

## VI.2 Elements for a Public Summary

[product name] 5 mg film-coated tablets

### VI.2.1 Overview of disease epidemiology

In the EU, 22 million women and 5.5 million men were estimated to suffer from osteoporosis in 2010. Bone is a living tissue. Old bone is constantly removed from your skeleton and replaced with new bone. Osteoporosis is a disease of the bone commonly occurring with age. Bone density reduces, the bones become weaker, more fragile and more likely to break after a fall or strain.

In 80% of the cases, osteoporosis occurs in postmenopausal women (women after the menopause). Many patients with osteoporosis have no symptoms and not even have known that they had it. In 30 % of the cases, the osteoporosis is clinically relevant and requires treatment. Osteoporosis is more likely to occur in women who have reached the menopause early and also in patients treated long-term with steroids.

The spine, hip and wrist are the most likely bones to break, although this can happen to any bone in your body. Osteoporosis –related fractures can also cause back pain, height loss and a curved back.

### VI.2.2 Summary of treatment benefits

[product name] is used for the treatment of osteoporosis  
in **postmenopausal women**

And the prevention of osteoporosis

in **women with an increased risk of osteoporosis** (including low bone mass, early menopause or a family history of osteoporosis).

in **postmenopausal women** who have been on **high doses of steroid drugs for a long time**. It maintains or increases bone mass.

[product name] belongs to a group of non-hormonal medicines called bisphosphonates which are used to treat bone diseases. It works directly on your bones to make them stronger and therefore less likely to break.

### VI.2.3 Unknowns relating to treatment benefits

The treatment benefit in patients older than 80 years is unknown.

### VI.2.4 Summary of safety concerns

#### Important identified risks

Risk	What is known	Preventability
Low calcium levels in your blood (Hypocalcaemia)	Up to 1 in 10 people may experience low calcium levels in your blood	DO NOT take [product name] if you have or ever had low calcium in your blood. In particular, tell your doctor

		or pharmacist if you are taking any of the following medicines: supplements containing calcium.
Inflammation of the eye which causes pain and redness (Iritis/uveitis)	This side effect may affect up to 1 in 100 people.  Inflammation of the coloured part of the eye (iris) may include red painful eyes with a possible change in vision.	Tell your doctor promptly if you experience the following side effects: Eye inflammation, usually with pain, redness and light sensitivity.
Allergic and skin reactions (Hypersensitivity and skin reactions )	Symptoms of a severe allergic reaction are e.g.: • Swelling of the face, tongue or throat • Difficulties in swallowing • Hives and difficulties in breathing Severe skin reactions can include blistering of the skin.	Do not take [product name] if you are allergic (hypersensitive) to risedronate sodium or any of the other ingredients of [product name].  Stop taking [product name] and contact a doctor immediately if you experience any symptoms of a severe allergic reaction.
Dead bone tissue in the jaw bone (Osteonecrosis of the jaw)	This side effect may affect up to 1 in 10,000 people. Pain or sore in your mouth or jaw are early signs of severe jaw problems.	A dental examination with appropriate preventive dentistry should be considered prior to treatment, especially if you have the following risk factors: e.g. cancer, chemotherapy, radiotherapy, corticosteroids, poor oral hygiene. If you have one of these risk factors, you should avoid invasive dental procedures if possible while on treatment. If you are having dental treatment or surgery or know that you need some in the future, tell your dentist that you are being treated with [product name].

**Important potential risks**

<b>Risk</b>	<b>What is known (Including reason why it is considered a potential risk)</b>
Atypical femoral fractures	The long-term use of bisphosphonates is thought to be the

	<p>main risk factor for atypical femoral fractures (unusual fracture of the thigh bone).</p> <p>Some patients experience thigh or groin pain, often associated with imaging features of stress fractures, weeks to months before presenting with a completed femoral fracture.</p> <p>During bisphosphonate treatment you should report any thigh, hip or groin pain.</p>
Serious upper GI irritation	<p>Inflammation or ulcer of the oesophagus may affect up to 1 in 100 users.</p> <p>Take special care and talk to your doctor BEFORE you start taking [product name] if you have had problems in the past with your oesophagus (the tube that connects your mouth with your stomach). For instance you may have had pain or difficulty in swallowing food or you have <u>previously</u> been told that you have Barrett's oesophagus (a condition associated with changes in the cells that line the lower oesophagus).</p>
Serious musculoskeletal pain	<p>Pain in your bones, muscles or joints may affect up to 1 in 10 users. Patients treated with risedronic acid may be at an increased risk for developing serious musculoskeletal pain. There had been single reports. However, a clear causal relationship could not be established.</p>
Serious hepatitis disorders	<p>Patients treated with risedronic acid may be at an increased risk for developing serious hepatic disorders. There had been single reports. In most of the reported cases the patients were also treated with other products known to cause hepatic disorders.</p>

### Missing information

Risk	What is known
Atrial fibrillation	<p>Patients treated with the medicinal product may be at an increased risk of developing atrial fibrillation.</p> <p>Cases of atrial fibrillation have been reported with the use of pamidronic acide, another bisphosphonate. However, a causal relationship to risedronic acid has not been established.</p>
Insufficient data on safety and efficacy in children and adolescents	<p>There is not enough clinical experience available. [product name] is not recommended for use in children below age 18 due to insufficient data on safety and efficacy.</p>
Insufficient evidence to support efficacy in the very elderly (>80 years)	<p>Data suggest that the very elderly (&gt;80 years) benefit less from treatment. This may because with increasing age, causes for hip fracture other than bone density dominate.</p>
No formal interaction studies	<p>No formal interaction studies have been performed, however</p>

	<p>no clinically relevant interactions with other medicinal products were found during clinical trials. Medicines containing calcium, magnesium, aluminium (for example some indigestion mixtures) or iron lessen the effect of [product name]. Due to the way how risedronic acid is degraded by the body, no further essential interactions are to be expected.</p>
No adequate data in pregnant and breast-feeding women	<p>There is not enough clinical experience available. Do not take [product name] if you may be pregnant, are pregnant or are planning to become pregnant or if you are breast-feeding.</p>

## **VI.2 Elements for a Public Summary**

[product name] 35 mg film-coated tablets

### **VI.2.1 Overview of disease epidemiology**

In the EU, 22 million women and 5.5 million men were estimated to suffer from osteoporosis in 2010. Bone is a living tissue. Old bone is constantly removed from your skeleton and replaced with new bone. Osteoporosis is a disease of the bone commonly occurring with age. Bone density reduces, the bones become weaker, more fragile and more likely to break after a fall or strain.

In 80% of the cases, osteoporosis occurs in postmenopausal women (women after the menopause). Many patients with osteoporosis have no symptoms and not even have known that they had it. In 30 % of the cases, the osteoporosis is clinically relevant and requires treatment. Osteoporosis is more likely to occur in women who have reached the menopause early and also in patients treated long-term with steroids. However, osteoporosis can also occur in men due to a number of causes including ageing and/or a low level of the male hormone, testosterone.

The spine, hip and wrist are the most likely bones to break, although this can happen to any bone in your body. Osteoporosis –related fractures can also cause back pain, height loss and a curved back. Many patients with osteoporosis have no symptoms and you may not even have known that you had it.

### **VI.2.2 Summary of treatment benefits**

[product name] is used for the treatment of osteoporosis  
in postmenopausal women, even if osteoporosis is severe. It reduces the risk of spinal and hip fractures.  
in men.

[product name] belongs to a group of non-hormonal medicines called bisphosphonates which are used to treat bone diseases. It works directly on your bones to make them stronger and therefore less likely to break.

### **VI.2.3 Unknowns relating to treatment benefits**

The treatment benefit in patients older than 80 years is unknown.

### **VI.2.4 Summary of safety concerns**

#### **Important identified risks**

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**Important potential risks**

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	<p>main risk factor for atypical femoral fractures (unusual fracture of the thigh bone).</p> <p>Some patients experience thigh or groin pain, often associated with imaging features of stress fractures, weeks to months before presenting with a completed femoral fracture.</p> <p>During bisphosphonate treatment you should report any thigh, hip or groin pain.</p>
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