CONSUMER INFORMATION

PrACLASTA®

(zoledronic acid injection)
for intravenous infusion

This leaflet is part III of a three-part "Product Monograph" published when ACLASTA® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ACLASTA®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

Since it is not known how long ACLASTA® should be continued for osteoporosis, you should discuss the need for re-treatment with your doctor regularly to determine if ACLASTA® is still right for you. (note: ACLASTA® is only approved to be used once for prevention of postmenopausal osteoporosis).

What is ACLASTA® used for?
ACLASTA® is used:

- In the treatment of osteoporosis in postmenopausal women to reduce the risk of hip, vertebral, non-vertebral fractures (breaking bone) when given once a year.
- In the treatment to increase bone mineral density in men with osteoporosis when given once a year.
- In the treatment and prevention of osteoporosis, in men and women caused by glucocorticoid medicines such as prednisone, to increase bone mineral density, when given once a year.
- In the prevention of osteoporosis in postmenopausal women with low bone mass, given as a single treatment.
- In the treatment of Paget's disease, given as a single treatment.

What it does
ACLASTA® contains zoledronic acid which is a member of a class of substances called Bisphosphonates.

ACLASTA® binds specifically to bone and it does not stay in your blood. ACLASTA® slows down bone resorption (caused by osteoclasts) which allows the bone-forming cells (osteoblasts) time to rebuild normal bone.

What is osteoporosis?
Osteoporosis is a disease that involves the thinning and weakening of the bones, which is common in women after the menopause and may also occur in men.

What is Paget's disease of bone?
In Paget's disease, bone breaks down too much and the new bone made is not normal. If Paget's disease is not treated, bones like the skull, spine, and legs become deformed and weaker than normal. This can cause problems like bone pain and arthritis. The bones can also break easily. Paget's disease of bone sometimes runs in families. Paget's disease may be discovered by X-ray examination or blood tests.

When should ACLASTA® not be used? You should not be treated with ACLASTA® if you:

- Have low calcium levels in your blood (*Hypocalcemia)* or vitamin D deficiency
- If you have severe kidney problems
- Are pregnant or plan to become pregnant.
- Are breast-feeding.
- Are allergic (*hypersensitive*) to zoledronic acid or any of the other ingredients of ACLASTA® or any other bisphosphonate

What is the medicinal ingredient?
zoledronic acid.

What are the important nonmedicinal ingredients?
Mannitol, sodium citrate, water for injection.

What dosage form does it comes in?
ACLASTA® is a solution for intravenous infusion and ~~it~~ comes in a 100 mL plastic bottle. Each 100 mL solution contains 5 mg of zoledronic acid.

WARNINGS AND PRECAUTIONS

Be sure that you have discussed ACLASTA® treatment with your doctor.

If you are being treated with another intravenous form of zoledronic acid (i.e. Zometa®), you should not be treated with ACLASTA®.

If you are being treated with ACLASTA®, you should not be treated with other bisphosphonates (such as alendronate, risedronate, clodronate, etidronate, ibandronate and pamidronate) at the same time.

BEFORE you take ACLASTA® talk to your doctor or pharmacist if you:

- Are unable to take daily calcium and/or vitamin D supplements
- Are pregnant or plan to become pregnant.
- Are breast-feeding.
- Have kidney problems. Worsening of kidney function, including kidney failure may happen when you take ACLASTA®.
- Had some or all of your parathyroid glands or thyroid gland surgically removed
- Had sections of your intestine removed
- Need any dental procedures such as a root canal or tooth extraction (this does not include regular dental cleaning). Your doctor may possibly request a dental examination with any necessary preventive dentistry carried out prior to treatment with ACLASTA®. You should continue regular dental cleanings and practice good oral hygiene.
- Have rapid and irregular heart beat

- Have a sudden headache, numbness in your face or limbs, particularly down one side of your body; experience confusion and have trouble talking or understanding what is being said to you; have vision problems, and trouble walking or keeping your balance.
- Have asthma from taking ASA (acetylsalicylic acid such as Aspirin®)
- Have any pain in your hip, groin, or thigh. ACLASTA® can cause unusual fractures in the thigh bone.

ACLASTA® is not recommended for patients under 18 years of age.

ACLASTA® is to be given by intravenous infusion in no less than 15 minutes.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including any you have bought without a prescription. It is especially important for your doctor to know if you are taking:

- any medicines known to be harmful to your kidneys (such as nonsteroidal anti-inflammatory drugs (NSAIDs)).
- water pill (diuretics)
- aminoglycoside antibiotics (a type of medicine used to treat severe infections).

Can I continue my daily activities? After your ACLASTA® infusion, there is no restriction on your normal activities such as standing, sitting, taking a walk or exercising.

PROPER USE OF THIS MEDICATION

How is ACLASTA® given?
ACLASTA® is given as an infusion into a vein for 15 minutes by your doctor or nurse.

Your doctor will ask you to drink at least two glasses of water (500 mL or 2 cups) before and after the treatment.

Usual dose:
For treatment of Osteoporosis: single dose of 5 mg once yearly
For prevention of Osteoporosis: single treatment of 5 mg.
For Paget's disease: single treatment of 5 mg. ACLASTA® may work for longer than one year, and your doctor will let you know if you need to be treated again.

The infusion nurse or doctor may ask you to stay for a short period of time after the infusion.

It is very important to take calcium and vitamin D supplements as directed by your doctor to reduce the possibility of having low blood calcium levels, to prevent loss of bone and to help rebuild bone.

Overdose

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, ACLASTA® may have some unwanted side effects in addition to its beneficial effects.

The most common side effects

Post-dose symptoms include:
- Fever
- Fatigue
- Chills
- Malaise (unwell feeling)
- Bone, joint and/or muscle pain or stiffness
- Headache
- Nausea
- Vomiting
- Abdominal pain
- Diarrhea
- Back pain
- Pain in extremity
- Influenza-like illness
- Weakness
- Pain
- Shortness of breath
- Dizziness
- Excessive sweating
- Tiredness
- Disturbed digestion
- Decreased appetite
- Non-cardiac chest pain

Other side effects:
- Low blood calcium (hypocalcaemia) the symptoms include numbness or tingling sensations (especially in the area around the mouth) or muscle spasms. Contact your doctor immediately if you notice any of these symptoms after your ACLASTA® treatment.
- Allergic reactions such as itchy rash and swelling mainly of the face and throat.
- Increased or irregular heartbeat
- Rheumatoid arthritis/arthritis (inflammation of the joints)
- Urinary tract infection
- Constipation
- High blood cholesterol levels
- Pain in jaw
- Pain in neck
- Joint sprain
- Post-traumatic pain
- Cough
- Congestion of the nose
- Pharyngolaryngeal pain (pain at the back of the mouth and

in the voice box)
- Seasonal allergy
- Vaginal dryness
- Sciatica (pain in the leg caused by injury to or compression of sciatic nerve)
- Hypoesthesia (reduced sense of touch)
- Rare cases of dehydration
- Persistent post-dose symptoms
- Jaw bone problems: rarely, patients have jaw problems associated with delayed healing and infection, often following tooth extraction.
- Very rare cases of low blood pressure
- Very rare cases of unusual fractures in a specific part of the thigh bone. If you develop new or unusual pain in the thigh or groin, contact your doctor.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your healthcare professional or pharmacist	
		Only if severe	In all cases
Common	*Post-dose symptoms*: fever, chills, fatigue, pain, malaise	√	
	Bone, joint, and/or muscle pain or stiffness		√
	Headache	√	
	Nausea, vomiting, diarrhea, abdominal pain	√	
	Shortness of breath		√
	Dizziness	√	
	Excessive sweating	√	
	Rash	√	
Uncommon	Tiredness, weakness, lethargy	√	
	Low blood calcium (hypocalcemia): numbness, tingling sensation (especially in the area around the mouth), muscle spasms		√
	Rapid and irregular heartbeat, palpitations		√
	A sudden headache, numbness in your face or limbs, particularly down one side of your body; experience confusion and have trouble talking or understanding what is being said to you; have vision problems, and trouble walking or keeping your balance.		√
	Kidney failure (weakness, tiredness, loss of appetite, puffy eyes, hands and feet, changes in urine color or absence of urine production, changes in kidney function laboratory tests)		√
	Eye disorder (Eye pain, light sensitivity, eye redness, decreased vision, eye inflammation)		√
	Skin reactions (redness, swelling and/or pain) at the infusion site	√	
Rare	*Osteonecrosis of the jaw*: (numbness or feeling of heaviness in the jaw, poor healing of the gums especially after dental work, loose teeth, exposed bone in mouth, pain in the mouth, teeth or jaw, swelling or gum infections, bad breath)		√
Very rare	Difficulty breathing with wheezing or coughing in asthma patients who are allergic to ASA		√
	Avascular necrosis (osteonecrosis) of the hip or knee: poor blood supply to an area of bone leading		√

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Symptom / effect		Talk with your healthcare professional or pharmacist	
		Only if severe	In all cases
	to bone death: bone pain, joint pain, muscle spasms, joint stiffness		
	Failure of broken bone to heal (*non-union*) or broken bone taking longer than usual to heal (*delayed union*): persistent pain at the fracture site, no or slow progress in bone healing on imaging tests.		√
	Severe allergic reactions (rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing, loss of conscious due to shock (dangerously low blood pressure))		√
	Thigh or groin pain		√

If you have questions about these side effects, talk to your doctor.

This is not a complete list of side effects. For any unexpected effects while taking ACLASTA®, contact your doctor or pharmacist.

HOW TO STORE IT

Store ACLASTA® at room-temperature between 15°C-30°C. Keep the original packaging unchanged and sealed until the doctor or the nurse administers ACLASTA®.

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Remember to keep ACLASTA® and all medications safely away from children.

REPORTING SUSPECTED SIDE EFFECTS

REPORTING SUSPECTED SIDE-EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
    Health Canada
    Postal Locator 0701E
    Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect ™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: http://www.novartis.ca

or by contacting the sponsor, Novartis Pharmaceuticals Canada Inc, at: 1-800-363-8883

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Last revised on September 11, 2014