



ZOLEDRONIC ACID

ZDONATE

4mg/5mL
Concentrate Solution for IV Infusion
Bisphosphonate



1 Vial x 5mL

FORMULATION:

Each vial contains:
Zoledronic Acid (as monohydrate).....4mg

Excepients:

S. No.	Ingredients	Qty/vial		Function
		Gland	RLD	
1.	Sodium citrate dihydrate	24 mg	24 mg	Buffering agent
2.	Mannitol	220 mg	220 mg	Tonicity adjusting agent
3.	Water for injection	q.s. to 5.0 mL	q.s. to 5.0 mL	Solvent/Vehicle

PRODUCT DESCRIPTION:

Zoledronic Acid Injection is a clear colorless solution containing 4mg of Zoledronic Acid per vial.

INDICATIONS:

- Prevention of skeletal related events (pathological fractures, spinal compression, radiation or surgery to bone, or hypocalcaemia) in adult patients with advanced malignancies involving bone.
- Treatment of adult patients with tumor-induced hypocalcaemia (TIH).

DOSAGE AND ADMINISTRATION:

Zoledronic Acid (ZDONATE) must only be prescribed and administered to patients by healthcare professionals experienced in the administration of intravenous bisphosphonates

Posology

Prevention of skeletal related events in patients with advanced malignancies involving bone

Adults and older people

The recommended dose in the prevention of skeletal related events in patients with advanced malignancies involving bone is 4mg

zoledronic acid every 3 to 4 weeks.

Patients should also be administered an oral calcium supplement of 500 mg and 400 IU vitamin D daily.

The decision to treat patients with bone metastases for the prevention of skeletal related events should consider that the on set of treatment effect is 2-3 months.

Treatment of TIH

Adults and older people

The recommended dose in hypercalcaemia (albumin -corrected serum calcium 2 12.0 mg/dl or 3.0 mmol/l) is a single dose of 4 mg zoledronic acid.

Renal impairment TIH:

Zoledronic Acid (ZDONATE) treatment in TIH patents who also have severe renal impairment should be considered only after evaluating the risks and benefits of treatment. No dose adjustment is necessary in TIH patients with serum creatinine < 400 molil or < 4.5 mg/dl (see Special Warnings and Precautions).

Prevention of skeletal related events in patients with advanced malignancies involving bone:

When initiating treatment with Zoledronic Acid (ZDONATE) in patients with multiple myeloma or metastatic bone lesions from solid tumours, serum creatinine and creatinine clearance (CLcr) should be determined. CLcr is calculated from serum creatinine using the Cockcroft-Gault formula. Zoledronic Acid (ZDONATE) is not recommended for patients presenting with severe renal impairment prior te initiation of therapy, which is defined for this population as CLcr < 30 ml/min.

In patients with bone metastases presenting with mild to moderate renal impairment prior to initiation of therapy, which is defined for this population as CLcr 30 -60 ml/min, the following Zoledronic Acid (ZDONATE) dose is recommended (see also Special Warnings and Precautions):

Baseline creatinine clearance (ml/min)	Zoledronic Acid (ZDONATE) recommended dose*
> 60	4.0 mg zoledronic acid
50-60	3.5 mg* zoledronic acid
40-49	3.3 mg* zoledronic acid
30-39	3.0 mg* zoledronic acid

* Doses have been calculated assuming target AUC of 0.66 (mg hr/l) (CLcr = 75 ml/min). The reduced doses for patient achieve the same AUC as that seen in patients with creatinine clearance of 75 ml/min.

Following initiation of therapy, serum creatinine should be measured prior to each dose of Zoledronic Acid (ZDONATE) and treatment should be withheld if renal function has deteriorated.

Paediatric population

The safety and efficacy of zoledronic acid in children aged 1 year to 17 years have not be established currently available data are described in Pharmacodynamics by no recommendation on a posology can be made.

Method of administration

Intravenous use. Zoledronic Acid (ZDONATE) 4 mg concentrate for solution for IV infusion, further diluted in 100ml (see Special Precautions for Disposal and Other Handling), should be given as a single intravenous infusion in no less than 15 minutes.

In patients with mild to moderate renal impairment, reduced Zoledronic Acid (ZDONATE) doses are recommended (see section "Posology" above and Special Warnings and Precautions).

Instructions for preparing reduced doses of Zoledronic Acid (ZDONATE)

Withdraw an appropriate volume of the concentrate needed, as follows:

- 4.4 ml for 3.5 mg dose
- 4.1 ml for 3.3 mg dose
- 3.8 ml for 3.0 mg dose

For instructions on the dilution of the medicinal product before administration, see Special Precautions for Disposal and Other Handling.

The withdrawn amount of concentrate must be further diluted in 100 ml of sterile 0.9% w/v sodium chloride solution or 5% w/v glucose solution. The dose must be given a single intravenous infusion over no less than 15 minutes.

Zoledronic Acid (ZDONATE) concentrate must not be mixed with calcium or other divalent cation-containing infusion solutions such as lactated Ringer's solution, and should be administered as a single intravenous solution in a separate infusion line.



Patients must be maintained well hydrated prior to and following administration of Zoledronic Acid (ZDONATE).

CONTRAINDICATIONS:

- Hypersensitivity to the active substance, to other bisphosphonates or to any of the excipients
- Breast-feeding (see Pregnancy and Lactation)

SPECIAL WARNING AND PRECAUTIONS:

General

Patients must be assessed prior to administration of Zoledronic Acid (ZDONATE) to ensure that they are adequately hydrated. Overhydration should be avoided in patients at risk of cardiac failure.

Standard hypercalcaemia-related metabolic parameters, such as serum levels of calcium, phosphate and magnesium, should be carefully monitored after initiating Zoledronic Acid (ZDONATE) therapy. If hypocalcaemia, hypophosphataemia, or hypomagnesaemia occurs, short-term supplemental therapy may be necessary. Untreated hypercalcaemia patients generally have some degree of renal function impairment, therefore careful renal function monitoring should be considered. Zoledronic Acid (ZDONATE) contains the same active substance as found in Aclasta (zoledronic acid).

Patients being treated with Zoledronic Acid (ZDONATE) should not be treated with Aclasta or any other bisphosphonate concomitantly, since the combined effects of these agents are unknown.

Renal insufficiency

Patients with TIH and evidence of deterioration in renal function should be appropriately evaluated with consideration given as to whether the potential benefit of treatment with Zoledronic Acid (ZDONATE) outweighs the possible risk.

The decision to treat patients with bone metastases for the prevention of skeletal related events should consider that the onset of treatment effect is 2-3 months.

Zoledronic Acid (ZDONATE) has been associated with reports of renal dysfunction. Factors that may increase the potential for deterioration in renal function include dehydration, pre-existing renal impairment, multiple cycles of Zoledronic Acid (ZDONATE) and other bisphosphonates as well as use of other nephrotoxic medicinal products. While the risk is reduced with a dose of 4 mg zoledronic acid administered over 15 minutes, deterioration in renal function may still occur.

Renal deterioration, progression to renal failure and dialysis have been reported in patients after the initial dose or a single dose of 4 mg zoledronic acid. Increases in serum creatinine also occur in some patients with chronic administration of Zoledronic Acid (ZDONATE) at recommended doses for prevention of skeletal related events, although less frequently.

Patients should have their serum creatinine levels assessed prior to each dose of Zoledronic Acid (ZDONATE).

Upon initiation of treatment in patients with bone metastases with mild to moderate renal impairment, lower doses of zoledronic acid are recommended. In patients who show evidence of renal deterioration during treatment, Zoledronic Acid (ZDONATE) should be withheld. Zoledronic Acid (ZDONATE) should only be resumed when serum creatinine returns to within 10% of baseline. Zoledronic Acid (ZDONATE) treatment should be resumed at the same dose as that given prior to treatment interruption in view of the potential impact of zoledronic acid on renal function, the lack of clinical safety data in patients with severe renal impairment (in clinical trials defined as serum creatinine ≥ 400 μmol/l or ≥ 4.5 mg/dl for patients with TIH and ≥ 265 μmol/l or ≥ 3.0 mg/dl for patients with cancer and bone metastases, respectively) at baseline and only limited pharmacokinetic data in patients with severe renal impairment at baseline (creatinine clearance < 30 ml/min), the use of zoledronic acid is not recommended in patients with severe renal impairment.

Hepatic insufficiency

No specific recommendations can be given for this patient population.

Osteonecrosis of the jaw

Osteonecrosis of the jaw (ONJ) has been reported uncommonly in patients receiving zoledronic acid.

The start of treatment or of a new course of treatment should be delayed in patients with unhealed open soft tissue lesions in the mouth, except in medical emergency situations. A dental examination with appropriate preventive dentist and an individual benefit.

-risk

assessment is recommended prior to treatment with bisphosphonates in patients with concomitant risk factors.

The following risk factors should be considered when evaluating an individual's risk of developing ONJ:

- Potency of the bisphosphonate (higher risk for highly potent compounds), route of administration (higher risk for parenteral administration) and cumulative dose of bisphosphonate.
- Cancer, co-morbid conditions (e.g., anemia, coagulopathies, infection), smoking
- Concomitant therapies: chemotherapy, angiogenesis inhibitors (see Interactions), radiotherapy to neck and head, corticosteroids.
- History of dental disease, poor oral hygiene, periodontal disease, invasive dental procedures (e.g., tooth extractions) and poorly fitting dentures.

All patients should be encouraged to maintain good oral hygiene, undergo routine dental check-ups, and immediately report any oral symptoms such as dental mobility, pain or swelling, or non-healing of sores or discharge during treatment with Zoledronic Acid (ZDONATE). While on treatment, invasive dental procedures should be performed only after careful consideration and be avoided in close proximity to zoledronic acid administration. For patients who develop osteonecrosis of the jaw while on bisphosphonate therapy, dental surgery may exacerbate the condition. For patients requiring dental procedures, there are no data available to suggest whether discontinuation of bisphosphonate treatment reduces the risk of osteonecrosis of the jaw. The management plan for patients who develop ONJ should be set up in close collaboration between the treating physician and a dentist or oral surgeon with expertise in ONJ. Temporary interruption of zoledronic acid treatment should be considered until the condition resolves and contributing risk factors are mitigated where possible.

Osteonecrosis of other anatomical sites

Osteonecrosis of the external auditory canal has been reported with bisphosphonates, mainly in association with long-term therapy. Possible risk factors for osteonecrosis of the external auditory canal include steroid use and chemotherapy and/or local risk factors such as infection or trauma. The possibility of osteonecrosis of the external auditory canal should be considered in patients receiving bisphosphonates who present with ear symptoms including chronic ear infections. Additionally, there have been sporadic reports of osteonecrosis of other sites, including the hip and femur, reported predominantly in adult cancer patients treated with Zoledronic Acid (ZDONATE).

Musculoskeletal pain

In post-marketing experience, severe and occasionally incapacitating bone, joint, and/or muscle pain have been reported in patients taking Zoledronic Acid (ZDONATE). However, such reports have been infrequent. The time to onset of symptoms varied from one day to several months after starting treatment. Most patients had relief of symptoms after stopping treatment. A subset had recurrence of symptoms when rechallenged with Zoledronic Acid (ZDONATE) or another bisphosphonate.

Atypical fractures of the femur

Atypical subtrochanteric and diaphyseal femoral fractures have been reported with bisphosphonate therapy, primarily in patients receiving long-term treatment for osteoporosis. These transverse or short oblique fractures can occur anywhere along the femur from just below the lesser trochanter to just above the supracondylar flare. These fractures occur after minimal or no trauma and 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. Fractures are often bilateral; therefore the contralateral femur should be examined in bisphosphonate-treated patients who have sustained a femoral shaft fracture. Poor healing of these fractures has also been reported. Discontinuation of bisphosphonate therapy in patients suspected to have an atypical femur fracture should be considered pending evaluation of the patient, based on an individual benefit/risk assessment.

During bisphosphonate treatment patients should be advised to report any thigh, hip or groin pain and any patient presenting with such symptoms should be evaluated for an incomplete femur fracture.

Hypocalcaemia

Hypocalcaemia has been reported in patients treated with Zoledronic Acid (ZDONATE). Cardiac arrhythmias and neurologic adverse events (including convulsions, hypoaesthesia and tetany) have been reported secondary to cases of severe hypocalcaemia. Cases of severe hypocalcaemia requiring hospitalisation have been reported. In some instances, the hypocalcaemia may be life-threatening (see Adverse Effects). Caution is advised when Zoledronic Acid (ZDONATE) is administered with medicinal products known to cause hypocalcaemia, as they may have a synergistic effect resulting in severe hypocalcaemia (see Interactions). Serum calcium should be measured and hypocalcaemia must be corrected before initiating Zoledronic Acid (ZDONATE) therapy. Patients should be adequately supplemented with calcium and vitamin D.

INTERACTION S:

Zoledronic acid has been administered concomitantly with commonly used anticancer agents, diuretics, antibiotics and analgesics without clinically apparent interactions occurring. Zoledronic acid shows no appreciable binding to plasma proteins and does not inhibit human P450 enzymes *in vitro* (see Pharmacokinetics), but no formal clinical interaction studies have been performed. Caution is advised when bisphosphonates are administered with aminoglycosides, calcitonin or loop diuretics, since these agents may have an additive effect, resulting in a lower serum calcium level for longer periods than required (see Special Warnings and Precautions). Caution is indicated when Zoledronic Acid (ZDONATE) is used with other potentially nephrotoxic medicinal products. Attention should also be paid to the possibility of hypomagnesaemia developing during treatment. In multiple myeloma patients, the risk of renal dysfunction may be increased when Zoledronic Acid (ZDONATE) is used in combination with thalidomide. Caution is advised when Zoledronic Acid (ZDONATE) is administered with anti-angiogenic medicinal products, as an increase in the incidence of ONJ has been observed in patients treated concomitantly with these medicinal products.

PREGNANCY AND LACTATION:

Pregnancy

There are no adequate data on the use of zoledronic acid in pregnant women. The potential risk for humans is unknown. Zoledronic Acid (ZDONATE) should not be used during pregnancy. Women of child-bearing potential should be advised to avoid becoming pregnant.

Breast-feeding

It is not known whether zoledronic acid is excreted into human milk. Zoledronic Acid (ZDONATE) is contraindicated in breast-feeding women (see Contraindications).

Fertility

Zoledronic acid was evaluated in rats for potential adverse effects on fertility of the parental and F1 generation. This resulted in exaggerated pharmacological effects considered to be related to the compound's inhibition of skeletal calcium metabolism, resulting in periparturient hypocalcaemia, a bisphosphonate class effect, dystocia and early termination of the study. Thus these results precluded determining a definitive effect of zoledronic acid on fertility in humans.

EFFECTS ON ABILITY OPERATE MACHINERY:

Adverse reactions, such as dizziness and somnolence, may have influence on the ability to drive or use machines, therefore caution should be exercised with the use of Zoledronic Acid (ZDONATE) along with driving and operating of machinery.

ADVERSE EFFECTS

Within three days after zoledronic acid administration, an acute phase reaction has commonly been reported, with symptoms including bone pain, fever, fatigue, arthralgia, myalgia, rigors and arthritis with subsequent joint swelling; these symptoms usually resolve within a few days (see description of selected adverse reactions). The following are the important identified risks with zoledronic acid in the approved indications: renal function impairment, osteonecrosis of the jaw, acute phase reaction, hypocalcaemia, atrial fibrillation, anaphylaxis, interstitial lung disease (see Table 1 for the frequencies):

Table 1

Adverse reactions are ranked under headings of frequency, the most frequent first, using the following convention: Very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000), not known (cannot be estimated from the available data).

Blood and lymphatic system disorder	Common:	Anemia
	Uncommon:	Thrombocytopenia, leukopenia
	Rare:	Pancytopenia
Immune system disorders	Uncommon:	Hypersensitivity reaction
	Rare:	Angioneurotic oedema
Psychiatric disorders	Uncommon:	Anxiety, sleep disturbance
	Rare:	Confusion
Nervous system disorders	Common:	Headache
	Uncommon:	Dizziness, paraesthesia, dysgeusia, hypoaesthesia, hyperaesthesia, tremor, somnolence
	Very rare:	Convulsions, hypoaesthesia and tetany (secondary to hypocalcaemia)
Eye disorders	Common:	Conjunctivitis
	Uncommon:	Blurred vision, scleritis and orbital inflammation
	Rare:	Uveitis
	Very rare:	Episcleritis
Cardiac disorders	Uncommon:	Hypertension, hypotension, atrial fibrillation, hypotension leading to syncope or circulatory collapse
	Rare:	Bradycardia, cardiac arrhythmia (secondary to hypocalcaemia)
Respiratory, thoracic and mediastinal disorders	Uncommon:	Dyspnea, cough, bronchoconstriction
	Rare:	Interstitial lung disease
Gastrointestinal disorders	Common:	Nausea, vomiting, decreased appetite
	Uncommon:	Diarrhea, constipation, abdominal pain, dyspepsia, stomatitis, dry mouth
Skin and subcutaneous tissue disorders	Uncommon:	Pruritus, rash (including erythematous and macular rash), increased sweating
Musculoskeletal and connective tissue disorders	Common:	Bone pain, myalgia, arthralgia, generalised pain
	Uncommon:	Muscle spasms, osteonecrosis of the jaw
	Very rare:	Osteonecrosis of the external auditory canal (bisphosphonate class adverse reaction) and other anatomicalsites including femur and hip
Renal and urinary disorders	Common:	Renal impairment
	Uncommon:	Acute renal failure, haematuria, proteinuria
	Rare:	Acquired Fanconi syndrome
General disorders and administration site conditions	Common:	Fever, flu-like syndrome (including fatigue, rigors, malaise and flushing)
	Uncommon:	Asthenia, peripheral edema, injection site reactions (including pain, irritation, swelling, induration), chest pain, weight increase, anaphylactic reaction/shock, urticaria
	Rare:	Arthritis and joint swelling as a symptom of acute phase reaction
Investigations	Very common:	Hypophosphataemia
	Common:	Blood creatinine and blood urea increased, hypocalcaemia
	Uncommon:	Hypomagnesaemia, hypokalaemia
	Rare:	Hyperkalaemia, hypernatraemia

OVERDOSAGE

The administration of doses up to 48 mg of zoledronic acid in error has been reported. Patients who have received doses higher than those recommended (see Dosage and Administration) should be carefully monitored, since renal function impairment (including renal failure) and serum electrolyte (including calcium, phosphorus and magnesium) abnormalities have been observed. In the event of hypocalcaemia, calcium gluconate infusions should be administered as clinically indicated.

PHARMACODYNAMICS

Pharmacotherapeutic group: Drugs for treatment of bone diseases, bisphosphonates, ATC code: M05BA08
Zoledronic acid belongs to the class of bisphosphonates and acts primarily on bone. It is an inhibitor of osteoclastic bone resorption.
The selective action of bisphosphonates on bone is based on their high affinity for mineralised bone, but the precise molecular mechanism leading to the inhibition of osteoclastic activity is still unclear. In long-term animal studies, zoledronic acid inhibits bone resorption without adversely affecting the formation, mineralisation or mechanical properties of bone In addition to being a potent inhibitor of bone resorption, zoledronic acid also possesses several anti-tumour properties that could contribute to its overall efficacy in the treatment of metastatic bone disease.

PHARMACOKINETICS

Single and multiple 5- and 15-minute infusions of 2, 4, 8 and 16 mg zoledronic acid in 64 patients with bone metastases yielded the following pharmacokinetic data, which were found to be dose independent. After initiating the infusion of zoledronic acid, the plasma concentrations of zoledronic acid rapidly increased, achieving their peak at the end of the infusion period, followed by a rapid decline to < 10% of peak after 4 hours and < 1% of peak after 24 hours, with a subsequent prolonged period of very low concentrations not exceeding 0.1% of peak prior to the second infusion of zoledronic acid on day 28.
Intravenously administered zoledronic acid is eliminated by a triphasic process: rapid biphasic disappearance from the systemic circulation, with half-lives of ta 0.24 and tx 1.87 hours, followed by a long elimination phase with a terminal elimination half-life of ty 146 hours. There was no accumulation of zoledronic acid in plasma after multiple doses given every 28 days. Zoledronic acid is not metabolised and is excreted unchanged via the kidney. Over the first 24 hours, 39 ÷ 16% of the administered dose is recovered in the urine, while the remainder is principally bound to bone tissue. From the bone tissue it is released very slowly back into the systemic circulation and eliminated via the kidney. The total body clearance is 5.04 ± 2.5 /h, independent of dose, and unaffected by gender, age, race, and body weight. Increasing the infusion time from 5 to 15 minutes caused a 30% decrease in zoledronic acid concentration at the end of the infusion, but had no effect on the area under the plasma concentration versus time curve
The interpatient variability in pharmacokinetic parameters for zoledronic acid was high, as seen with other bisphosphonates No pharmacokinetic data for zoledronic acid are available in patients with hypercalcaemia or in patients with hepatic insufficiency. Zoledronic acid does not inhibit human P450 enzymes in vitroshows no biotransformation and in animal studies < 3% of the administered dose was recovered in the faeces, suggesting no relevant role of liver function in the pharmacokinetics of zoledronic acid. The renal clearance of zoledronic acid was correlated with creatinine clearance, renal clearance representing 75 + 33% of the creatinine clearance, which showed a mean of 84 + 29 ml/min (range 22 to 143 ml/min) in the 64 cancer patients studied. Population analysis Sore trator pater an are ane showed that for a patient with creatinine clearance of 20 ml/min (severe renal impairment), or 50 ml/min (moderate impairment), the corresponding predicted clearance of zoledronic acid would be 37% or 72%, respectively, of that of a patient showing creatinine clearance of 84 ml/min. Only limited pharmacokinetic data are available in patients with severe renal insufficiency (creatinine clearance < 30 ml/min).

In an in vitro study, zoledronic acid showed low affinity for the cellular components of human blood, with a mean blood to plasma concentration ratio of 0.59 in a concentration range of 30 ng/ml to 5000 ng/ml. The plasma protein binding is low, with the unbound fraction ranging from 60% at 2 ng/ml to 77% at 2000 ng/ml of zoledronic acid.

Special populations

Pediatric patients

Limited pharmacokinetic data in children with severe osteogenesis imperfecta suggest that zoledronic acid pharmacokinetics in children aged 3 to 17 years are similar to those in adults at a similar mg/kg dose level. Age, body weight, gender and creatinine clearance appear to have no effect on zoledronic acid systemic exposure.

INCOMPATIBILITIES:

To avoid potential incompatibilities, Zoledronic Acid (ZDONATE) concentrate is to be diluted with 0.9% w/v sodium chloride solution or 5% w/v glucose solution.
This medicinal product must not be mixed with calcium or other divalent cation-containing infusion solutions such as lactated Ringer's solution, and should be administered as a single intravenous solution in a separate infusion line.

SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING

Prior to administration, 5.0 ml concentrate from one vial or the volume of the concentrate withdrawn as required must be further diluted with 100 ml of calcium-free infusion solution (0.9% w/v sodium chloride solution or 5% w/v glucose solution).

Additional information on handling of Zoledronic Acid (ZDONATE), including guidance on preparation of reduced doses, is provided in section "Instructions for preparing reduced doses of Zoledronic Acid (ZDONATE)".

Aseptic techniques must be followed during the preparation of the infusion. For single use only.
Only clear solution free from particles and discoloration should be used.
Healthcare professionals are advised not to dispose of unused Zoledronic Acid (ZDONATE) via the domestic sewage system. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

CAUTION:

Food, Drugs, Devices and Cosmetics Act prohibits dispensing without a prescription.

ADR Reporting Statement:

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph and BIOCare: pv@biocarelifesciences.com
Seek medical attention immediately at the first sign of any adverse drug reaction.

STORAGE CONDITIONS:

Store at temperatures not exceeding 30°C.

AVAILABILITY:

Zoledronic Acid (ZDONATE) 4mg/5mL Solution for Intravenous Infusion is supplied in box of 1's.

Date of First Authorization/Renewal of Authorization: 31/OCT/2020

Reg. No. DRP-8925

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