Drug treatments for osteoporosis: Ibandronate (Bonviva)

What is osteoporosis?
Osteoporosis occurs when the struts which make up the mesh-like structure within bones become thin causing them to become fragile and break easily, often following a minor bump or fall. These broken bones are often referred to as 'fragility fractures'. The terms 'fracture' and 'broken bone' mean the same thing. Although fractures can occur in different parts of the body, the wrists, hips and spine are most commonly affected. It is these broken bones or fractures which can lead to the pain associated with osteoporosis. Spinal fractures can also cause loss of height and curvature of the spine.

What is Ibandronate?
Ibandronate is one of the bisphosphonate drug treatments which are widely used to reduce the risk of broken bones in people with osteoporosis. It is available either as a monthly tablet or as an injection into a vein. The injection, which will be given by a healthcare professional, comes in a pre-filled syringe (3mg dose in 3ml of fluid) and is given once every three months. The drug is given via a small needle that is placed in a vein in the arm or the back of your hand. It is likely that referral to an appropriate hospital consultant will be needed and that the procedure will take place in a hospital or clinic setting, although some GP surgeries may also have facilities to give intravenous drugs.

Why do I need a drug treatment for osteoporosis and how do the bisphosphonates work?
Drug treatments are prescribed if you have osteoporosis and are at a high risk of broken bones. These treatments help strengthen your bones and reduce your risk of having fractures. They do not help the pain that occurs when bones break.

Bone is constantly being broken down (resorption) and rebuilt by specialist bone cells (formation). This is called bone remodelling. When this becomes out of balance and more bone is broken down than is rebuilt osteoporosis occurs. Bisphosphonates such as ibandronate, known as antiresorptive drugs, inhibit the cells that wear down bone (osteoclasts) and as a consequence improve bone strength.

Which products contain ibandronate?

<table>
<thead>
<tr>
<th>Ibandronic acid</th>
<th>Monthly 150mg tablet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose</td>
<td>Three - monthly 3mg intravenous injection</td>
</tr>
<tr>
<td>Licensing details</td>
<td>FS</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Bonviva*</th>
<th>Monthly 150mg tablet</th>
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<tbody>
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<td>Dose</td>
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<tr>
<th>Bonviva injection*</th>
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Key:
- **F** = Post-menopausal women
- **M** = Men
- **S** = shown to reduce the risk of broken bones in the spine
- **H** = shown to reduce the risk of a broken hip
- **GIOP** = shown to reduce the risk of broken bones in people who have osteoporosis caused by corticosteroid medication

*Generic (non-branded) forms of ibandronate (both tablet and IV) are also available.

A licensed drug has been checked for safety and effectiveness and can be prescribed by a doctor for a specific condition.

Sometimes an unlicensed drug will be given at the discretion of your doctor e.g. those licenced specifically for women may be prescribed for men.
How can I get the most out of my drug treatment?

1. Be informed

Find out about your drug treatment so that you can be involved in decisions being made and you will know what to expect. Talk to your doctor and/or contact the helpline at the Royal Osteoporosis Society if you have any questions or concerns. If you have been recommended ibandronate as an injection ask your doctor for a copy of the Patient Information leaflet which describes how the drug is given and the possible side effects. It is important that you gather as much information as possible and discuss any worries you may have prior to having the first injection.

2. Make sure the drug is properly absorbed (if you are taking ibandronate tablets)

If you are taking ibandronate in tablet form, it is important that it is properly absorbed. To make sure this happens, you will be instructed to take ibandronate at least 1 hour before the first food or drink (other than plain tap water) of the day. It is also important that you avoid any other medication during this time. This instruction is important because the ibandronate tablet will only be absorbed if taken on an empty stomach. If you are taking a calcium supplement it is important to leave at least 3-4 hours after taking your ibandronate as calcium will prevent its absorption.

3. Make sure ibandronate is the treatment for you

If you have one of the following, ibandronate may not be appropriate for you:

- If you cannot swallow tablets whole due to a physical problem, have an abnormality in your gullet or suffer from Barrett's oesophagus (only applicable to ibandronate in tablet form).
- If you have severe kidney problems.
- If you are pregnant or breast feeding (although only licensed for post-menopausal use, occasionally it may be prescribed by specialists for younger women).

4. Continue to take your treatment regularly for the correct length of time

Ibandronate is generally prescribed long term so you need to be happy with the treatment. If you are taking the tablet, choose one day of the month that will be easy to remember. You can choose either the same date (such as the 1st of each month) or the same day (such as the first Sunday of each month). If you continually forget or struggle to take your medication it would be sensible to speak to your doctor about other treatment options that you may find easier to take.

Ask your doctor about how long you need to take your osteoporosis treatment. The current advice from the UK drug regulatory organisation (MHRA) is for a formal treatment review after about five years, primarily because of the potential (but rare) risk of atypical fractures (see the factsheet on atypical (unusual) thigh bone fracture for more information about this).

At this review your doctor will make sure that the drugs are still needed, that they aren't causing side-effects and also that the benefits of continuing to take the drug continue to outweigh any potential harm. You may be advised to continue to take the drug, have a ‘pause’ in your treatment or be advised to stop taking it altogether. Because of its structure ibandronate will continue to have an effect on bone and provide some benefit even after it is stopped. Your doctor will be able to advise you on what is best for you based on your individual circumstances.

5. Lead a healthy lifestyle to keep your bones strong

Factors that can help to maintain healthy bones are a well-balanced diet with adequate calcium rich foods, safe exposure to sunlight to obtain vitamin D, regular weight bearing exercise, avoiding smoking and keeping alcohol consumption within the recommended limits.

If you have been diagnosed with osteoporosis and are taking a drug treatment, you may need to boost your calcium intake up to around 1000mg a day. Your doctor can prescribe supplements of calcium and/or vitamin D if you need them.
6. Understand the risk of side effects and what can be done to reduce them

As with any drug, there are potential side effects with ibandronate. It is important to remember that:

- Most people will not experience side effects or if they do, they are short lived.
- Not all the symptoms you may read about online or see listed on your patient information leaflet are necessarily caused by the drug. Symptoms that have been reported by patients taking part in the research trials may be included as possible side effects even if they were seen in as many people who took the placebo (dummy treatment) as those taking ibandronate. So common conditions such as coughs, colds, headaches and diarrhoea will often be reported in this way and people may think they are due to their treatment. We can only be sure that such symptoms are likely to be caused by ibandronate if they were seen in more patients treated with ibandronate than with placebo. The symptoms overleaf are those that can be thought of as “true side effects”.

If you are taking medications for other conditions it is important to establish that it is not these that are causing your side effects. Talk to your doctor who may be able to suggest ways of investigating this further.

If you are taking ibandronate as an injection you may worry that you will experience side effects that you can do nothing about. Although this is an understandable concern this does not appear to occur and although as explained you may experience side effects following the injection they are generally short lived.

If you experience these or any other symptoms which you think may be due to this medicine, speak with your doctor or pharmacist about other treatment options.

As more research findings become available more symptoms may be found to be “true side effects” so information could change in the future.

### What side effects can ibandronate cause?

<table>
<thead>
<tr>
<th>Potential side effects</th>
<th>How common is it?</th>
<th>What can I do to reduce the risk of this occurring and what should I do if I experience this problem?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tablets</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inflamed food pipe</td>
<td>1 in 10 to 1 in 100</td>
<td>To make sure the tablet doesn't stick in your food pipe where it can cause irritation remain standing or sitting for at least one hour after swallowing the tablet with a full glass of plain water. Try to avoid bending forward during this time. If you get heartburn that doesn't resolve, let your doctor know.</td>
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<td>This is most commonly associated with the ibandronate given via injection affecting up to 30% of people following the first injection. They generally occur within the first 24 hrs following the dose of ibandronate. The symptoms are usually mild to moderate and go away within days. Your doctor can recommend a mild pain reliever such as ibuprofen or paracetamol to reduce these side effects. Try not to plan any strenuous activities for the few days following your injection in case you experience this reaction. The chance of experiencing these side effects decreases with subsequent doses of ibandronate</td>
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If you are taking ibandronate as a tablet you may worry that you will experience side effects that you can do nothing about. Although this is an understandable concern this does not appear to occur and although as explained you may experience side effects they are generally short lived.

If you experience these or any other symptoms which you think may be due to this medicine, speak with your doctor or pharmacist about other treatment options.

As more research findings become available more symptoms may be found to be “true side effects” so information could change in the future.
What other side effects can ibandronate tablets or injections cause?

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<td>Bone, joint or muscle pains (this can also occasionally occur in people taking the ibandronate tablet)</td>
<td>1 in 10 to 1 in 100</td>
<td>This is sometimes an initial response that often improves as your body adjusts to the new medicine and may be alleviated by taking a pain reliever such as paracetamol. Occasionally this is a long term problem in which case speak to your doctor about other treatment options</td>
</tr>
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<td>Inflammation in the eye (uveitis and scleritis) causing eye pain or disturbed vision</td>
<td>1 in 100 to 1 in 1000</td>
<td>If you have an existing inflammatory eye condition or develop any symptoms such as a painful red eye you should see your doctor.</td>
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</tbody>
</table>

Are there any other health risks associated with ibandronate?

- Osteonecrosis of the jaw
  - This is an extremely rare jaw problem in which there is delayed healing in the mouth usually following invasive dental procedures. The general advice is to maintain good oral hygiene and receive routine dental check-ups

- Atypical (unusual) thigh bone fracture
  - This is an unusual and rare type of thigh bone fracture which can occur after long term treatment and as a result of little or no force

For more information see our factsheets on these very rare conditions

This factsheet covers specific information on drug treatments. If you would like more general information on drug treatments for osteoporosis, such as how to decide which drugs to take, please see our information resources.

For osteoporosis information and support contact our free specialist nurse Helpline:

- Email: nurses@theros.org.uk
- Phone: 0808 800 0035

This information is provided free of charge.

If you would like to become a member or support the charity with a donation, please go online or call us:

- theros.org.uk
- Phone: 01761 473 287

This information reflects current evidence and best practice but is not intended to replace the medical advice provided by your own doctor or other healthcare professional.

This is one of many information resources available about osteoporosis and bone health. View the range at theros.org.uk and order more by calling us on 01761 471 771 or emailing info@theros.org.uk

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