# ALENDRONATE
## Brand Name: FOSAMAX®
## Generics: Apo-, Novo-, Gen-, Sandoz-, PMS-, Ratio-, Co-Alendronate

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WOMEN'S COLLEGE HOSPITAL
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**The Centre for Osteoporosis and Bone Health**

**Why is this medication being prescribed?**
Alendronate is a medication used for the prevention and treatment of osteoporosis. Alednronate has been shown to decrease bone loss, increase bone density, and reduce the risk for fractures.

**What is Alendronate (Fosamax®) and how does the medication work?**
Alendronate belongs to a family of medications called "bisphosphonates". Other medications in this family include Etidronate (Didronel®, Didrocal®), Risedronate (Actonel®), and Pamidronate (Aredia®). The bisphosphonates are medications that are similar to a natural mineral that is found in your bones. Alendronate, as well as the other bisphosphonates, becomes absorbed into the skeleton and has a direct action on bone. Alendronate prevents the osteoclasts (or bone eroding cells) from "breaking down" the bone material. This, in turn, allows more bone to be deposited or "built up" over a period of time.

Treatment will be most effective if 1) adequate amounts of calcium and vitamin D are consumed; 2) regular weight bearing exercises and exercises for posture and balance are adhered to; and 3) fall prevention strategies, are implemented, i.e. IN ADDITION to taking Alendronate. If interested, you can be referred to our allied health team – dietitian, physical therapist, athletic therapist and/or occupational therapist for individualized assessment and education for the above.

**How should this medication be used?**

**Take Alendronate (Fosamax®) _____ mg _____, first thing in the morning on an EMPTY STOMACH with a full glass (250mL) of water, at least 60 minutes before breakfast. Stay in an upright position (either sitting or standing; do NOT lie down) for at least 30 minutes afterwards.**

**What SPECIAL INSTRUCTIONS should I follow while using this medication?**
All bisphosphonates are poorly absorbed from the stomach. Food (especially calcium-rich food), beverages (including milk, juice, coffee, tea, and mineral water, etc) and many vitamin/mineral supplements, antacids, prescription and over-the-counter (OTC) drugs will interfere with the absorption of Alendronate, i.e. if taken too close to OR at the same time as this medication. Therefore:

1. **Alendronate must be taken on the EMPTY STOMACH first thing in the morning, at least 60 minutes before breakfast.**

2. **Calcium supplements, multivitamin/mineral supplements, iron or magnesium supplements, and/or antacids, should be taken at least TWO to THREE hours AWAY FROM your dose of Alendronate.**

3. **Calcium-rich foods (e.g. milk, dairy products, etc.) should be consumed at least TWO to THREE hours AWAY FROM your dose of Alendronate.**

4. **Take other prescription and OTC medications at least 60 minutes after your dose of Alendronate.**

Heartburn and esophageal irritation have been reported with this medication, although it is uncommon. Therefore, it is recommended to drink a full glass (250mL) of water with Alendronate and to stay in an upright position for at least 30 minutes after your dose, to prevent this from occurring.

**What should I do if I forget to take a dose in the morning?**

☐ **ONCE DAILY** Alendronate:
If you remember your missed dose later that same day, skip it and take it the following morning. Do not take two doses at the same time.

☐ **ONCE WEEKLY** Alendronate:
If you remember your missed dose later in the day, take it the following morning. Resume your next dose on your usual designated day of the week.

**What side effects can this medication cause?**

Alendronate is generally well tolerated. Aside from possible heartburn and esophageal irritation, other side effects include abdominal pain, gas, bloating, diarrhea, constipation, difficulty swallowing, and/or a change in taste (metallic taste). Side effects usually occur at the beginning of treatment and may subside with continued use. Rare side effects, such as dizziness, muscle and/or joint pain, bone pain, eye disturbances, and/ or rash, may also occur. If any of these side effects [or others] persist and/or become bothersome, contact your doctor or pharmacist.

Rare cases of Osteonecrosis of the jaw (ONJ) or jaw bone problems, have been reported with the use of IV Bisphosphonates, such as Pamidronate and Zoledronic Acid, in cancer patients. Many of these cancer patients had also received chemotherapy, radiation, and corticosteroids – all of which may be co-factors related to ONJ. Higher doses of IV Bisphosphonates, frequency of administration and length of treatment may also be contributing factors. The majority of reports have been associated with poor dental hygiene, dental infection, and invasive dental procedures, such as tooth extractions/surgery. It is important to inform your dentist that you have been prescribed Alendronate. Please be advised to have regular dental check-ups and to practice proper dental hygiene, to help prevent this potential (though rare) effect. If you and/or your dentist have any concerns about your dental health and the use of Alendronate, please contact the osteoporosis program.

**What storage conditions are necessary for this medication?**

Keep this medication out of reach of children. Store at room temperature, away from light and excess heat. Do not store in the bathroom.

**Description:**

☐ 10mg: white OVAL tablets (Fosamax & Novo®); white ROUND tablets (Apo®), etc.
☐ 70mg: white OVAL tablet (Fosamax®); OR
75mL Raspberry-Flavoured oral solution (Fosamax®)

**Your Osteoporosis Program Pharmacist:**

☐ **Elaine Beltijar**

**Phone #: (416) 323-6400 ext. 4547**

# RISEDRONATE Delayed-Release (DR) (Actonel DR®)

*Patient Medication Information* © January 2019

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**The Centre for Osteoporosis and Bone Health**

You have been prescribed: **Risedronate Delayed-Release 35mg once weekly**

**What is Risedronate DR (Actonel DR®)?**

Risedronate is a medication used to prevent and treat osteoporosis by decreasing bone loss and increasing bone density to reduce the risk of fractures.

Risedronate belongs to a family of medications called "Bisphosphonates"

- these medications are similar to a natural mineral found in your bones
- other medications in this family include Alendronate (Fosamax®) and Zoledronic acid (Aclasta®)

**How does the medication work?**

Risedronate absorbs into the skeleton and acts directly in bones by:

- preventing osteoclasts (or bone-eating cells) from "breaking down" bone
- allowing more bone / minerals to be deposited or "built up" over a period of time

Treatment with Risedronate will be most effective, if you also:

1. take adequate amounts of calcium and vitamin D
2. do regular weight-bearing exercises, muscle-strengthening, and exercises for balance and posture
3. implement and practice fall prevention strategies

**What does "delayed-release" mean?**

Delayed-Release (DR) means that the tablets have a special coating that delays the release of the medication until the tablet reaches the small intestine

- This allows the medication to be taken with food
- This also helps to improve absorption of the medication

***Instructions for use:***

- ✓ **Take Risedronate DR (ACTONEL DR) in the morning <u>WITH BREAKFAST</u> (this may include most foods, coffee, tea, milk, orange juice, etc.)**
- ✓ **Swallow each tablet whole with at least HALF to FULL cup (125-250ml) of plain water.**
- ✓ **Stay upright (either sitting or standing) and <u>DO NOT LIE DOWN</u> for at least 30 minutes after the dose.**
- ✓ **Calcium supplements, Multivitamin/Mineral supplements, Iron or Magnesium supplements, and/or Antacids, should be taken at least <u>THREE HOURS AFTER</u> taking Risedronate DR.**

# RISEDRONATE 150mg tablets
# Brand Name: ACTONEL®

Women's College Hospital

**Osteoporosis Program**

**Why is this medication being prescribed?**
Risedronate is a medication used for the prevention and treatment of osteoporosis. Risedronate has been shown to decrease bone loss, increase bone density, and reduce the risk for fractures.

**What is Risedronate (Actonel®) and how does the medication work?**
Risedronate belongs to a family of medications called "bisphosphonates". Other medications in this family include Etidronate (Didronel®, Didrocal®), Alendronate (Fosamax®, Apo-Alendronate®, Novo-Alendronate®), and Pamidronate (Aredia®). The bisphosphonates are medications that are similar to a natural mineral that is found in your bones. Risedronate, as well as the other bisphosphonates, becomes absorbed into the skeleton and has a direct action on bone. Risedronate prevents the osteoclasts (or bone eroding cells) from "breaking down" the bone material. This, in turn, allows more bone to be deposited or "built up" over a period of time.

In order for treatment to be most effective, adequate amounts of calcium and vitamin D (as recommended by our program dietitian) should be consumed; regular weight bearing exercises and exercises for posture and balance (as recommended by our program physiotherapist) should be adhered to; and fall prevention strategies (as recommended by our program occupational therapist), should be implemented, i.e. IN ADDITION to taking Risedronate.

**How should this medication be used?**

**Take Risedronate (Actonel®) 150 mg ONCE A MONTH, FIRST THING in the MORNING on an EMPTY STOMACH (see below) with a full glass (250mL) of water. Stay in an upright position (either sitting or standing; do NOT lie down) for at least 30 minutes afterwards.**

**What SPECIAL INSTRUCTIONS should I follow while using this medication?**
All bisphosphonates are poorly absorbed from the stomach. Food (especially calcium-rich food), beverages (including milk, juice, coffee, tea, and mineral water, etc) and many vitamin/mineral supplements, antacids, prescription and over-the-counter (OTC) medications will interfere with the absorption of Risedronate, i.e. if taken too close to OR at the same time as this medication.

Therefore:

1. **Risedronate must be taken on the EMPTY STOMACH, FIRST THING in the MORNING, AT LEAST 60 minutes (1 hour) BEFORE BREAKFAST.**

2. **Calcium supplements, multivitamin/mineral supplements, iron or magnesium supplements, and/or antacids, should be taken at least THREE hours AWAY FROM your dose of Risedronate.**

3. **Calcium-rich foods (e.g. milk, dairy products, etc.) should be consumed at least THREE hours AWAY FROM your dose of Risedronate.**

4. **Take other prescription and OTC medications AT LEAST 60 minutes AFTER your dose of Risedronate**

Heartburn and esophageal irritation have been reported with this medication, although it is uncommon. Therefore, it is recommended to drink a full glass (250mL) of water with Risedronate and to stay in an upright position for at least 30 minutes after your dose, to prevent this from occurring.

**What should I do if I forget to take my dose(s) on the usual day(s) the month?**
If you miss your dose on your usual day of the month, you may take it the following morning OR within the next seven days (or 1 week). Resume your next month's dose on your usual designated day of the month. To help you remember, consider the 1st day, or 1st weekend of the month, or your favourite number between 1 and 30/31, to be your days to take Risedronate 150mg tablet.

**What side effects can this medication cause?**
Risedronate is generally well tolerated. Aside from possible heartburn and esophageal irritation, other side effects include abdominal pain, gas, bloating, loose stools/diarrhea, nausea/vomiting, difficulty swallowing, and/or a change in taste (metallic taste). Side effects may occur at the beginning of treatment and may subside with continued use.

The ONCE-A-MONTH dose may also cause an "ACUTE PHASE REACTION" which is described as feelings of tiredness/fatigue, joint/bone aches and pains, headache, and/or a slight fever. This reaction, if experienced, may occur for 2-3 days AFTER your FIRST dose of Risedronate, and may be less commonly experienced with the next dose(s) that are taken.

Rare side effects, such as dizziness, weakness, muscle aches and/or continued joint/ bone pain, eye disturbances, eye inflammation, irregular heartbeats, and/ or rash, may also occur. If any of these side effects [or others] persist and/or become bothersome, contact your doctor or pharmacist.

Rare cases of Osteonecrosis of the jaw (ONJ) or jaw bone problems, have been reported with the use of IV Bisphosphonates, such as Pamidronate and Zoledronic Acid, in cancer patients. Many of these cancer patients had also received chemotherapy, radiation, and corticosteroids – all of which may be co-factors related to ONJ. Higher doses of IV Bisphosphonates, frequency of administration and length of treatment may also be contributing factors. The majority of reports have been associated with poor dental hygiene, dental infection, and invasive dental procedures, such as tooth extractions/surgery. It is important to inform your dentist that you have been prescribed Risedronate. Please be advised to have regular dental check-ups and to practice proper dental hygiene, to help prevent this potential (though rare) effect. If you and/or your dentist have any concerns about your dental health and the use of Risedronate, please contact the osteoporosis program.

**What storage conditions are necessary for this medication?**
Keep this medication out of reach of children. Store at room temperature, away from light and excess heat. Do not store in the bathroom.

**Description:** ☐ 150mg BLUE oval film-coated tablets


**Your Osteoporosis Program Pharmacist:**

☐ **Elaine Beltijar** ☐ **Farida Meghji**

**Phone #: (416) 323-6400 ext. 4547**

# ZOLEDRONIC ACID IV
# Brand Name: ACLASTA® (Novartis)
# Generic Product: Zoledronic Acid (Dr. Reddy)

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**Osteoporosis Program**

**Why is this medication being prescribed?**
Zoledronic acid is a medication used for the treatment of osteoporosis. It is the first IV bisphosphonate to be officially approved by Health Canada for osteoporosis. Data from a three-year fracture study showed that Zoledronic acid was effective for decreasing bone loss, maintaining or increasing bone density, and most importantly, for reducing the risk of fractures.

**What is Zoledronic acid and how does the medication work?**
Zoledronic acid belongs to a family of medications called "bisphosphonates." Other bisphophonates include Etidronate (Didronel®, Didrocal®), Alendronate (Fosamax®, Apo-Alendronate®, Novo-Alendronate®, etc.), Risedronate (Actonel®) and Pamidronate IV (Aredia®). Zoledronic acid and the other bisphosphonates, acts directly on the bone by preventing the osteoclasts (bone eroding cells) from "breaking down" the bone material, and by slowing down "bone turnover". These effects, allow more time for the bone to rebuild, re-mineralize, and strengthen itself.

Zoledronic acid is also used for the treatment of Paget's disease (a disorder where bones are enlarged and deformed). Furthermore, Zoledronic acid is also available under a different brand name Zometa® (zoledronic acid 4mg) Injection. Zometa® is used in cancer patients to prevent the spread of disease into the bones and to lower excess levels of calcium in the blood, caused by the presence of bone tumours. NOTE: Doses of Zoledronic Acid, used for these bone diseases, are higher and given more frequently than the dose used for osteoporosis.

Given in the veins (intravenously or IV), Zoledronic acid avoids passing through the gastrointestinal [GI] tract (the esophagus, stomach and intestines). Therefore, this eliminates or reduces the chance of GI irritation and side effects reported with oral bisphosphonates (e.g. heartburn, stomach upset, loose stools, etc.).

Zoledronic acid IV can be prescribed for both women and men with osteoporosis, in general. However, it may also be appropriately prescribed for patients who:

- have NOT tolerated any of the oral bisphosphonates; and/or
- have existing gastrointestinal disorders (such as Crohn's disease, Colitis) or malabsorption problems (such as Celiac disease, or as a result of surgery)

Treatment will be most effective if 1) adequate amounts of calcium and vitamin D are consumed; 2) regular weight bearing exercises and exercises for posture and balance are adhered to; and 3) fall prevention strategies, are implemented, i.e. IN ADDITION to receiving Zoledronic Acid IV.

**How should this medication be given?**
The medication comes in a ready-to-use 100mL solution for intravenous infusion, which provides 5mg of Zoledronic acid.

**The dose of Zoledronic acid IV is 5mg once a year, by slow infusion over at least 30 minutes.**

This medication will be given at Women's College Hospital in our Acute Ambulatory Care Unit (AACU) located on the first floor. Our program Nurse and/or Pharmacist will be your main person of contact to: a) co-ordinate your appointments with the AACU, b) arrange your prescription for Zoledronic Acid with the pharmacy Rexall Pharmacy at Women's College Hospital [or any pharmacy of your choice], and c) discuss issues related to the medication [e.g. cost, general questions and concerns, etc.].

For your convenience, the medication may also be given at an IV Administration Centre closer to your home (as arranged through the Aclasta® Patient Support Program [PSP] by Novartis, called "For My Bones", or Dr. Reddy PSP, called "the ***infuZe*** Program"). Please note: the WCH Osteoporosis Program does NOT have any ties to or associations with these administration centres.

**Also, please make sure that you drink a sufficient amount of water (at least two glasses, i.e. 500mL or 2 cups), within the day, both before and after the infusion of Zoledronic acid.**

**What side effects can this medication cause?**
During the infusion, irritation in the veins may be felt. Please notify the nurse if you experience any discomfort. A slower infusion over at least 30 minutes helps to minimize this particular side effect.

The most common side effects are "flu-like symptoms" - fever, fatigue, chills, and muscle aches/pains. These symptoms usually appear within 24 to 48 hours after your dose of Zoledronic Acid and resolve within 1 to 2 days. Similar symptoms may occur with subsequent doses. Acetaminophen (e.g. Tylenol™) or Ibuprofen (e.g. Advil™, Motrin™) may be taken to relieve these symptoms.

Some patients may temporarily have low blood calcium after an infusion of Zoledronic acid. Your physician may decide to order blood tests to monitor this effect. Although rarely associated with once yearly Zoledronic acid IV, signs and symptoms of very low calcium include nausea, vomiting, diarrhea, irritability, muscle cramps, spasms, numbness or tingling in the fingers and toes. If you experience any of these side effects, please report them immediately to your doctor and/or the osteoporosis program nurse and/or pharmacist.

Rare cases of osteonecrosis of the jaw (ONJ) or jaw bone problems have been reported with the use of bisphosphonates. The majority of cases occurred in cancer patients who received IV bisphosphonates such as Zoledronic acid (Zometa®) and Pamidronate IV. Many of these cancer patients were also receiving chemotherapy, radiation, and corticosteroids – all of which may be risk factors for ONJ. The dose of Zoledronic acid, frequency of administration and length of treatment may also be contributing factors. [NOTE: Zoledronic acid is given every 3 to 4 weeks to cancer patients vs. once-a-year to osteoporosis patients]. The majority of reports have been associated with poor dental hygiene, dental infection, and invasive dental procedures, (e.g. tooth extractions/surgery).

Please inform your dentist that you have been prescribed Zoledronic acid. Be sure to have regular dental check-ups and practice proper dental hygiene to avoid this possible (though rare) effect. If you and/or your dentist have any concerns about your dental health and the use of Zoledronic acid, please contact the osteoporosis program.

Other uncommon and rare side effects include: tiredness, weakness, kidney problems, vision disturbances, fast/irregular heart rhythms, chest pain, allergic reaction (rash, itching, swelling, severe dizziness, trouble breathing). In one three-year trial, a very small increase in the incidence of atrial fibrillation (irregular heart rhythm) in patients on Zoledronic acid 5mg once yearly was observed. However, further clinical trials have not reported this side effect. If you experience any of the above, please consult with your doctor and/or contact the osteoporosis program.

**Your Osteoporosis Program Pharmacist:**
**Elaine Beltijar, BScPhm**
**Phone #: (416) 323-6400 ext. 4547**

**Your Osteoporosis Program Nurse:**
**Sue Tyrell – Phone # (416) 323-6400 ext. 4659**

# DENOSUMAB 60 mg injection
# Brand Name: PROLIA®

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**The Centre for Osteoporosis and Bone Health**

**Why is this medication being prescribed?**
Denosumab is a medication used for the treatment of osteoporosis. Denosumab has been shown to decrease bone loss, increase bone density, and reduce the risk for fractures.

**What is Denosumab (Prolia®) and how does the medication work?**
Prolia is a RANK Ligand inhibitor. It works by inhibiting Rank Ligand, a protein responsible for the activation of the cells that break down bone (osteoclasts). Therefore, Prolia stops the activation of osteoclasts and in turn, slows down the break down of bone. This leads to an increase in bone mass as well as a reduced risk for fractures of the hip, spine and other sites.

Treatment will be most effective if 1) adequate amounts of calcium and vitamin D are consumed; 2) regular weight bearing exercises and exercises for posture and balance are adhered to; and 3) fall prevention strategies, are implemented, i.e. IN ADDITION to taking Prolia. If interested, you can be referred to our allied health team – dietitian, physical therapist, athletic therapist and/or occupational therapist for individualized assessment and education for the above.

**How should this medication be given?**

**The dose of Denosumab is 60 mg every 6 months given by a subcutaneous (ie under the skin) injection in the upper arm, upper thigh or abdomen, administered by a doctor.**

**What side effects can this medication cause?**
Denosumab is generally well tolerated. The most common side effect is pain in muscles, arms, legs or back. Side effects may occur at the beginning of treatment and may subside over time.

Rare side effects, such as skin problems or infections may also occur. Skin problems may present as redness, itchiness, rash, dry or leathery skin, and/or blisters. Symptoms of infection include fever, chills, red/swollen/hot/tender skin, severe abdominal pain, frequent/urgent need to urinate or burning feeling when urinating. If any of experience any of these side effects [or others], contact your doctor or pharmacist.

Very rarely, denosumab can cause hypocalcemia, or low blood calcium. Symptoms include muscle spasms, twitches, cramps, weakness or tingling. Contact your doctor if you experience any of these symptoms.

Rare cases of osteonecrosis of the jaw (ONJ) or jaw bone problems, have been reported with the use of denosumab. Please be advised to have regular dental check-ups and to practice proper dental hygiene, to help prevent this potential (though rare) effect. Also, inform your dentist that you are on denosumab. If you and/or your dentist have any concerns about your dental health and the use of denosumab, please contact the osteoporosis program.

**What storage conditions are necessary for this medication?**
Keep this medication out of reach of children. Store in the refrigerator until your injection appointment. Do not freeze. The medication can also be stored at room temperature, away from light and excess heat, for up to 30 days.

**Your Osteoporosis Program Pharmacist:**

**Elaine Beltijar**

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