

INFORMATION FOR PATIENTS

Bisphosphonates for breast cancer

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 thereby 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, like 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, 1 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 bisphosphonate?

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 in breast cancer patients to prevent recurrence of the disease. As a result they must be started by a specialist in hospital who has the appropriate experience. He/she will advise your GP on the recommended treatment and for how long you should take the medication for.

How do I take bisphosphonate?

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

Bisphosphonates will either be administered through an infusion into a vein using a drug called zoledronic acid (Zometa) or as a daily tablet called ibandronate.

Zoledronic acid (Zometa) infusion (drip)

The infusion is given 6 monthly in the chemotherapy suite and should only take around 15 minutes. If you are receiving chemotherapy the first infusion can sometimes be administered with one of the chemotherapy cycles.

Your doctor can then discuss switching you to the daily ibandronate tablets once chemotherapy finishes or continuing with the Zometa infusion. You will be able to get further supplies of the tablets from your GP.

Ibandronate tablets

When taken as a tablet (called ibandronate), there are some important things to note:

- They must be taken at least 30 minutes before the first food or drink of the day (other than plain tap water). **These instructions are important because these drugs will only be effective if taken on an empty stomach.**
- Tablets must be swallowed whole and taken with a glass of plain tap water (not less than 200ml or 7fl oz).
- It is important to stay upright (sitting, standing or walking) for at least 60 minutes after taking the tablet to help it 'go down' properly.
- It is recommended that it is taken at the same time each day. If you forget to take it on one day it can be taken the following day, do not double up to make up for a forgotten dose.

If you find that the ibandronate tablets do not suit you, your doctor may recommend that you receive the Zometa infusion.

How long should I take bisphosphate?

We recommend that you take the treatment for 3 years, so you will either continue on daily oral ibandronate prescribed by your GP or return to the hospital clinic for the intravenous Zometa.

What are the side effects?

The side effects of bisphosphonates depend upon whether they are given through the veins as a drip or swallowed as a tablet. Most people will not experience side effects and if they do, they are usually short lived. Specific side effects are described below. If you are taking other medications make sure you talk through these treatments with your specialist or GP.

Ibandronate tablets

- Inflammation and ulceration of the oesophagus (food pipe)
- Nausea
- Stomach pains
- Inflammation of the tongue
- Joint pain.

Zoledronate drip

- Flu like symptoms such as fever, aching muscles or headache
- Irregular heartbeats (very rare)
- Inflammation in the eye (very rare).

Both treatments

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

- Osteonecrosis 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 6 monthly intravenous treatments. There have been only a small number of cases described worldwide, so the risk with the treatments we are recommending is low (affecting probably less than 1 patient in 100). 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.
- There is also some information suggesting a link to osteonecrosis of the auditory canal. This is very rare (fewer than 1 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 (affecting probably less than 1 patient in 10,000) as we will be asking you to take the medication for only 3 years in total. If you develop aching pain in the thigh while taking treatment you should let your doctor know.

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

Ibandronate tablets

Tablet bisphosphonates may not be appropriate for those who cannot stay upright after taking the medication or who have a history of digestive problems.

This is why there are special instructions for taking this drug. If you experience any difficulty or pain on swallowing, chest pain or worsening heartburn, the bisphosphonate should be stopped and you should contact your specialist or GP.

Zoledronate drip

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

Both treatments

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
- Aching pain in the thigh.

You are also advised to have regular dental check-ups whilst taking this medication.

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. For vitamin D you should take an over the counter supplement (available from chemists and supermarkets at a recommended dose of 800-1000 IU daily).

Try to take the vitamin D supplement at a different time of the day to the tablet bisphosphonate. We also recommend regular weight bearing exercise i.e. activity where your feet and legs support your weight, avoiding smoking and keeping alcohol consumption within the recommended limits after a breast cancer diagnosis.

Where can I find further information?

Further information about bisphosphonates may be obtained from the Breast Care Nurse Specialists on telephone 01623 622515, extension 3884.

You can also obtain information from your GP.

Information is also available from the National Osteoporosis Society:

National Osteoporosis Society

Camerton

Bath BA2 0PJ

- Website: www.nos.org.uk

- Helpline: **0808 800 0035** (9.00am - 5.00pm Monday - Friday)

- Helpline email: nurses@nos.org.uk

For National Osteoporosis Society publications and information sheets, please go to:

- Website: www.nos.org.uk
- Publications: **01761 471 771**
- National Osteoporosis Society general enquiries email: info@nos.org.uk

Further sources of information

NHS Choices: www.nhs.uk/conditions

Our website: www.sfh-tr.nhs.uk

Patient Experience Team (PET)

PET is available to help with any of your compliments, concerns or complaints, and will ensure a prompt and efficient service.

King's Mill Hospital: 01623 672222

Newark Hospital: 01636 685692

Email: sfh-tr.PET@nhs.net

If you would like this information in an alternative format, for example large print or easy read, or if you need help with communicating with us, for example because you use British Sign Language, please let us know. You can call the Patient Experience Team on 01623 672222 or email sfh-tr.PET@nhs.net.

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