WINWA	Printing Request Form	Version No.: A.LPdVF-I.06
Vusimide 10mg/ml Furosemide Oral Solution - PI		Reg. No.: **MAL15065040ACZ**
Printer: Pencetak Son Hin Sdn Bhd		*Issued Date:* 26 March 2018

Material	Dimension	Colour	Finishing
60gm Simili Paper (2 Side Printing 1 Side Folding)	85mm x 200mm	Dark Blue (Pantone 2767U)	-

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Vusimide®

Vusimide® 10mg/ml
Furosemide Oral Solution

Active Ingredient:
Each ml contains -
Furosemide ….. 10mg

Presentation:
Bottle of 120ml.

Product Descriptions:
Orange flavoured with orange coloured clear solution. Sugar free and alcohol free. Contains 0.3g/ml Sorbitol 70% Solution.

Pharmacology:
Furosemide is a potent diuretic with a rapid action. It inhibits the re-absorption of electrolytes primarily in the thick ascending limb of the loop of Henle and also in the distal renal tubules. Furosemide may also have a direct effect in the proximal tubules. Excretion of sodium, potassium, calcium, and chloride ions is increased and water excretion enhanced. It has no clinically significant effect on carbonic anhydrase.
Furosemide is fairly rapidly absorbed from the gastrointestinal tract; bioavailability has been reported to be about 60 to 70% but absorption is variable and erratic. The half-life of Furosemide is up to about 2 hours. Furosemide is up to 99% bound to plasma albumin, and is mainly excreted in the urine, largely unchanged. There is also some excretion via the bile and non-renal elimination is considerably increased in renal impairment. Furosemide crosses the placental barrier and is distributed into breast milk. The clearance of Furosemide is not increased by haemodialysis.

Indications:
Vusimide® 10mg/ml Furosemide Oral Solution is indicated for the treatment of oedema associated with heart failure, including pulmonary oedema, and with renal and hepatic problems. It is also used in the treatment of hypertension, either alone or with other antihypertensives.

Dosage and Administration: For oral administration only.
For the treatment of oedema:
Adults: The usual initial oral dose is 40mg once daily, adjusted as necessary according to response. Mild cases may respond to 20mg daily or 40mg on alternate days. Some patients may need doses of 80mg or more daily given as one or two doses daily, or intermittently. Severe cases may require gradual titration of the Furosemide dosage up to 600mg daily.
Children: The usual oral dose is 1 to 3mg/kg daily up to a maximum of 40mg daily.
For the treatment of hypertension:
Adults: The usual initial dose of Furosemide is given in oral doses of 40 to 80mg daily. Dosage should be adjusted according to response. If response is not satisfactory, other antihypertensive can be added.

Symptoms and Treatments of Overdose:
The principal signs and symptoms of overdose with Furosemide are dehydration, blood volume reduction, hypotension, electrolyte imbalance, hypokalemia and hypochloremic alkalosis, and are extensions of its diuretic action.

Treatment of overdosage is supportive and consists of replacement of excessive fluid and electrolyte losses. Serum electrolytes, carbon dioxide level and blood pressure should be determined frequently. Adequate drainage must be assured in patients with urinary bladder outlet obstruction (such as prostatic hypertrophy).

Contraindications:
Not suitable for individual with known hypersensitivity to Furosemide.
Furosemide should not be given in patients with anuria or renal failure caused by nephrotoxic or hepatotoxic drugs nor in renal failure associated with hepatic coma. It should be avoided in patients with severe hepatic impairment.
Furosemide should not be given in pre-comatose states associated with hepatic cirrhosis.

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Warnings/Precautions:
If symptoms persist, please consult a physician.
Furosemide should be used with caution in patients with existing fluid and electrolyte disturbances or who are at risk from changes in fluid and electrolyte balance, such as the elderly.
Furosemide should be used with care in patients with prostatic hyperplasia or impairment of micturition since it can precipitate acute urinary retention.
In patients with chronic heart failure and moderate liver congestion, high-dose Furosemide therapy could produce increases in liver enzymes suggestive of hepatitis. Special care should be taken with the dosage and mode of administration of Furosemide in such patients to avoid severe ischaemic liver damage caused by a drop in systemic blood pressure.

Use in Pregnancy and Lactation:
There is clinical evidence of safety of the drug in the third trimester of human pregnancy; however, Furosemide crosses the placental barrier. It must not be given during pregnancy unless there are compelling medical reasons. Treatment during pregnancy requires monitoring of foetal growth. Furosemide passes into breast milk and may inhibit lactation. Women must not breast-feed if they are treated with Furosemide.

Interactions with Other Medicaments:
Furosemide may enhance the nephrotoxicity of cephalosporin antibacterials such as Cefalotin and can enhance the ototoxicity of aminoglycoside antibacterials and other ototoxic drugs.
The diuretic effect of Furosemide has been shown to be substantially reduced by mixed antiepileptic therapy that included Phenytoin.
Diuretic-induced hypokalaemia may enhance the toxicity of digitalis glycosides and may also increase the risk of arrhythmias with drugs that prolong the QT interval, such as Astemizole, Terfenadine, Halofantrine, Pimozide, and Sotalol.
Diuretics may enhance the effect of other anti hypertensives. The antihypertensive effects of diuretics may be antagonised by drugs that cause fluid retention, such as corticosteroids, NSAIDs, or Carbenoxolone. Diuretics may enhance the nephrotoxicity of NSAIDs.
Severe electrolyte disturbances may occur in patients given Metolazone with Furosemide. Possible increase in plasma-lithium concentrations in patients receiving loop diuretics.
Probenecid has been shown to reduce the renal clearance of Furosemide, and to reduce the diuretic effect.

Undesirable Effects:
The most common adverse effect is fluid and electrolyte imbalance including hyponatraemia, hypokalaemia, and hypochloraemic alkalosis. Signs of electrolyte imbalance include headache, hypotension, muscle cramps, dry mouth, thirst, weakness, lethargy, drowsiness, restlessness, oliguria, cardiac arrhythmias, and gastrointestinal disturbances. Hypovolaemia and dehydration may occur, especially in the elderly.
Furosemide may cause hyperuricaemia and precipitate gout in some patients.
Skin rashes and photosensitivity reactions may be severe; hypersensitivity reactions include interstitial nephritis and vasculitis; fever has also been reported.

Storage:
Store below 30°C. Protect from light. Keep cap tightly closed.
Keep out of reach of children. *Jauhi daripada kanak-kanak.*
Discard opened bottle after 90 days.

Shelf Life:
18 months from the date of manufacture.
Registration No: MAL 15065040ACZ

Manufactured by:
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