

# Extended dosing is possible with ALPROLIX®

In the B-LONG study

**54%**  
of subjects  
**extended to  
≥14-day dosing**

in the fixed-dose arm (n=26)<sup>1</sup>

- Overall median dosing interval on study was 12.5 days [IQR: 10.4, 13.4]
- During last 6 months on study in subjects on study ≥9 months, median dosing interval was 13.8 days [IQR: 10.5, 14.0]
- Subjects in the fixed-dose prophylaxis arm received 100 IU/kg fixed dose with the initial 10-day interval adjusted. Dosing interval of ≥14 days achieved for their last 3 months on study<sup>1</sup>

## The recommended starting regimen is 50 IU/kg every 7 days or 100 IU/kg every 10 days

- ◊ 50 IU/kg dosing every 7 days is appropriate for those patients who prefer weekly dosing
- ◊ 100 IU/kg dosing gives you the potential to extend patient dosing intervals to 14 days or more based on patient response<sup>1</sup>

### INDICATIONS:

ALPROLIX is a recombinant DNA derived, coagulation Factor IX concentrate indicated in adults and children with hemophilia B for:

- On-demand treatment and control of bleeding episodes
- Perioperative management of bleeding
- Routine prophylaxis to reduce the frequency of bleeding episodes

#### Limitation of Use

ALPROLIX is not indicated for induction of immune tolerance in patients with hemophilia B.

### CONTRAINDICATIONS:

ALPROLIX is contraindicated in patients who have a known history of hypersensitivity reactions, including anaphylaxis, to the product or its excipients.

Please see the back for additional Important Safety Information and [Full Prescribing Information](#).

 **ALPROLIX®**  
[Coagulation Factor IX  
(Recombinant), Fc Fusion Protein]

# How to extend dosing for appropriate patients who want more time between infusions

# 1

## Initiate treatment

with 100 IU/kg  
every 10 days

# 2

## Extend dosing

interval to 100 IU/kg  
up to every 14 days or longer  
based on patient response<sup>1</sup>



The recommended starting regimen is 50 IU/kg every 7 days or 100 IU/kg every 10 days.

**Only ALPROLIX offers the potential for your patients to receive their recommended dose with just one vial<sup>2-8</sup>**

ALPROLIX has the widest range of dosage strengths in hemophilia B, including a 4000-IU vial<sup>2-8</sup>

*Graphic is for illustrative purposes only.*

Visit [ALPROLIXpro.com](http://ALPROLIXpro.com) to learn more about the potential for extended dosing with ALPROLIX

## IMPORTANT SAFETY INFORMATION

### WARNINGS AND PRECAUTIONS:

Allergic-type hypersensitivity reactions, including anaphylaxis, are possible with factor replacement therapies, and have been reported with ALPROLIX. Discontinue use of ALPROLIX if hypersensitivity symptoms occur, and initiate appropriate treatment.

Formation of neutralizing antibodies (inhibitors) to Factor IX has been reported following administration of ALPROLIX, including in previously untreated patients. Patients using ALPROLIX should be monitored for the development of Factor IX inhibitors. Clotting assays (e.g., one-stage) may be used to confirm that adequate Factor IX levels have been achieved and maintained.

The use of Factor IX products has been associated with the development of thromboembolic complications. Nephrotic syndrome has been reported following attempted immune tolerance induction in hemophilia B patients with Factor IX inhibitors and a history of allergic reactions to Factor IX. The safety and efficacy of using ALPROLIX for immune tolerance induction have not been established.

### ADVERSE REACTIONS:

Common adverse reactions (incidence  $\geq 1\%$ ) observed in clinical trials were headache, oral paresthesia, and obstructive uropathy.

Please see [Full Prescribing Information](#).

**References:** 1. Powell JS, Pasi KJ, Ragni MV, et al; B-LONG Investigators. Phase 3 study of recombinant factor IX Fc fusion protein in hemophilia B. *N Engl J Med*. 2013;369(24):2313-2323. 2. BeneFIX® [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals Inc, a subsidiary of Pfizer Inc; 2015. 3. Rixubis® [package insert]. Westlake Village, CA: Baxalta US Inc; 2016. 4. IDELVION® [package insert]. Marburg, Germany: CSL Behring GmbH; 2017. 5. AlphaNine® SD [package insert]. Los Angeles, CA: Grifols Biologicals Inc; 2013. 6. Ixinity® [package insert]. Berwyn, PA: Aptevio BioTherapeutics LLC; 2016. 7. Mononine® [package insert]. Kankakee, IL: CSL Behring LLC; 2016. 8. Profilnine® SD [package insert]. Los Angeles, CA: Grifols Biologicals Inc; 2010.

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 **ALPROLIX**<sup>®</sup>  
[Coagulation Factor IX  
(Recombinant), Fc Fusion Protein]