Bendamustine HCl For Injection
25 mg/vial
For Intravenous Infusion Only
Reconstitution and Dilution Required (see insert)

Reconstitute with 5 mL Sterile Water for Injection, USP, to
5 mg/mL. Immediately transfer to 0.9% Sodium Chloride
Injection, USP, or 2.5% dextrose/0.45% Sodium Chloride
Injection, USP (see insert)

Store up to 25°C (77°F) (See USP Controlled Room
Temperature) in original package.

Protect from light.
Discard unused portion.

Manufactured by: NerPharMa, Italy
Manufactured for: InnoPharma Licensing LLC
Piscataway, NJ 08854
Bendamustine HCl For Injection

100 mg/vial

For Intravenous Infusion Only
Reconstitution and Dilution Required (see insert)

NDC 50912 110 17
Rx Only
Single Use Vial

Sterile

Reconstitute with 20 mL Sterile Water for Injection, USP, to 5 mg/mL. Immediately transfer to 0.9% Sodium Chloride Injection, USP, or 2.5% dextrose/0.45% Sodium Chloride Injection, USP (see insert)

Store up to 25°C (77°F) (See USP Controlled Room Temperature) in original package.

Protect from light.
Discard unused portion.

Manufactured by: NerPharMa, Italy
Manufactured for: InnoPharma Licensing LLC
Piscataway, NJ 08854

250%
Brandname: Bendamustine HCl For Injection
Developed on: 05/06/2015
Location: NJ 08854 USA
Dimension: LxWxH 36 x 36 x 80mm
Item-code:
Barcode:
Packaging Component: 25mg/vial
Colours:
Style: Top Flap
Board:
Modified Date: 09/06/2015
Country: US
Revision No: 03
Path: D:Inno Pharma
Designed by
Bendamustine Hydrochloride for Injection is a cytotoxic drug. Follow applicable special handling and disposal procedures. Care should be exercised in the handling and disposal of empty containers.

14 CLINICAL PHARMACOLOGY

14.1 Chronic Lymphocytic Leukemia (CLL)

In a randomized CLL clinical study, 153 patients received Bendamustine Hydrochloride for Injection. The overall response rate for patients younger than 65 years of age was 66% and the median duration for responders was 57 weeks. The median progression-free survival was 19 months in the Bendamustine Hydrochloride for Injection treatment group and 6 months in the chlorambucil treatment group. No clinically significant differences between genders were seen in the overall incidences of adverse reactions in CLL study.

In the randomized CLL clinical study, 153 patients received Bendamustine Hydrochloride for Injection. The overall response rate for patients younger than 65 years of age was 66% and the median duration for responders was 57 weeks. The median progression-free survival was 19 months in the Bendamustine Hydrochloride for Injection treatment group and 6 months in the chlorambucil treatment group. No clinically significant differences between genders were seen in the overall incidences of adverse reactions in CLL study.

14.1 Chronic Lymphocytic Leukemia (CLL)

In a randomized CLL clinical study, 153 patients received Bendamustine Hydrochloride for Injection. The overall response rate for patients younger than 65 years of age was 66% and the median duration for responders was 57 weeks. The median progression-free survival was 19 months in the Bendamustine Hydrochloride for Injection treatment group and 6 months in the chlorambucil treatment group. No clinically significant differences between genders were seen in the overall incidences of adverse reactions in CLL study.

In a randomized CLL clinical study, 153 patients received Bendamustine Hydrochloride for Injection. The overall response rate for patients younger than 65 years of age was 66% and the median duration for responders was 57 weeks. The median progression-free survival was 19 months in the Bendamustine Hydrochloride for Injection treatment group and 6 months in the chlorambucil treatment group. No clinically significant differences between genders were seen in the overall incidences of adverse reactions in CLL study.

14.1 Chronic Lymphocytic Leukemia (CLL)

In a randomized CLL clinical study, 153 patients received Bendamustine Hydrochloride for Injection. The overall response rate for patients younger than 65 years of age was 66% and the median duration for responders was 57 weeks. The median progression-free survival was 19 months in the Bendamustine Hydrochloride for Injection treatment group and 6 months in the chlorambucil treatment group. No clinically significant differences between genders were seen in the overall incidences of adverse reactions in CLL study.

In a randomized CLL clinical study, 153 patients received Bendamustine Hydrochloride for Injection. The overall response rate for patients younger than 65 years of age was 66% and the median duration for responders was 57 weeks. The median progression-free survival was 19 months in the Bendamustine Hydrochloride for Injection treatment group and 6 months in the chlorambucil treatment group. No clinically significant differences between genders were seen in the overall incidences of adverse reactions in CLL study.

In a randomized CLL clinical study, 153 patients received Bendamustine Hydrochloride for Injection. The overall response rate for patients younger than 65 years of age was 66% and the median duration for responders was 57 weeks. The median progression-free survival was 19 months in the Bendamustine Hydrochloride for Injection treatment group and 6 months in the chlorambucil treatment group. No clinically significant differences between genders were seen in the overall incidences of adverse reactions in CLL study.

In a randomized CLL clinical study, 153 patients received Bendamustine Hydrochloride for Injection. The overall response rate for patients younger than 65 years of age was 66% and the median duration for responders was 57 weeks. The median progression-free survival was 19 months in the Bendamustine Hydrochloride for Injection treatment group and 6 months in the chlorambucil treatment group. No clinically significant differences between genders were seen in the overall incidences of adverse reactions in CLL study.

14.1 Chronic Lymphocytic Leukemia (CLL)

In a randomized CLL clinical study, 153 patients received Bendamustine Hydrochloride for Injection. The overall response rate for patients younger than 65 years of age was 66% and the median duration for responders was 57 weeks. The median progression-free survival was 19 months in the Bendamustine Hydrochloride for Injection treatment group and 6 months in the chlorambucil treatment group. No clinically significant differences between genders were seen in the overall incidences of adverse reactions in CLL study.

In a randomized CLL clinical study, 153 patients received Bendamustine Hydrochloride for Injection. The overall response rate for patients younger than 65 years of age was 66% and the median duration for responders was 57 weeks. The median progression-free survival was 19 months in the Bendamustine Hydrochloride for Injection treatment group and 6 months in the chlorambucil treatment group. No clinically significant differences between genders were seen in the overall incidences of adverse reactions in CLL study.

In a randomized CLL clinical study, 153 patients received Bendamustine Hydrochloride for Injection. The overall response rate for patients younger than 65 years of age was 66% and the median duration for responders was 57 weeks. The median progression-free survival was 19 months in the Bendamustine Hydrochloride for Injection treatment group and 6 months in the chlorambucil treatment group. No clinically significant differences between genders were seen in the overall incidences of adverse reactions in CLL study.