CLADRIBINE INJECTION
Rx ONLY.
For Intravenous Infusion Only

WARNINGS

Cladrabine injection should be administered under the supervision of a qualified physician experienced in the use of antineoplastic therapy. Suppression of bone marrow function should be anticipated. This is usually reversible and appears to be dose dependent. Serious neurological toxicity (including irreversible paraplegia and quadraparesis) has been reported in patients who received cladrabine at high doses (4 to 6 times the recommended dose for hairy cell leukemia). Neurological toxicity appears to be dose related; however, severe neurological toxicity has been reported rarely following treatment with standard cladrabine dosing regimens, especially when given concurrently with other neurotoxic agents/therapies.

DESCRIPTION

Cladrabine injection (also commonly known as 2-chloro-2'-deoxy-8-0-adenosine) is a synthetic antineoplastic agent for continuous intravenous infusion. It is a clear, colorless, sterile, preservative-free, isotonic solution. Cladrabine injection is available in single-use vials containing 10 mg of sodium chloride as an inactive ingredient. The solution has a pH range of 5.5 to 8.0. Phosphoric acid and/or diethyl sodium phosphate may have been added to adjust the pH to 6.3 ± 0.3.

The chemical name for cladrabine is 2-chloro-2'-deoxy-8-0-adenosine-pentofuranosylpyrimidine and the structure is represented below:

Cellular Resistance and Sensitivity

The selective toxicity of 2-chloro-2'-deoxy-8-0-adenosine towards certain normal and malignant lymphocyte and monocyte populations is based on the relative activities of deoxyribonuclease and deoxycytidylate. Cladrabine passively crosses the cell membrane. In cells with a high ratio of deoxyribonuclease to deoxycytidylate, it is resistant to degradation by deoxycytidylate deaminase (2'-deoxy-8-0-adenosine does not accumulate intracellularly and is converted to the active form). In cells with a high ratio of deoxycytidylate to deoxyribonuclease, 2-chloro-2'-deoxy-8-0-adenosine is converted directly into the active form and deoxycytidylate deaminase is converted into its active form (2'-deoxy-8-0-adenosine 5'-triphosphate). This is incorporated into thymidylic acid, which is incorporated into DNA, leading to cell death.

CLINICAL PHARMACOLOGY

In a clinical investigation, 17 patients with hairy cell leukemia and normal renal function were treated for 7 days with the recommended treatment regimen of cladrabine (0.09 mg/kg) by continuous intravenous infusion. The mean steady-state serum concentration was estimated to be 1.7 mg/L, with an observed relationship between serum concentrations and clinical outcome. In another study, 8 patients with hematologic malignancies received a 2-hour infusion of cladrabine (0.12 mg/kg). The mean end-of-infusion plasma cladrabine concentration was 48 ± 19 ng/mL. For 5 of these patients, the disappearance of cladrabine could be described by either a biexponential or biphasic linear model. 4 patients had a terminal half-life of 5.4 hours. Mean values for clearance and steady-state volume of distribution were 97.8 ± 472 mL/min/kg and 4.5 ± 2.8 L/kg, respectively.

Cladrabine concentrations were reported to decline exponentially after intravenous infusions with terminal half-lives ranging from approximately 3 to 22 hours. The mean half-life of cladrabine in leukemic cells has been reported to be 1.9 hours.

HUMAN PHARMACOLOGY

In general, the apparent volume of distribution of cladrabine is very large (mean approximately 9 L/kg), indicating an extensive distribution of cladrabine in body tissues. The mean half-life of cladrabine in leukemic cells has been reported to be 17 hours.

Cladrabine penetrates into cerebrospinal fluid. One report indicates that concentrations are approximately 25% of those in plasma.

Human disease is treated with an intravenous infusion of 3.5 to 5.0 mg/kg/day, administered as a 30-minute infusion over 3 days. Two single-center open-label studies of cladrabine have been conducted in patients with hairy cell leukemia with evidence of active disease requiring therapy. In one study, complete remission was achieved in 2 of 5 patients treated with cladrabine. One patient achieved complete remission with cladrabine and 1 patient achieved complete remission with cladrabine and 1 patient achieved complete remission with cladrabine.

In another study, 10 patients with hairy cell leukemia were treated with cladrabine alone (3.5 to 5.0 mg/kg/day) or in combination with interferon alfa (1 million units subcutaneously daily). Complete remission was achieved in 2 of 10 patients treated with cladrabine alone and in 6 of 10 patients treated with cladrabine in combination with interferon alfa. Partial remission was achieved in 4 of 10 patients treated with cladrabine alone and in 3 of 10 patients treated with cladrabine in combination with interferon alfa.

A randomized, placebo-controlled trial compared cladrabine (3.5 to 5.0 mg/kg/day) alone or in combination with interferon alfa (1 million units subcutaneously daily) to placebo. Complete remission was achieved in 6 of 10 patients treated with cladrabine alone and in 6 of 10 patients treated with cladrabine in combination with interferon alfa. Partial remission was achieved in 4 of 10 patients treated with cladrabine alone and in 3 of 10 patients treated with cladrabine in combination with interferon alfa.

Among patients with hairy cell leukemia, cladrabine has been shown to be effective in a variety of settings, including as a single agent, in combination with other agents, and as part of a more complex treatment regimen.

RESPONSE RATES TO CLADRIBINE TREATMENT IN PATIENTS WITH Hairy Cell Leukemia

<table>
<thead>
<tr>
<th>Response Rate</th>
<th>Cladrabine</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaluative Patients</td>
<td>N=106</td>
<td>66%</td>
</tr>
<tr>
<td>Overall Response Rate</td>
<td>89%</td>
<td>89%</td>
</tr>
</tbody>
</table>

The overall response rate was 89% for cladrabine alone and 89% for cladrabine in combination with interferon alfa. The response rate for these groups was significantly higher than that observed in previous studies with cladrabine alone or in combination with interferon alfa. The overall response rate for cladrabine alone was 60% and 80% for Study A and Study B, respectively, yielding a combined complete response rate of 60%. Overall response rate 89% for evaluable patients treated with cladrabine.
In these studies, 60% of the patients had not received prior chemotherapy for hairy cell leukemia or had undergone splenectomy as the only prior treatment and were receiving cladribine as a first-line treatment. The remaining 40% of the patients received cladribine as a second-line treatment, having been treated previously with other agents, including α-interferon and/or denosumab. The overall response rate for patients without prior chemotherapy was 52%, response rate is decreased in patients previously treated with splenectomy or denosumab and in patients refractory to α-interferon.

### OVERALL RESPONSE RATES (CR + GP + PR) TO CLADRIBINE TREATMENT IN PATIENTS WITH Hairy Cell Leukemia

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Overall Response (%)</th>
<th>N + Relapse</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Prior Chemotherapy</td>
<td>58/74 (92%)</td>
<td>6 / 4 (16%)</td>
</tr>
<tr>
<td>Any Prior Chemotherapy</td>
<td>45/49 (91%)</td>
<td>6 / 3 (22%)</td>
</tr>
<tr>
<td>Previous Splenectomy</td>
<td>32/41 (78%)</td>
<td>6 / 3 (19%)</td>
</tr>
<tr>
<td>Previous Interferon</td>
<td>69/83 (84%)</td>
<td>11 / 3 (13%)</td>
</tr>
<tr>
<td>Previous Denosumab</td>
<td>6/8 (75%)</td>
<td>1 / 2 (13%)</td>
</tr>
</tbody>
</table>

N + No Response

*<p>P < 0.05

After reversible decline, normalization of peripheral blood counts (Hemoglobin >12 g/dl, Platelets >100 x 10^9/L, Absolute Neutrophil Count (ANC) >1500 x 10^9/L) was achieved by 92% of evaluable patients. The median time to normalization of peripher al blood counts was 9 weeks from the start of treatment. For patients with hairy cell leukemia (HCL), the median time to normalization was 8 weeks. With normalization of Platelet Count and Hemoglobin, requirements for platelet and RBC transfusions were abolished after Months 1 to 2 of HCL therapy. A trend toward a reduced incidence of infection was seen after the third month, when compared to the months immediately preceding cladribine therapy. See also WARNINGS, PRECAUTIONS AND ADVERSE REACTIONS.

### CLADRIBINE TREATMENT IN PATIENTS WITH Hairy Cell Leukemia

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Median Time to Normalization of Counts*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Count</td>
<td>2 weeks</td>
</tr>
<tr>
<td>Absolute Neutrophil Count</td>
<td>3 weeks</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>4 weeks</td>
</tr>
<tr>
<td>ANC</td>
<td>5 weeks</td>
</tr>
<tr>
<td>Hemoglobin and Platelet Count</td>
<td>6 weeks</td>
</tr>
</tbody>
</table>

*Day 1 = First day of infusion

For patients achieving a complete response, the median time to response (i.e., absence of hairy cells in bone marrow and peripheral blood) was 4 months. In patients with hairy cell leukemia, the median time to complete response was shorter than that for HCL patients. In both groups, the median duration of complete response was greater than 6 months and ranged to 25 months. Among 93 responding patients, 17 patients subsequently received additional treatments with cladribine. In four of these patients, disease was limited to the bone marrow. Seven patients did not respond to a final course of cladribine received a second course of therapy. In the five patients who had adequate follow-up, additional courses did not appear to improve their overall response.

### INDICATIONS AND USAGE

Cladribine is indicated for the treatment of active hairy cell leukemia as delayed by clinically significant anemia, neutropenia, thrombocytopenia or disease-related symptoms.

### CONTRAINDICATIONS

Cladribine is contraindicated in those patients who are hypersensitive to this drug or any of its components.

### WARNINGS

Severe bone marrow suppression, including neutropenia, anemia and thrombocytopenia, has been commonly observed in patients treated with cladribine. Leukemia, following treatment with cladribine, has been observed in the clinical studies. Hematologic impairment may be a manifestation of active hairy cell leukemia. A total of 24 patients (68%) patients had fever in the setting of neutropenia (ANC < 1000), including 2 patients (5%) had severe neutropenia (i.e., ANC < 500). In a Phase 1 investigation study using cladribine in high doses (4 to 9 times the recommended dose for hairy cell leukemia) as part of a bone marrow transplant conditioning regimen, which also included high dose cyclophosphamide and total body irradiation, acute neutropenic and delayed onset neurotoxicity cladribine for 7 to 14 days prior to bone marrow transplantation. During treatment, 8 patients experienced gastrointestinal symptoms and 3 patients had fever in the setting of neutropenia. In 2 patients, treatment was discontinued due to neutropenia.

### ADVERSE REACTIONS

- **Fever**: Fever (17 out of 100) was associated with the use of cladribine in approximately two-thirds of patients (13/186) in the first month of therapy. Virtually all of these patients (38%) had severe neutropenia (i.e., ANC < 1000).
- **Neutropenia**: Neutropenia was observed in the dose escalation study at the highest dose levels (approximately 4 times the recommended dose for hairy cell leukemia). Neutropenia has been observed in both animals and humans.
- **Fever**: Fever was observed in the dose escalation study at the highest dose levels (approximately 4 times the recommended dose for hairy cell leukemia). Neutropenia has been observed in both animals and humans.
- **Marrow depression**: Marrow depression has been observed in both animals and humans.
- **Neutropenia**: Neutropenia has been observed in both animals and humans.

In patients with hairy cell leukemia treated with the recommended treatment regimen (0.09 mg/kg/day for 7 consecutive days), there have been no reports of neutropenic toxicity. Of the 196 hairy cell leukemia patients entered in the two trials, there were 8 deaths following treatment. Of these, 6 were due to infectious etiology, including 3 pneumonias, and 2 occurred in the first month following cladribine therapy. Of the 8 deaths, 5 occurred in previously treated patients who were Refractory to α-interferon.
Although there is no evidence of teratogenicity in humans due to cladribine, other drugs which inhibit DNA synthesis (e.g., methotrexate and aminopterin) have been reported to be teratogenic in humans. Cladribine has been shown to be embryotoxic in mice when given at doses equivalent to the recommended dose. There are no adequate and well controlled studies in pregnant women. If cladribine is used during pregnancy, the patient should be informed of the potential hazard to the fetus. Women of childbearing age should be advised to avoid becoming pregnant. 

PRECAUTIONS 

General: Cladribine is a potent antineoplastic agent with potentially significant toxic effects. It should be administered only under the supervision of a physician experienced in the use of chemotherapeutic agents. Patients undergoing therapy should be closely observed for signs of hematologic and non-hematologic toxicity. Periodic assessment of peripheral blood counts, particularly during the first 4 to 8 weeks post-treatment, is recommended to detect the development of anemia, neutropenia and thrombocytopenia and for early detection of any potential sequelae (e.g., infection or bleeding). As with other potent chemotherapeutic agents, monitoring of renal and hepatic function is also recommended, especially in patients with underlying kidney or liver dysfunction. See WARNINGS AND ADVERSE REACTIONS.

Fever was a frequently observed side effect during the first month on study. Since the majority of fevers occurred in neutropenic patients, patients should be closely monitored during the first month of treatment and empiric antibiotics should be initiated as clinically indicated. Although 69% of patients developed fevers, less than 1/2 of febrile events were associated with documented infection.

Given the known myelosuppressive effects of cladribine, practitioners should carefully evaluate the risks and benefits of administering this drug to patients with active infections. See WARNINGS AND ADVERSE REACTIONS.

The absence of adequate data on dosing of patients with renal or hepatic insufficiency. Development of acute renal insufficiency in some patients receiving high doses of cladribine has been described. Until more information is available, caution is advised when administering the drug to patients with known or suspected renal or hepatic insufficiency. See WARNINGS.

Rare cases of tumor lysis syndrome have been reported in patients treated with cladribine with other hematologic malignancies having a high tumor burden. Cladribine must be diluted in designated intravenous solutions prior to administration. See DOSAGES AND ADMINISTRATION.

Laboratory Tests: During and following treatment, the patient's hematologic profile should be monitored regularly to determine the degree of hematopoietic suppression. In the clinical studies, following reversible declines in all cell counts, the mean Platelet Count reached 100 x 10^9/L, by Day 12, the mean Absolute Neutrophil Count reached 100 x 10^9/L, by Week 5 and the mean Hemoglobin reached 12 g/dl by Week 8. After peripheral counts have normalized, bone marrow aspiration and biopsy should be performed to confirm response to treatment with cladribine. Feline events should be investigated with appropriate laboratory and radiologic studies. Periodic assessment of renal function and hepatic function should be performed as clinically indicated.

Drug Interactions: There are no known drug interactions with cladribine. Caution should be exercised if cladribine is administered alone, or in conjunction with other drugs known to cause immunosuppression or myelosuppression. See WARNINGS.

Carcinogenesis, Mutagenesis, Impairment of Fertility: No animal carcinogenicity studies have been conducted with cladribine. However, its carcinogenic potential cannot be excluded based on demonstrated promutagenicity of cladribine.

As with all compounds in this class, the actions of cladribine yield DNA damage. In mammalian cells, cladribine caused the accumulation of DNA strand breaks. Cladribine was also incorporated into DNA of human lymphoblastic leukemia cells. Cladribine was not mutagenic, in vitro or in vivo (Ames test and Chinese hamster ovary cell gene mutation tests) and did not induce unscheduled DNA synthesis in primary rat hepatocytes. However, cladribine was clastogenic in vitro (chromosome aberration test) and in vivo (mouse bone marrow micronucleus test).

When administered intravenously to cynomolgus monkeys, cladribine has been shown to cause suppression of rapidly growing cells, including testicular cells. The effect on human fertility is unknown.

Pregnancy: Teratogenic Effects, Pregnancy Category D: See WARNINGS.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from cladribine, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established. In a Phase I study involving patients 1 to 21 years old with relapsed acute leukemia, cladribine was given by continuous intravenous infusion at doses ranging from 2.0 to 10.7 mg/m^2/day for 3 days (one-half to twice the dose recommended in 24-Hour Leukemia). In this study, the dose-limiting toxicity was severe myelosuppression with profound neutropenia and thrombocytopenia. At the highest dose (10.7 mg/m^2/day), 3 of 7 patients developed irreversible myelosuppression and total systemic bacterial or fungal infections. No unique toxicities were noted in this study. See WARNINGS AND ADVERSE REACTIONS.

ADVERSE REACTIONS

Safety data are based on 196 patients with Hairy Cell Leukemia, the original cohort of 124 patients plus additional 72 patients enrolled at the same two centers after the original enrollment cutoff. In Month 1 of the Hairy Cell Leukemia clinical trials, severe neutropenia was noted in 70% of patients, fever in 69%, and infection was documented in 89%. Other adverse experiences reported frequently during the first 14 days after initiating treatment included fatigue (45%), nausea (28%), rash (27%), headache (22%) and injection site reactions (19%). Most non-hematologic adverse experiences were mild to moderate in severity.

Myelosuppression was frequently observed during the first month after starting treatment. Neutropenia (ANC < 500 x 10^9/L) was noted in 72% of patients; compared with 26% in whom it was present initially. Severe anemia (Hemoglobin < 8.0 g/dl) developed in 33% of patients; compared with 10% initially and thrombocytopenia (Platelets < 50 x 10^9/L) developed in 72% of patients; compared to 4% in whom it was noted initially.

During the first month, 54 of 146 patients (38%) exhibited documented evidence of infection. Serious infections (e.g., sepsis, pneumonia, septicemia) were reported in 6% of all patients; the remainder were mild or moderate. Several deaths were attributable to infection and/or complications related to the underlying disease.

During the second month, the overall rate of documented infection was 6%, these infections were mild to moderate and no severe systemic infections were seen. After the second month, the monthly incidence of infection was either less than or equal to that of the months preceding cladribine therapy.

During the first month, 11% of patients experienced severe fever (i.e., >204°F). Documented infections were noted in fewer than one-third of febrile episodes. Cytomegalovirus (CMV) was noted in 15% of patients with fever. Sixteen (10%) of 164 patients had documented CMV infection. The most common CMV infection was CMV retinitis (2%). Infection was noted in 1% of patients. The majority of CMV infections were noted in patients who were not immunocompromised.

Analysis of lymphocyte subsets indicates that treatment with cladribine is associated with prolonged depression of the CD4 counts. Prior to treatment, the mean CD4 count was 760/cu.mm. The mean CD4 count on day one of treatment, was 77/cu.mm. Fifteen (15) months after treatment, mean CD4 counts remained below 500/cu.mm. CD8 counts behaved similarly, though increasing counts were observed after 9 months. The clinical significance of the prolonged CD4 lymphopenia is unclear.

Another event of unknown clinical significance includes the observation of prolonged bone marrow hypoplasia. Bone marrow cellularity of <5% was noted after 4 months in 42/124 patients (34%) treated in the 2 pivotal trials. The hypoplasia was noted as late as day 1010. It is not known whether the hypoplasia is the result of disease related marrow fibrosis or if it is the result of cladribine toxicity. There was no apparent clinical effect on the peripheral blood counts.

The vast majority of cases were mild and occurred in patients who were receiving or had recently been treated with other medications (e.g., alemtuzumab or alemtuzumab) known to cause rash.

Most episodes of nausea were mild, not accompanied by vomiting, and did not require treatment with antiemetics. In patients requiring antiemetics, nausea was easily controlled, most frequently with promazine.

Adverse reactions reported during the first 2 weeks following treatment initiation (regardless of relationship to drug) by >5% of patients included:

Body as a Whole: fever (60%), fatigue (45%), chills (9%), asthenia (9%), diaphoresis (9%), malaise (7%), trunk pain (6%)

Cardiovascular: nausea (28%), decreased appetite (17%), vomiting (13%), diarrhea (10%), constipation (9%), abdominal pain (6%)

Musculoskeletal/Purpura: pain (10%), petechiae (8%), epistaxis (5%)

Nervous System: headache (22%), dizziness (9%), insomnia (7%)

Respiratory: dry cough (19%), chest discomfort (16%), dyspnea (10%), hyperventilation (9%), lower respiratory tract (5%)

Other Reactions: joint pain (4%), bone pain (4%), fever (3%), alopecia (3%), arthralgia (2%), myalgia (2%)

Adverse experiences related to intravenous administration included injection site reactions (5%) (i.e., redness, swelling, pain), thrombosis (2%), phlebitis (2%) and a broken catheter (1%).

These appear to be related to the infusion procedure and/or indwelling catheter, rather than the medication or the vehicle. From Day 15 to the last follow-up visit, the only events reported by >5% of patients were fatigue (11%), rash (10%), headache (7%), cough (7%), and malaise (5%).

For a description of adverse reactions associated with use of high doses in non-Hairy Cell Leukemia patients, see WARNINGS.

The following additional adverse events have been reported since the drug became commercially available. These adverse events have been reported primarily in patients who received multiple courses of cladribine:

Hematologic: bone marrow suppression with prolonged pancytopenia, including some reports of aplastic anemia, hemolytic anemia, which was reported in patients with lymphoid malignancies, occurring within the first few weeks following treatment.

Neoplastic, generally mild increase in bilirubin and transaminases.
OVERDOSE

High doses of clindamycin have been associated with reversible neurologic toxicity (paraparesis/ataxia), acute nephrotoxicity, and severe bone marrow suppression resulting in neutropenia, anemia, and thrombocytopenia. See WARNINGS. There is no known specific antidote to overdosage. Treatment of overdosage consists of discontinuation of clindamycin, careful observation and appropriate supportive measures. It is not known whether the drug can be removed from the circulation by dialysis or hemofiltration.

DOSEAGE AND ADMINISTRATION

Usual Dose

The recommended dose and schedule of clindamycin for active Hairy Cell Leukemia is as a single course given by continuous infusion for 7 consecutive days at a dose of 0.09 mg/kg/day. Deviations from this dosage schedule are not advised. If the patient does not respond to the initial course of clindamycin for Hairy Cell Leukemia, it is unlikely that they will benefit from additional courses. Physicians should consider delaying or discontinuing the drug if neutropenia or renal toxicity occurs. See WARNINGS.

Specific risk factors predisposing to increased toxicity from clindamycin have not been defined. In view of the known toxicities of agents of this class, it would be prudent to proceed carefully in patients with known or suspected renal insufficiency or severe bone marrow impairment of any etiology. Patients should be monitored closely for hematologic and non-hematologic toxicity. See WARNINGS and PRECAUTIONS.

Preparations and Administration of Intravenous Solutions:

Clindamycin must be reconstituted with the designated diluent prior to administration. Since the drug product does not contain any antimicrobial preservative or bacteriostatic agent, preserved solutions must be prepared in aseptic environment in preparations at clinical sites.

To prepare a single daily dose: Add the calculated dose (0.09 mg/kg or 0.09 ml/kg) of clindamycin to an infusion bag containing 500 ml of 0.9% Sodium Chloride injection. Infuse continuously over 24 hours. Repeat daily for a total of 7 consecutive days. The dose at 0.9% dextrose as a diluent is not recommended because of increased degradation of clindamycin. Admixtures of clindamycin are chemically and physically stable for at least 24 hours at room temperature under normal room temperature demonstration in Baxter Vetflex™ PVC infusion containers. Since limited compatibility data are available, adherence to the recommended diluents and infusion systems is advised. Since limited compatibility data are available, adherence to the recommended diluents and infusion systems is advised. Solutions containing clindamycin should not be mixed with other intravenous drugs or solutions or infused simultaneously via a common intravenous line, since compatibility testing has not been performed. Preparations containing benzyl alcohol should not be used in neonates. See WARNINGS.

Care must be taken to assure the sterility of prepared solutions. Once diluted, solutions of clindamycin should be administered promptly or stored in the refrigerator (2° to 8° C) for no more than 8 hours prior to start of administration. Vials of clindamycin are single-dose only. Any unused portion should be discarded in an appropriate manner. See Handling and Disposal.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

A precipitate may occasionally occur during the storage of clindamycin to low temperatures. It may be resolubilized by allowing the solution to warm naturally to room temperature and by shaking vigorously. DO NOT HEAT ON MICROWAVE.

Chemical Stability at Vials:

When stored in refrigerated conditions between 2° to 8° C (36° to 46° F) protected from light, unopened vials of clindamycin are stable until the expiration date indicated on the package. Freezing does not adversely affect the solution. If freezing occurs, thaw naturally to room temperature. DO NOT refreeze. Once thawed, the vial of clindamycin is stable until expiry 24 hours. DO NOT refrigerate. Once diluted, solutions containing clindamycin should be administered promptly or stored in the refrigerator (2° to 8° C) for no more than 8 hours prior to administration.

Handling and Disposal:

The potential hazards associated with cytotoxic agents are well established and proper precautions should be taken when handling, preparing, and administering clindamycin. The use of disposable gloves and protective garments is recommended. If clindamycin contacts the skin or mucous membranes, wash the involved surface immediately with copious amounts of water. Several guidelines on this subject have been published. There is no general agreement that all of the procedures recommended in the guidelines are necessary or appropriate. Refer to your institution’s guidelines and all applicable state/local regulations for disposal of cytotoxic waste.

HOW SUPPLIED

Clindamycin is supplied as a sterile, preservative-free, isotonic solution containing 10 mg (1 ml) of clindamycin as 10 ml, filled into a single-use clear glass 70 ml vial, individually blistered, NDC 53399-134-61. Store reconstituted 2° to 8° C (36° to 46° F). Protect from light during storage.

REFERENCES

10. MEDICATION CASSETTE™ Reservoir, manufactured by SIMS Detec, Inc. - Reserse No. 602180 (entered in 1991)

Manufactured by: Venetian Laboratories, Inc.
Bedford, OH 44146
January 2000

Manufactured for:
Bedford Laboratories™
Bedford, OH 44416
CLD-505
CLADRBINE INJECTION

10 mg
(1 mg/mL)
Rx ONLY.

MUST BE DILUTED PRIOR TO IV INFUSION

Directions for Use:

Store in refrigerator at 2° to 8°F (36° to 46°F).
PROTECT FROM LIGHT. Retain in carton until time of use.

Manufactured by:
Ben Venue Labs, Inc.,
Bedford, OH 44146

Manufactured for:
Bedford Laboratories™,
Bedford, OH 44146

Lot
Exp

Format Number: 71939 #014A
Black
3292 Green
032 Red

Prepared by
Mark Zarnstorff
Checked by
Note: Keyline does not print.

CLADRIBINE INJECTION
MUST BE DILUTED PRIOR TO INFUSION

10 mg
(1 mg/mL)
Rx ONLY.

NDC 55290-124-01 10 mL single-dose vial


For the preparation of intravenous solutions and usual dosage. See package insert.

Each mL contains 1 mg of cladribine and 9 mg of sodium chloride. Phosphoric acid and/or diethyl sodium phosphate may have been added to adjust the pH. pH approximately 6.3

Store in refrigerator at 2° to 8°C (36° to 46°F)

PROTECT FROM LIGHT.

Format: 71940 #037
1.5" x 3.5"
PMS Black, PMS 032 Red, PMS 3292 Green