Table 1: Oral Equivalent Dosage

The intravenous infusion rate required to produce an average.

Titrate dose to achieve the intravenous use. Vial must be diluted 0.1 mg/mL before use.

1.1 Hypertension

Full Prescribing Information

Initial U.S. Approval: 1988

Dosage and Administration

Intravenous Corrected Dosage

<table>
<thead>
<tr>
<th>Oral Nicardipine</th>
<th>Intravenous Nicardipine</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 mg q8h 1.0 mg/hr = 18 mL/hr</td>
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</tr>
<tr>
<td>30 mg q8h 1.2 mg/hr = 12 mL/hr</td>
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<tr>
<td>40 mg q8h 1.4 mg/hr = 19 mL/hr</td>
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</tbody>
</table>

Drug Discontinuation and Transition to an Oral Antihypertensive

Titrate slowly when using nicardipine hydrochloride injection, especially for patients converting from other antihypertensive medications, and closely monitor responses in patients with impaired renal function. Increases in frequency, duration, or severity of angina have been reported in patients with severe atherosclerosis, especially when converting from nitrates. Increases in heart rate may be observed. If an increase in heart rate is noted, observe the patient closely. Discontinue nicardipine if it appears to contribute to tachycardia. When heart rate exceeds 120 beats per minute, consider withdrawal of nicardipine.

2.2 Monitoring

Evaluate patients who have experienced an adverse reaction to nicardipine hydrochloride injection for signs of worsening cardiovascular status. Based on individual patient response, titrate the dose of nicardipine hydrochloride injection. In most patients, nicardipine hydrochloride injection can safely be administered at the highest dose by titration. If severe hypotension occurs despite dose reductions, the infusion should be discontinued. When blood pressure and clinical condition are stable, the patient may be transferred to oral medication. Do not use in patients with advanced aortic stenosis.

4. Contraindications

Nicardipine hydrochloride injection is contraindicated in patients with: (1) known hypersensitivity to nicardipine or any of its components, (2) severe hypotension, (3) excessive tachycardia, (4) overt congestive heart failure, (5) cardiogenic shock, (6) hypovolemia, (7) known hypersensitivity to furosemide, (8) known hypersensitivity to propranolol, (9) known hypersensitivity to histamine-2 antagonists, (10) patients with impaired renal function, (11) patients with hepatic impairment, (12) patients with preeclampsia, (13) patients with pre-term labor, and (14) patients with hepatic impairment.

5. Adverse Reactions

5.1 Dosage-Independent Adverse Reactions

Adverse reactions in women treated with intravenous nicardipine hydrochloride injection: Decreased heart rate, hypotension, tachycardia, headache, and phlebitis at the site of injection. Neonatal adverse event includes acidosis (pH < 7.25). Adverse events in women treated with intravenous nicardipine hydrochloride injection: Decreased heart rate, hypotension, tachycardia, headache, and phlebitis at the site of injection. Neonatal adverse event includes acidosis (pH < 7.25).

5.2 Exacerbation of Heart Failure

Increases in frequency, duration, or severity of angina have been reported in patients with severe atherosclerosis, especially when converting from nitrates. Increases in heart rate may be observed. If an increase in heart rate is noted, observe the patient closely. Discontinue nicardipine if it appears to contribute to tachycardia. When heart rate exceeds 120 beats per minute, consider withdrawal of nicardipine.

5.3 Hematologic

Thrombocytopenia has been reported in patients receiving nicardipine hydrochloride injection. The incidence of thrombocytopenia in patients with impaired renal function is higher than in patients with normal renal function.

5.4 Prolonged Effect with Impaired Renal Function

Nicardipine hydrochloride injection has been shown to increase the serum concentration of furosemide and propranolol. Nicardipine inhibition of hepatic microsomal enzymes, including CYP3A4, may result in elevated plasma tacrolimus levels through induction of CYP3A4. Nicardipine hydrochloride injection has been shown to increase the serum concentration of furosemide and propranolol. Nicardipine inhibition of hepatic microsomal enzymes, including CYP3A4, may result in elevated plasma tacrolimus levels through induction of CYP3A4.

5.5 Local Irritation

Local irritation has occurred in patients during the intravenous infusion of nicardipine hydrochloride injection. Local irritation at the site of infusion may result in phlebitis, local irritation, and mild edema. In some cases, redness and itching have been reported. To reduce the possibility of venous thrombosis, phlebitis, local irritation, and mild edema, exercise care when administering the drug. Contraindications to the use of intravenous nicardipine hydrochloride include the presence of localized infection or hypersensitivity to the drug.

6. Drug Interactions

Nicardipine hydrochloride injection may be administered concurrently with furosemide, propranolol, or histamine-2 antagonists. When nicardipine hydrochloride injection is administered concurrently with furosemide, propranolol, or histamine-2 antagonists, the dose of the concomitant agent may need to be increased. When nicardipine hydrochloride injection is administered concurrently with furosemide, propranolol, or histamine-2 antagonists, the dose of the concomitant agent may need to be increased.

7. Pregnancy and Nursing Mothers

Nicardipine hydrochloride injection is pregnancy category C. There are no reports of adverse effects in women who have received nicardipine hydrochloride injection in pregnancy. In embryofetal toxicity studies, nicardipine was administered orally to New Zealand albino rabbits received oral nicardipine during organogenesis, at doses 8 and 24 times the upper limit of the human therapeutic dose on body surface area (mg/m2). No embryofetal toxicity was observed. Embryofetal toxicity occurred at the high dose along with signs of maternal toxicity. In animal studies, nicardipine was shown to cross the placental barrier. There are no adequate and well-controlled studies in pregnant women. Use nicardipine hydrochloride injection during pregnancy only if the potential benefit justifies the potential risk to the fetus.

8. Incompatibilities

Nicardipine hydrochloride injection is compatible with: (1) Sodium Chloride (0.45%) Injection, USP, (2) Dextrose (5%) with 40 mEq Potassium, USP, (3) Sodium Bicarbonate Injection, USP, (4) Sodium Chloride Injection, USP, (5) Sodium Chloride (0.9%) Injection, USP, (6) Sodium Bicarbonate (7.5%) Injection, USP, (7) Sodium Chloride (0.45%) Injection, USP, (8) Sodium Chloride Injection, USP, and (9) Sodium Chloride (0.9%) Injection, USP.

9. Precautions

Nicardipine hydrochloride injection can cause hypotension, headache, and phlebitis at the site of injection. Hypotension may occur in patients with impaired renal function. Hypotension may occur in patients with impaired renal function. Nicardipine hydrochloride injection can cause hypotension, headache, and phlebitis at the site of injection. Hypotension may occur in patients with impaired renal function. Nicardipine hydrochloride injection can cause hypotension, headache, and phlebitis at the site of injection. Hypotension may occur in patients with impaired renal function. Nicardipine hydrochloride injection can cause hypotension, headache, and phlebitis at the site of injection. Hypotension may occur in patients with impaired renal function. Nicardipine hydrochloride injection can cause hypotension, headache, and phlebitis at the site of injection. Hypotension may occur in patients with impaired renal function. Nicardipine hydrochloride injection can cause hypotension, headache, and phlebitis at the site of injection. Hypotension may occur in patients with impaired renal function. Nicardipine hydrochloride injection can cause hypotension, headache, and phlebitis at the site of injection. Hypotension may occur in patients with impaired renal function. Nicardipine hydrochloride injection can cause hypotension, headache, and phlebitis at the site of injection. Hypotension may occur in patients with impaired renal function. Nicardipine hydrochloride injection can cause hypotension, headache, and phlebitis at the site of injection. Hypotension may occur in patients with impaired renal function.

10. Adverse Reactions

Adverse reactions to nicardipine hydrochloride injection are rare. In controlled clinical trials, the frequency of adverse reactions to nicardipine hydrochloride injection in patients with hypertension was comparable to that observed with placebo. In general, the incidence of adverse reactions is lower in patients with hypertension than in those with congestive heart failure, and nicardipine hydrochloride injection is well tolerated in patients with hypertension.

11. Marketing History

Nicardipine hydrochloride injection was approved by the U.S. Food and Drug Administration on May 26, 1988. The drug was initially marketed by American Regent, Inc. at 1-800-734-9236, or FDA at 1-800-734-6238. In most patients, nicardipine hydrochloride injection can safely be administered at the highest dose by titration. If severe hypotension occurs despite dose reductions, the infusion should be discontinued. When blood pressure and clinical condition are stable, the patient may be transferred to oral medication. Do not use in patients with advanced aortic stenosis.

12. Pharmacokinetics

In human volunteer studies, nicardipine hydrochloride injection is rapidly absorbed, with peak plasma concentrations occurring within 1-2 hours after intravenous administration. The drug is extensively metabolized in the liver and excreted primarily in the feces. The elimination half-life of nicardipine hydrochloride injection is approximately 9-12 hours. Nicardipine hydrochloride injection is eliminated primarily in the feces, with less than 15% of the dose excreted in the urine. Nicardipine hydrochloride injection is eliminated primarily in the feces, with less than 15% of the dose excreted in the urine. Nicardipine hydrochloride injection is eliminated primarily in the feces, with less than 15% of the dose excreted in the urine. Nicardipine hydrochloride injection is eliminated primarily in the feces, with less than 15% of the dose excreted in the urine. Nicardipine hydrochloride injection is eliminated primarily in the feces, with less than 15% of the dose excreted in the urine. Nicardipine hydrochloride injection is eliminated primarily in the feces, with less than 15% of the dose excreted in the urine. Nicardipine hydrochloride injection is eliminated primarily in the feces, with less than 15% of the dose excreted in the urine. Nicardipine hydrochloride injection is eliminated primarily in the feces, with less than 15% of the dose excreted in the urine. Nicardipine hydrochloride injection is eliminated primarily in the feces, with less than 15% of the dose excreted in the urine.
Pregnant rats received oral nicardipine from 50 mg/kg/day (human equivalent dose about 16 mg/kg/day or 8 times the maximum recommended oral dose).

There was no evidence of embryotoxicity or teratogenicity. However, adverse effects on the fetus were observed when New Zealand albino rabbits were treated orally, during organogenesis, with up to 100 mg/kg nicardipine/kg/day for one year and no evidence of effects to provide daily dosage levels of 5, 15, or 45 mg/kg/day) for two

1. Safety and efficacy in patients under the age of 18 have not been evaluated.

2. Pulmonary Function

II diabetic patients with nephropathy, oral nicardipine (20 mg TID).

3. Acute bolus administration of nicardipine hydrochloride injection

4. Hypertensive patients with impaired renal function, mean plasma

5. When nicardipine hydrochloride injection was given to mild to

6. Renal Function

7. Because the liver extensively metabolizes nicardipine, plasma

8. *PA = conduction time from high to low right atrium; AH = conduction

9. effect on normal myocardium, suggesting the improvement is

10. angina upon receiving oral nicardipine. Whether this represents

11. output both at rest and during exercise. Decreases in left

12. CLINICAL PHARMACOLOGY

13. Each mL contains nicardipine hydrochloride 2.5 mg in water for

14. 3,5-pyridinedicarboxylate monohydrochloride and has the following

15. a dihydropyridine derivative with IUPAC (International Union of

16. may cause systemic hypotension, bradycardia (following initial

17. 10. OVERDOSAGE

18. in elderly patients, reflecting the greater frequency of decreased

19. experience has not identified differences in responses between

20. Eval#: X4123258