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 occuring with age. Bone density reduces, the bones become weaker, more fragile and more likely to break after a fall or strain.

In 80% of cases, osteoporosis occurs in postmenopausal women (women after the menopause). Many patients with osteoporosis have no symptoms and have not even known they had it. In 30 % of the cases, 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 under long-term treatment with steroids.

The spine, hip and wrist are the most likely sites of bones fractures, 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 effect: 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 my 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

Risk	**What is known** **(Including reason why it is considered a potential risk)**
Atypical femoral fractures	The long-term use of bisphosphonates is thought to be the main risk factor for atypical femoral fractures (unusual

	fracture of the thigh bone). 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. During bisphosphonate treatment you should report any thigh, hip or groin pain.
Serious upper GI irritation	Inflammation or ulcer of the oesophagus may affect up to 1 in 100 users. 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 previously been told that you have Barrett's oesophagus (a condition associated with changes in the cells that line the lower oesophagus).
Serious musculoskeletal pain	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.
Serious hepatitis disorders	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.

Missing information

Risk	**What is known**
Atrial fibrillation	Patients treated with the medicinal product may be at an increased risk of developing atrial fibrillation. 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.
Insufficient data on safety and efficacy in children and adolescents	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.
Insufficient evidence to support efficacy in the very elderly (>80 years)	Data suggest that the very elderly (>80 years) benefit less from treatment. This may because with increasing age, causes for hip fracture other than bone density dominate.
No formal interaction studies	No formal interaction studies have been performed, however 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]. Given how risedronic acid is degraded by the body, no further essential interactions are to be expected.
No adequate data in pregnant and breast-feeding women	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.

VI.2 Elements for a Public Summary

[product name] 30 mg film-coated tablets

VI.2.1 Overview of disease epidemiology

Paget's disease (osteitis deformans) mainly occurs in Western countries (people from Europe and North America), and is rare in people from Asia or Africa. Therefore, it is suspected that genetic modifications are the cause of this disease. The risk of getting ill starts to increase from the age of 55. Men are more frequently affected than women. However, most of the patients (70 – 90%) do not develop complaints and do not need to be treated.

Tretament options include drugs against pain and inflammation (NSAIDs), physiotherapy, and drugs to make the bone stronger.

VI.2.2 Summary of treatment benefits

[product name] is used for the treatment of Paget's disease of the bone (osteitis deformans).

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

Bone is a living tissue. Old bone is constantly removed from your skeleton and replaced with new bone. Paget's disease occurs when this process, called remodelling, happens too quickly and in a disordered way. The new bone that is produced is weaker than normal and the affected bones may become enlarged, painful and may fracture. [product name] changes the bone remodelling process back to normal, returning the strength to the bone structure.

In clinical studies, patients with Paget's disease were tretaed with 30 mg risedronic acid per day for 2 months. Parameters in blood and urine which reflect bone remodelling as well as the occurrence of bone lesions were measured. Blood and urine parameters were clearly better in patients treated with risedronic acid compared with another medicine. No new lesions occurred in the patients treated with risedronic acid.

VI.2.3 Unknowns relating to treatment benefits

There is only little available data, and therefore use of risedronic acid is not recommended in children < 18 years.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Low calcium levels in your blood (Hypocalcaemia)	Rarely, at the beginning of treatment, a patient's blood calcium levels may fall. These changes are usually small and cause no symptoms.	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 supplements containing calcium.
Inflammation of the eye which causes pain and redness (Iritis/uveitis)	. Inflammation of the coloured part of the eye (iris) may affect up to 1 in 100 people. Inflammation of the surrounding structures (the white of the eye in addition to coloured part), has also occurred, but the frequency of this reaction in patients treated with [product name] is unknown. Both reactions may result in 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. The frequency of these reactions in patients treated with [product name] can not be estimated.	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)	Osteonecrosis of the jaw has been observed in patients treated with [product name], and often follows tooth extraction. Pain or sore in your mouth or	Tell your doctor before you start taking [product name] if you have or have had pain, swelling or numbness of the jaw, a strange feeling in the jaw, or loosening of a tooth.

	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]. Immediately talk to your doctor if you notice bone necrosis of the jaw, associated with delayed healing and infection, while receiving [product name].

Important potential risks

Risk	**What is known** **(Including reason why it is considered a potential risk)**
Atypical femoral fractures	Unusual factures of the thigh bone have rarely been observed in patients receiving bisphosphonates. The long-term use of bisphosphonates for osteoporosis is thought to be the main risk factor. Fractures can occur without or with only minimal known impact (trauma). 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. During bisphosphonate treatment, you should report any thigh, hip or groin pain, weakness or discomfort.
Serious upper GI irritation	Inflammation or ulcer of the oesophagus may affect up to 1 in 100 users. 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 previously been told that you have Barrett's oesophagus (a condition associated with changes in the cells that line the lower oesophagus).
Serious musculoskeletal pain	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 have been single reports. However, a clear causal relationship could not be established.
Serious hepatitis disorders	Patients treated with risedronic acid may be at an increased risk for developing serious hepatic disorders. There have been single reports. In most of the reported cases, the patients were also treated with other products known to cause hepatic disorders.

Missing information

Risk	**What is known**
Atrial fibrillation	Patients treated with the medicinal product may be at an increased risk of developing atrial fibrillation. Cases of atrial fibrillation have been reported with the use of pamidronic acid, another bisphosphonate. Therefore, it can not be excluded that atrial fibrillation may also occur with risedronic acid.
Insufficient data on safety and efficacy in children and adolescents	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.
Insufficient evidence to support efficacy in the very elderly (>80 years)	Data suggest that the very elderly (>80 years) benefit less from treatment. This may because with increasing age, causes for hip fracture other than bone density dominate.
No formal interaction studies	No formal interaction studies have been performed, however 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]. Given how risedronic acid is degraded by the body, no further essential interactions are to be expected.
No adequate data in pregnant and breast-feeding women	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.

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 occuring 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 have not even known 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 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 sites ofbone fractures, 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

Risk	**What is known**	**Preventability**
Low calcium levels in your blood (Hypocalcaemia)	Rarely, at the beginning of treatment, a patient's blood calcium levels may fall. These changes are usually small and cause no	DO NOT take [product name] if you have or ever had low calcium in your blood. In particular, tell your doctor

	symptoms. Up to 1 in 10 people may experience low calcium levels in their blood	or pharmacist if you are taking any supplements containing calcium.
Inflammation of the eye which causes pain and redness (Iritis/uveitis)	Inflammation of the coloured part of the eye (iris) alon or in addition to the white of the eye, has occurred during treatement with [product name], but the frequency of this reaction is unknown. Both reactions may result in red painful eyes with a possible change in vision	Tell your doctor promptly if you experience 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. The frequency of hypersensitivity reactions in patients treated with [product name] is unknown.	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)	Osteonecrosis of the jaw has been observed in patients treated with [product name], and often follows tooth extraction. Pain or sore in your mouth or jaw are early signs of severe jaw problems.	Tell your doctor before you start taking [product name] if you have or have had pain, swelling or numbness of the jaw, a strange feeling in the jaw, or loosening of a tooth. 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]. Immediately talk to your doctor if you notice bone necrosis of the jaw, associated with delayed healing and infection, while receiving [product name].

Important potential risks

Risk	**What is known** **(Including reason why it is considered a potential risk)**
Atypical femoral fractures	Unusual factures of the thigh bone have rarely been observed in patients receiving bisphosphonates. The long-term use of bisphosphonates for osteoporosis is thought to be the main risk factor. Fractures can occur without or with only minimal known impact (trauma). 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. During bisphosphonate treatment, you should report any thigh, hip or groin pain, weakness or discomfort.
Serious upper GI irritation	Inflammation or ulcer of the oesophagus may affect up to 1 in 100 users. 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 previously been told that you have Barrett's oesophagus (a condition associated with changes in the cells that line the lower oesophagus).
Serious musculoskeletal pain	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.
Serious hepatitis disorders	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.

Missing information

Risk	**What is known**
Atrial fibrillation	Patients treated with the medicinal product may be at an increased risk of developing atrial fibrillation. Cases of atrial fibrillation have been reported with the use of pamidronic acide, another bisphosphonate. . Therefore, it can not be excluded that atrial fibrillation may also occur with risedronic acid
Insufficient data on safety and efficacy in children and adolescents	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.
Insufficient evidence to support efficacy in the very elderly (>80 years)	Data suggest that the very elderly (>80 years) benefit less from treatment. This may because with increasing age, causes for hip fracture other than bone density dominate.
No formal interaction studies	No formal interaction studies have been performed, however 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]. Given how risedronic acid is degraded by the body, no further essential interactions are to be expected.
No adequate data in pregnant and breast-feeding women	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.