Ibandronat Stada 50 mg film-coated tablets

Ibandronat Stada 150 mg film-coated tablets

3.11.2014, Version V2.1

PUBLIC SUMMARY OF THE RISK MANAGEMENT PLAN

VI.2 Elements for a Public Summary

<[Ibandronic acid 50 mg film-coated tablets]>

VI.2.1a Overview of disease epidemiology

Breast cancer is the most common cancer in women. Whereas 1.15 million patients were newly diagnosed in 2002, it is estimated that 2.7 million will be affected in 2030. Rates for Asian and Black females (appr. 60 – 108 per 100,000) are lower than for White females (122 to 125 per 100,000). Among men, less than 1% of cancer cases account for breast cancer. The risk for developing breast cancer increases with age in both males and females.

Bone metastases are a significant complication in patients with breast cancer, and occur in 50 – 70 % of the patients. Bone metastases lead to pain and more complicated events such as fractures, bone marrow infiltrations or hypercalcaemia.

VI.2.2a Summary of treatment benefits

<Ibandronic acid 50 mg> contains the active substance ibandronic acid. This belongs to a group of medicines called bisphosphonates.

<Ibandronic acid 50 mg> is used in adults and is prescribed to you if you have breast cancer that has spread to your bones (called bone “metastases”).
- It helps to prevent your bones from breaking (fractures).
- It also helps to prevent other bone problems that may need surgery or radiotherapy.

<Ibandronic acid 50 mg> works by reducing the amount of calcium that is lost from your bones. This helps to stop your bones from getting weaker.

<[Ibandronic acid 150 mg film-coated tablets]>

VI.2.1b 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 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. At the menopause, a woman’s

ovaries stop producing the female hormone, oestrogen, which helps to keep her skeleton healthy.

Other things that can increase the risk of fractures include:
- not enough calcium and vitamin D in the diet
- smoking, or drinking too much alcohol
- not enough walking or other weight-bearing exercise
- a family history of osteoporosis

A healthy lifestyle will also help you to get the most benefit from your treatment. This includes:
- eating a balanced diet rich in calcium and vitamin D
- walking or any other weight-bearing exercise
- not smoking; and not drinking too much alcohol.

VI.2.2b Summary of treatment benefits

<Ibandronic acid 150 mg> is prescribed to treat postmenopausal osteoporosis.

<Ibandronic acid 150 mg> belongs to a group of medicines called **bisphosphonates**. It contains the active substance ibandronic acid. <Ibandronic acid 150 mg> may reverse bone loss by stopping more loss of bone and increasing bone mass in most women who take it, even though they won't be able to see or feel a difference. <Ibandronic acid 150 mg> may help lower the chances of breaking bones (fractures). This reduction in fractures was shown for the spine but not for the hip.

<[Ibandronic acid 50 mg film-coated tablets]>
<[Ibandronic acid 150 mg film-coated tablets]>

VI.2.3 Unknowns relating to treatment benefits

The treatment benefit in children and adolescents below 18 years of age has not been established.
Efficacy of <[ibandronic acid 150mg]> in femoral neck fractures has not been established yet.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	**What is known**	**Preventability**
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 <Ibandronic acid >.
Low calcium levels in your blood (Hypocalcaemia)	Up to 1 in 10 people may experience low calcium levels in your blood	DO NOT take <Ibandronic acid> if you have or have ever had low calcium in your blood. In particular, tell your doctor or pharmacist if you are taking any supplements containing calcium.
Inflammatory immune response in the whole body (Acute phase reaction)	This side effect may affect up to 1 in 100 people. The symptomy are similar to flu-like symtoms and you could feel generally unwell or in pain.	Always take this medicine as prescribed by your doctor and as indicated in the Package Leaflet. This will minimise the risk of developing adverse drug reactions. If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in the package leaflet.
Severe irrittation of the tube that connects your mouth and your stomach (esophagus) (severe esophageal irritation)	This side effect may affect up to 1 in 100 people. The risk of severe irrittation of the tube that connects your mouth and your stomach (esophagus) appears to be greater in patients who do not comply with the dosing instruction and/or who continue to take <Ibandronic acid> after developing symptoms suggestive of irritation (such as heartburn, acid reflux,hoarse voice, chest pain when eating, difficulty or pain when swallowing).	Always take this medicine as prescribed by your doctor and as indicated in the Package Leaflet. This will minimise the risk of developing adverse drug reactions. Tell your doctor if you have active upper gastrointestinal problems. Stop taking <Ibandronic acid> and contact your doctor immediately if you have difficulty swallowing, painful swallowing, pain behind the breastbone, or new or worsening heartburn.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Atypical fractures of the femur	The long-term use of bisphosphonates is thought to be the main risk factor for atypical femoral fractures. 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.
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. However, a causal relationship to ibandronic acid has not been established.
Kidney dysfunction (renal dysfunction)	Patients treated with the medicinal product may be at an increased risk of developing kidney problems. There are concerns about using bisphosphonates in patients with existing kidney problems and also in older people. Tell your doctor if you experience urination changes, ankle swelling, weakness, dizziness, skin rash or itching, or a metallic taste in your mouth.

Missing information

Risk	What is known
None	NA

VI.2.5 Summary of risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimisation measures.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

No post-authorisation studies have been imposed or are planned.

VI.2.7 Summary of changes to the Risk Management Plan over time

Version	Date	Safety Concerns	Comment
V01	2011-Sep-21	Atypical fractures of the femur	--
V02	2014-Jun-16	Important identified risks: • Osteonecrosis of the jaw • Hypocalcaemia • Acute phase reaction Important potential risk: • Atrial fibrillation Missing information: • None	--
V2.1	2014-Nov-03	Important identififed risks: • Osteonecrosis of the jaw • Hypocalcaemia • Acute phase reaction • Severe oesophageal irritation Important potential risk: • Atrial fibrillation • Renal dysfunction Missing information: • None	