided you do not need chemotherapy then treatment can begin on the chemotherapy day unit. This is given every six months until three years of therapy has been completed.

If you find that the zoledronic acid infusion does not suit you, your doctor may recommend that you receive oral ibandronate tablets instead for three years.

How long should I take bisphosphonates for?

We recommend that you take zoledronic acid for three years. You will need to return to the hospital clinic for the intravenous zoledronic acid every six months.

What are the side effects?

Most people will not experience side effects and if they do, they are usually short-term.

If you are taking other medications, make sure you talk through these treatments with your specialist or GP.

Zoledronic acid

Potential side effects include:

- Flu-like symptoms such as fever, aching muscles, dizziness, vomiting or headache (seen in at least one in every 100 people).
- Reduced levels of calcium in the blood (hypocalcaemia, seen in at least one in every 100 people), sometimes leading to muscle cramps, dry skin, burning sensation, have been reported in patients treated with zoledronic acid.
- Irregular heart beat (cardiac arrhythmia), seizures, spasm and twitching (tetany) have been reported as secondary to severe hypocalcaemia. In some instances the hypocalcaemia may be life-threatening (seen in one in every 1,000 to one in 10,000 people).
- Changes in kidney function (affecting less than one patient in 100 but more than one in 1,000). Our doctor will check how well your kidneys are working with regular blood tests.

- Inflammation in the eye (seen in at least one in every 100 people).

There is information suggesting a link between drugs from the bisphosphonate family and the following rare conditions.

- Osteonecrosis (ON) of the jaw is a condition where some cells in the jawbone die. This means that the jaw may be slow to heal. It is mostly associated with high doses of bisphosphonate drugs and so is unlikely to occur in relation to tablet bisphosphonates or six monthly intravenous treatments. There have only been a small number of cases described worldwide, so the risk with the treatments we are recommending is low (affecting less than one patient in 100 but more than one in 1,000).

As a precautionary measure, people taking this treatment are advised to have regular check-ups with their dentist and inform them that they are taking a bisphosphonate. It is important to maintain good dental and gum health. Make sure dentures fit well. During treatment and for several years afterwards, patients are advised not to have dental extractions unless advised by an experienced dentist aware of this treatment. Dental implants may also pose a risk of ON even years after treatment.

- There is also some information suggesting a link to osteonecrosis of the auditory canal. This is very rare (fewer than one in 10,000 patients). People taking this treatment are advised to report persistent ear pain and/or discharge from the ear.
- There is also a possible link between taking bisphosphonate treatment over a long period of time and developing a stress fracture of the thigh bone. This is extremely unlikely to be a problem in the treatment of breast cancer (seen in one in every 1,000 to one in 10,000 people) as we will be asking you to take the medication for only three years in total.

If you develop aching pain in the thigh while taking treatment, you should let your GP, or the Open Access Follow Up (OAFU) team know.

- Women are advised to avoid becoming pregnant and should avoid breastfeeding during treatment with zoledronic acid. The effect of zoledronic acid on fertility is unknown.

Is there anything I should look out for whilst taking bisphosphonates?

Zoledronic acid

Some patients experience flu-like symptoms such as fever, aching muscles, dizziness, vomiting or headache with the first dose, but these usually resolve after the first couple of days and are less likely to occur with following treatments. Mild painkillers can be taken such as paracetamol or ibuprofen. If symptoms persist, speak to your specialist or GP.

If you experience any of the following symptoms whilst taking this medication you are advised to see your doctor:

- Persistent ear pain and/or discharge from the ear
- Persistent jaw pain and/or ulceration of the gum
- Persistent aching pain in the thigh.

Do I need to take extra calcium or vitamin D?

It is recommended that you have an adequate calcium and vitamin D intake. Calcium should be sufficient if you have a well-balanced diet. We will give you additional supplements at the start of zoledronic acid treatment. Some patients may need to continue this during the three years of infusions.

We also recommend regular weight bearing exercise (activity where your feet and legs support your weight), avoiding smoking and keeping alcohol consumption within the recommended limits.

Where can I find further information?

For further information about bisphosphonates, please ask the staff treating you at hospital or ask your GP. Information is also available from The Royal Osteoporosis Society.

The Royal Osteoporosis Society

Camerton, Bath, BA2 0PJ

Website: *www.theros.org.uk*

ROS Helpline: Information and support from specialist nurses - for questions about osteoporosis and bone health.

Email: nurses@theros.org.uk

Freephone: 0808 800 0035

(Monday to Friday, 9am–1pm and 2pm–5pm)

Alternatively, a summary of product characteristics is available via the Electronic Medicines Compendium

www.medicines.org.uk/emc

Contact details

Please contact us if you have any concerns or questions.

Open Access helpline: 020 7811 8114

Email: oafu@rmh.nhs.uk

Clinical Nurse Specialist (Chelsea and Sutton) via switchboard
on 020 8642 6011

Name:

Telephone:

Alternatively, please call:

The Royal Marsden Macmillan Hotline: 020 8915 6899

(available 24 hours a day, 7 days a week)

This patient information leaflet is adapted from a leaflet originally developed by the Breast Unit at Sheffield Teaching Hospitals NHS Foundation Trust.

Notes and questions

References

This booklet is evidence based wherever the appropriate evidence is available, and represents an accumulation of expert opinion and professional interpretation.

Details of the references used in writing this booklet are available on request from:

The Royal Marsden Help Centre

Telephone: Chelsea 020 7811 8438 / 020 7808 2083

Sutton 020 8661 3759 / 3951

Email: patientcentre@rmh.nhs.uk

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Should you require information in an alternative format, please contact The Royal Marsden Help Centre.

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