Real-time quantitative polymerase chain reaction (RQ-PCR) acts like an early warning system for measuring response and identifying potential relapse. This is why it is such an important tool for Philadelphia chromosome–positive chronic myeloid leukemia (Ph+ CML) response monitoring.

RQ-PCR can help you detect early trends in response status.

RQ-PCR testing enables you to detect trends, such as rising levels of BCR-ABL, that would not be apparent through cytogenetic testing alone. Rising BCR-ABL levels have been associated with mutations and resistance, so the sooner you detect and confirm rising levels of BCR-ABL, the sooner you can test for mutations and evaluate adherence or tolerability issues to manage treatment accordingly.

Monitoring with RQ-PCR may help indicate the durability of response.

Traditionally, complete cytogenetic response (CCyR) has been the gold standard for evaluating the potential durability of response. More recently, studies have shown that achievement of major molecular response (MMR) also correlates with durability of response. In fact, patients who achieve both CCyR and MMR are less likely to progress to advanced disease phases than patients who achieve CCyR alone.

Why it’s important to monitor with RQ-PCR tests standardized to the IS

An MMR can only be defined by IS measurement, and appropriate assessment of patient response can only be performed by an IS lab. This means that only IS results can tell you if your patient has achieved MMR.

Understanding how IS works—using international currency as an example

IS normalizes the RQ-PCR results of different laboratories to a unified scale by a conversion factor. As illustrated below, RQ-PCR results from different laboratories are like different international currencies (e.g., Lab A=US dollars and Lab B= Euros).

Through use of a conversion factor (i.e., exchange rate), the absolute value of residual BCR-ABL can be known among different labs. This means you can compare IS RQ-PCR results between labs.

IS-standardized RQ-PCR tests provide the most consistent measure of residual BCR-ABL.

An additional benefit of IS-standardized results is that they have a lower degree of fluctuation over time compared with nonstandardized laboratory results. This consistency can help avoid overtreatment or undertreatment of a patient due to a numerical fluctuation in the test.

Summary: The importance of monitoring Ph+ CML patients with IS RQ-PCR tests

- RQ-PCR is the most sensitive way to monitor BCR-ABL fluctuations, which can act as an early warning signal for potential relapse
- Monitoring for achievement of MMR in addition to CCyR may help predict response
- IS-standardized RQ-PCR tests are the only way to know if your patient has achieved MMR and to ensure consistency of test results

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Learn more about the MMSAP and volunteer to be a mentor at [www.hematology.org/mmsap](http://www.hematology.org/mmsap).

**Questions?**

Contact ASH at awards@hematology.org or by phone at 202-776-0544.
Jakafi™ demonstrated superior reductions in spleen volume and improvements in symptom scores at Week 24\(^1,2\)†‡

- Significantly more patients receiving Jakafi achieved a ≥35% reduction from baseline in spleen volume vs those taking placebo (41.9% vs 0.7%, \(P < 0.0001\))\(^1\)
- A significantly higher proportion of patients receiving Jakafi had a ≥50% reduction in Total Symptom Score (TSS) vs those taking placebo (45.9% vs 5.3%, \(P < 0.0001\))\(^1\)
- Responses in spleen volume reduction were seen with Jakafi in both JAK2\(^{V617F}\)-positive and JAK2\(^{V617F}\)-negative patients, relative to placebo\(^2\)

Indications and Usage
Jakafi is indicated for treatment of patients with intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis.

Important Safety Information
- Treatment with Jakafi can cause hematologic adverse reactions, including thrombocytopenia, anemia and neutropenia, which are each dose-related effects, with the most frequent being thrombocytopenia and anemia. A complete blood count must be performed before initiating therapy with Jakafi. Complete blood counts should be monitored as clinically indicated and dosing adjusted as required
- The three most frequent non-hematologic adverse reactions were bruising, dizziness and headache
- Patients with platelet counts <200 \(\times 10^9/L\) at the start of therapy are more likely to develop thrombocytopenia during treatment. Thrombocytopenia was generally reversible and was usually managed by reducing the dose or temporarily withholding Jakafi. If clinically indicated, platelet transfusions may be administered
- Patients developing anemia may require blood transfusions. Dose modifications of Jakafi for patients developing anemia may also be considered
- Neutropenia (ANC <0.5 \(\times 10^9/L\)) was generally reversible and was managed by temporarily withholding Jakafi
- Patients should be assessed for the risk of developing serious bacterial, mycobacterial, fungal and viral infections. Active serious infections should have resolved before starting Jakafi. Physicians should carefully observe patients receiving Jakafi for signs and symptoms of infection (including herpes zoster) and initiate appropriate treatment promptly
- A dose modification is recommended when administering Jakafi with strong CYP3A4 inhibitors or in patients with renal or hepatic impairment [see Dosage and Administration]. Patients should be closely monitored and the dose titrated based on safety and efficacy
- There are no adequate and well-controlled studies of Jakafi in pregnant women. Use of Jakafi during pregnancy is not recommended and should only be used if the potential benefit justifies the potential risk to the fetus
- Women taking Jakafi should not breast-feed. Discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother

Please see Brief Summary of Full Prescribing Information on the following page.

\(^\dagger\) As studied in COMFORT-I, a randomized, double-blind, placebo-controlled phase III study with 309 total patients (United States, Canada, Australia). The primary endpoint was the proportion of subjects achieving a ≥35% reduction in spleen volume from baseline to Week 24 as measured by magnetic resonance imaging (MRI) or computed tomography (CT). A secondary endpoint was the proportion of subjects with a ≥50% reduction in TSS from baseline to Week 24 as measured by the daily patient diary, the modified Myelofibrosis Symptom Assessment Form (MFSAF v2.0).\(^1,2\)

\(^\ddagger\) Symptom scores were captured by a daily patient diary recorded for 25 weeks. TSS encompasses debilitating symptoms of MF including abdominal discomfort, early satiety, pain under left ribs, pruritus, night sweats and bone/muscle pain. Symptom scores ranged from 0 to 10 with 0 representing symptoms "absent" and 10 representing "worst imaginable" symptoms. These scores were added to create the daily total score, which has a maximum of 60. At baseline, the mean TSS was 18.0 in the Jakafi group and 16.5 in the placebo group.\(^1,2\)

The Cmax and AUC of ruxolitinib decreased 32% and 61%, respectively, with Jakafi administration. The median number of units transfused per month was 1.2 in patients treated with Jakafi and 1.7 in placebo. Anemia was observed in 16.8% of patients treated with Jakafi and 0.7% of patients treated with placebo developed newly occurring or worsening Grade 1 anemia. In patients receiving Jakafi, 2.0% of patients developed Grade 3 or 4 anemia, versus 7.2%). There was an 8% and 27% increase in the Cmax and AUC of ruxolitinib, respectively, with Jakafi administration compared to receiving placebo (2.4). In the placebo-controlled study, the change in the pharmacodynamic marker, pSTAT3 inhibition, was consistent with the corresponding ruxolitinib AUC following concurrent administration with ketoconazole. When administering Jakafi with strong CYP3A4 inhibitors a dose reduction is recommended (see Dosage and Administration (2.4) in Full Prescribing Information). No dose adjustment is recommended when Jakafi is coadministered with mild or moderate CYP3A4 inhibitors (eg. erythromycin). CYP3A4 inhibitors were bracing, dizziness and headache [see Table 1]. Discontinuation for adverse events, regardless of causality, was observed in 11.0% of patients treated with Jakafi and 10.6% of patients treated with placebo. In patients treated with Jakafi, 2.0% of patients developed Grade 3 or 4 anemia, versus 7.2%. There was a 9% and 24% increase in the Cmax and AUC of ruxolitinib, respectively, with Jakafi administration compared to receiving placebo (2.4). The incidence of Grade 2 ALT elevations increased from 2.1% to 8.5% with Jakafi administration. The safety and pharmacokinetics of single dose Jakafi (25 mg) were evaluated in a study in healthy subjects (27-719 kg). Three groups of subjects were treated with placebo or Jakafi on 1-, 2- or 3-hourly dose (60 mg/kg/day). In the placebo-controlled study, the change in the pharmacodynamic marker, pSTAT3 inhibition, was consistent with the corresponding increase in Jakafi exposure [see Table 2]. There was an 8% and 27% increase in the Cmax and AUC of ruxolitinib, respectively, with Jakafi administration compared to receiving placebo (2.4). The incidence of Grade 2 ALT elevations increased from 2.1% to 8.5% with Jakafi administration. The safety and pharmacokinetics of single dose Jakafi (25 mg) were evaluated in a study in healthy subjects (27-719 kg). Three groups of subjects were treated with placebo or Jakafi on 1-, 2- or 3-hourly dose (60 mg/kg/day). In the placebo-controlled study, the change in the pharmacodynamic marker, pSTAT3 inhibition, was consistent with the corresponding increase in Jakafi exposure [see Table 2]. There was an 8% and 27% increase in the Cmax and AUC of ruxolitinib, respectively, with Jakafi administration compared to receiving placebo (2.4). The incidence of Grade 2 ALT elevations increased from 2.1% to 8.5% with Jakafi administration. The safety and pharmacokinetics of single dose Jakafi (25 mg) were evaluated in a study in healthy subjects (27-719 kg). Three groups of subjects were treated with placebo or Jakafi on 1-, 2- or 3-hourly dose (60 mg/kg/day). In the placebo-controlled study, the change in the pharmacodynamic marker, pSTAT3 inhibition, was consistent with the corresponding increase in Jakafi exposure [see Table 2]. There was an 8% and 27% increase in the Cmax and AUC of ruxolitinib, respectively, with Jakafi administration compared to receiving placebo (2.4). The incidence of Grade 2 ALT elevations increased from 2.1% to 8.5% with Jakafi administration. The safety and pharmacokinetics of single dose Jakafi (25 mg) were evaluated in a study in healthy subjects (27-719 kg). Three groups of subjects were treated with placebo or Jakafi on 1-, 2- or 3-hourly dose (60 mg/kg/day). In the placebo-controlled study, the change in the pharmacodynamic marker, pSTAT3 inhibition, was consistent with the corresponding increase in Jakafi exposure [see Table 2]. There was an 8% and 27% increase in the Cmax and AUC of ruxolitinib, respectively, with Jakafi administration compared to receiving placebo (2.4). The incidence of Grade 2 ALT elevations increased from 2.1% to 8.5% with Jakafi administration. The safety and pharmacokinetics of single dose Jakafi (25 mg) were evaluated in a study in healthy subjects (27-719 kg). Three groups of subjects were treated with placebo or Jakafi on 1-, 2- or 3-hourly dose (60 mg/kg/day). In the placebo-controlled study, the change in the pharmacodynamic marker, pSTAT3 inhibition, was consistent with the corresponding increase in Jakafi exposure [see Table 2].
Indications and usage
Soliris is a complement inhibitor indicated for:

• The treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis
• The treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy

The effectiveness of Soliris in aHUS is based on the effects on thrombotic microangiopathy (TMA) and renal function. Prospective clinical trials in additional patients are ongoing to confirm the benefit of Soliris in patients with aHUS.

Limitation of Use
Soliris is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).

Adverse reactions
The most frequently reported adverse reactions in the PNH randomized trial (≥10% overall and greater than placebo) are: headache, nasopharyngitis, back pain, and nausea.

The most frequently reported adverse reactions in aHUS single arm prospective trials (≥15% combined per patient incidence) are: hypertension, upper respiratory tract infection, diarrhea, headache, anemia, vomiting, nausea, urinary tract infection, and leukopenia.

Soliris: significantly reduces hemolysis.

- 86% reduction in hemolysis (as measured by LDH)\(^1\)
- Fewer thrombotic events were observed with Soliris in clinical trials\(^2\)
  - The majority of patients (63%) received concomitant anticoagulant therapy\(^2,3\)
  - The effect of anticoagulant withdrawal during Soliris treatment has not been studied\(^2\)
- 73% reduction in the need for transfusions across all patient populations\(^1\)
- 78% clinically meaningful improvement in fatigue; significant improvement in a broad range of QoL measures\(^1,2\)
- Adverse event profile similar to placebo in PNH clinical trials\(^2\)

Visit [www.soliris.net/hcp](http://www.soliris.net/hcp) or call 1.888.SOLIRIS (1.888.765.4747) to learn more about the benefits of Soliris.

**IMPORTANT SAFETY INFORMATION**

**WARNING: SERIOUS MENINGOCOCCAL INFECTIONS**

*See full prescribing information for complete boxed warning*

Life-threatening and fatal meningococcal infections have occurred in patients treated with Soliris. Meningococcal infection may become rapidly life-threatening or fatal if not recognized and treated early.

- Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccination in patients with complement deficiencies
- Immunize patients with a meningococcal vaccine at least 2 weeks prior to administering the first dose of Soliris, unless the risks of delaying Soliris therapy outweigh the risks of developing a meningococcal infection. (See *Serious Meningococcal Infections* for additional guidance on the management of the risk of meningococcal infection.)
- Monitor patients for early signs of meningococcal infections, and evaluate immediately if infection is suspected

Soliris is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS). Under the Soliris REMS prescribers must enroll in the program. Enrollment in the Soliris REMS program and additional information are available by telephone: 1-888-SOLIRIS (1-888-765-4747).

Please see brief summary on following pages.
Serious Meningococcal Infections

Soliris is contraindicated in:
- Meningococcal infection may become rapidly life-threatening or fatal if not recognized and treated early. Discontinue Soliris in patients who are suspected of having meningococcal infection.
- Life-threatening and fatal meningococcal infections have occurred in patients with PNH who are unvaccinated or who have received a meningococcal vaccine within the last 5 years.

Vaccination
- No data are available on the safety and effectiveness of Soliris in patients with meningococcal infection or in patients who have been vaccinated. The effect of Soliris on the immune response to meningococcal vaccines is unknown. It is recommended that patients continue to receive meningococcal vaccines in the usual manner.

TABLE 1 (CONT’D): ADVERSE REACTIONS OCCURRING IN AT LEAST 15% OF PATIENTS LESS THAN 18 YEARS OF AGE ENROLLED IN AHEMIS STUDY

**Table 1**

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory</td>
<td>3 (6.0%)</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>3 (6.0%)</td>
</tr>
<tr>
<td>Cardiac Disorders</td>
<td>2 (4.0%)</td>
</tr>
</tbody>
</table>

**Notes:**
- *Includes patients with upper respiratory tract infections and sinusitis.
- Meningococcal infections were defined as meningococcal disease or meningococcal carrier state.

**Immunogenicity**
- With all proteins there is a potential for immunogenicity. The immunogenicity of Soliris has been evaluated using two different immunoassays for the detection of anti-eculizumab antibodies: a direct enzyme-linked immunosorbent assay (ELISA) using the eculizumab molecule and an electro-chemiluminescence (ECL) bridging assay using the eculizumab molecule. In the ELISA, a cutoff was used for the positive results. The limit of antibodies to Soliris in 3/16 (20%) of all patients treated with Soliris by the ELISA assay. In patients with aHUS treated with Soliris, antibodies to Soliris were detected in 16/90 (18%) of all patients treated with Soliris by the ELISA-based neutralization assay with a low sensitivity of 2 mg/mL was performed to detect neutralizing antibodies for the 30 patients with aHUS. No neutralizing activity to Soliris was detected in patients with aHUS treated with Soliris. No apparent correlation of antibody development to clinical response was observed in both indications. The immunoassay data reflect the percentage of patients whose test results were considered positive for antibodies to Soliris in an ELISA-based assay and an ECL-based assay are highly dependent on the sensitivity and specificity of the assay used. Additionally, the observed incidence of antibodies posttreatment in the assay may be influenced by several factors including the incidence of infection, concomitant medications and underlying diseases. For these reasons, comparison of the incidence of antibodies to Soliris with the incidence of antibodies to other products is not meaningful.

**Postmarketing Experience**
- Cases of serious or fatal meningococcal infections have been reported.
Author guide

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Authors are invited to contact the Editor-in-Chief (bloodeditor@hematology.org) prior to submission if they are uncertain whether their work falls within the general scope.

Immunobiology encompasses a wide spectrum of research, but _Blood_ can accommodate only papers that have clear and important implications for hematology. Preference is given to papers focusing on human immunobiology and which have significant implications for understanding of normal or malignant hematologic processes. Papers on tumor immunology and tumor vaccine development may be appropriate if the target cells are hematologic malignancies, but _Blood_ can no longer accommodate tumor immunology papers that focus solely on nonhematologic tumor models. Papers focusing on autoimmunity and utilizing nonhematologic models are not within the scope of _Blood_. Papers on the immune response to specific microbe-logic pathogens are also generally outside the scope of _Blood_, except those focusing on the direct links of Epstein-Barr virus, hepatitis virus, or HTLV to hematologic malignancies. These and other papers fell to be outside the scope of _Blood_ and more appropriate for an immunology, infectious diseases, or tumor immunology journal will be returned to the author without full peer review.

**Regular Articles.** Maximum length for a Regular Article is 5,000 words of text, not counting the abstract, tables, figure legends, and references; abstracts must not exceed 200 words and should be constructed as a single narrative paragraph with no subheadings or references. Submissions are limited to a total of 7 figures and digital images are required. There is no limit on the number of tables. References should be limited to 50. The sections of a Regular Article should be ordered Abstract, Introduction, Methods, Results, Discussion, Acknowledgments, Authorship Contributions and Disclosure of Conflicts of Interest, References, Tables, Figure Legends, and Figures. Supplemental files to be published online-only may include additional information regarding methodology, supplemental figures or tables, or primary data sets. Any involvement of medical writers/researchers, particularly those employed or supported by the pharmaceutical industry, in the writing of an article must be clearly defined and disclosed in the Authorship and/or the Acknowledgments section as appropriate. This type of involvement must also be disclosed to the Editor-in-Chief in the cover letter. Definitive original research articles of exceptional scientific importance may be considered for designation as Plenary Papers. The decision to highlight an article as a Plenary Paper rests entirely with the Editors.

**Brief Reports.** Short manuscripts definitively documenting either experimental results or informative clinical observations will be considered for publication in this category. Single-case reports or case series can almost never be accommodated, unless they elucidate novel and important disease biology or approaches to therapy. Brief Reports are not intended to allow publication of incomplete or preliminary findings. The review process is equally rigorous as for Regular Articles and the acceptance rate is lower. Brief Reports may not exceed 1,200 words of text not counting the abstract, figure legends, and references; abstracts must not exceed 150 words and should be a single paragraph with no subheadings. Only 2 figures/tables and 25 references may be included. The sections of a Brief Report should be ordered Abstract, Introduction, Methods sufficiently informative to allow reproduction of the data, followed by a combined Results and Discussion section, Acknowledgments, Authorship Contributions and Disclosure of Conflicts of Interest, References, Tables, Figure Legends, and Figures.

**e-Blood.** _e-Blood_ is a new manuscript category for publication of very well designed systems biology work (e.g., genomics, proteomics etc.) that is largely descriptive. Such work will be published as an online-only paper if utilization of the data by others will significantly advance the field. _e-Blood_ articles will be fully citable, and will represent genuine _Blood_ publication. They will undergo standard rigorous peer review if deemed potentially appropriate for publication by _Blood_ Editors. Accepted _e-Blood_ articles will be published in First Edition and then copyedited and composed identical to other _Blood_ papers, but will not be included in a print edition of the Journal, although they will be listed in a printed Table of Contents when their final typeset version is available online. Papers may be submitted by authors directly for consideration as _e-Blood_ articles, or may be recommended by Editors for publication as an _e-Blood_ article after being considered for publication as a Regular Article, if deemed more appropriate for the _e-Blood_ article type. The maximum length for an
e-Blood article is 5,000 words of text, not counting the abstract, tables, figure legends, and references; abstracts must not exceed 200 words and should be a single paragraph with no subheadings. Digital images are mandatory. References should be limited to 50. Primary data must be deposited in a public repository. The sections of an e-Blood article should be ordered Abstract, Introduction, Methods, Results, Discussion, References, Acknowledgments, Authorship Contributions, Disclosure of Conflicts of Interest, References, Tables, Figure Legends, and Figures.

**Review Articles.** Review Articles are welcomed by the Journal and are generally solicited by the Editor-in-Chief; however, authors wishing to submit an unsolicited Review Article are invited to contact the Editor-in-Chief prior to submission, in order to screen the proposed topic for relevance and priority, given other Review Articles that may already be in preparation. Review Articles should focus on recent scientific or clinical advances in an area of broad interest to those in the field of hematology. Such articles must be concise and critical and should include appropriate references to the literature. All Review Articles, even those solicited by the Editors, are rigorously peer reviewed before a final publication decision is made.

Review Articles should not exceed 5,000 words in length, must include an abstract of 200 words or fewer, and may not have more than 100 references. The use of tables and color figures to summarize critical points is encouraged; the Journal offers assistance with preparation or improvement of figures by professional illustrators, once the article is accepted.

Any involvement of medical writers/researchers, particularly those employed or supported by the pharmaceutical industry, in the writing of a Review Article must be clearly defined and disclosed in the Authorship section. For Review Articles, this type of involvement must be discussed with the Editor-in-Chief before the submission of the article. Generally, involvement of medical writers/researchers supported by the pharmaceutical industry is not acceptable for Review Articles published in Blood.

**How I Treat.** The Journal welcomes articles written by expert clinicians offering up-to-date information and guidance regarding diagnosis and treatment of hematological diseases and clinical situations. Clear distinctions should be made between evidence-based versus experience-based recommendations. The pieces can be constructed as a standard narrative or be structured around a case or cases illustrating specific clinical situations. These pieces are generally solicited by the Editor-in-Chief, but any interested author is invited to correspond with the Editor-in-Chief prior to submission to discuss the suitability of the proposed subject matter. The length should not exceed 5,000 words; the abstract must not exceed 200 words; and references are limited to 100.

Any involvement of medical writers/researchers, particularly those employed or supported by the pharmaceutical industry, in the writing of an article must be clearly defined and disclosed in the Authorship section. For How I Treat articles, this type of involvement must be discussed with the Editor-in-Chief before the submission of the article. Generally, involvement of medical writers/researchers supported by the pharmaceutical industry is not acceptable for How I Treat articles published in Blood.

**Perspectives.** Perspectives are articles discussing significant topics and controversies relevant to hematology, generally from a more personal or opinion-based standpoint than a Review Article. Interested authors should correspond with the Editor-in-Chief prior to submission to discuss the suitability of the proposed subject matter. The length should not exceed 5,000 words; the abstract must not exceed 200 words; and references are limited to 100. Typically, Perspectives should state the topic and background information concisely, discuss opposing viewpoints, and make recommendations for further investigations or actions.

**Inside Blood.** The Editors invite experts in the field to write brief commentaries introducing and placing into context several selected primary research articles included in each issue of Blood.

**Plenary Papers.** Definitive original research articles of exceptional scientific importance may be considered for designation as Plenary Papers. The decision to highlight an article as a Plenary Paper rests entirely with the Editors.

**Data Supplements.** The Journal encourages the submission of Data Supplements linked to primary research articles, including videos and short movies, that enhance the understanding of the science discussed in the manuscript. Data Supplements must be submitted for peer review during the initial submission of the manuscript. The Editors will review the supplemental material along with the manuscript, but acceptance of the manuscript does not guarantee ultimate acceptance of the supplement.

**Blood Work.** Blood welcomes submissions of photo micrographs and brief case descriptions to serve as a regular teaching feature and comprehensive reference accessible to physicians and hematology students around the world. These images and cases are published by the Journal monthly in the Blood Work section, in the first issue of each month. Each submission must contain a single, or at most two related, high-resolution figure(s) formatted as TIFFs (minimum 300 dpi) and a discussion of no more than 200 words describing the clinical case linked to the image(s). Generally each piece should have a single or very few authors and no references. If your submission is accepted, your figure(s) will also be submitted for consideration to the ASH Image Bank. All other policies governing submissions to the Journal also apply to Blood Work. There will be no submission fee and no color figure charges for publication if accepted.

**Letters to the Editor.** Constructive comments on published articles or on current topics in hematology are welcome and will be published if appropriate and based on priority and interest to readership. Letters should include no more than 500 words of text, 5–10 references, and 1 figure or table. No abstract is required, but please include a brief title. Submission fees and page charges do not apply to Letters. Letters are screened by the Editor-in-Chief and, if deemed appropriate and relevant, may also be peer reviewed and/or accompanied by a Response from the authors of the initial article.

**Public Access.** The American Society of Hematology supports free access to Blood on the broadest possible basis, although ASH and Blood cannot adopt or support a publishing model that is not economically sustainable over a long horizon. Blood maintains a 12-month access embargo to non-subscribers while offering an inexpensive pay-per-view option; however, online content older than 12 months is free to all. Also, significant sections of each new issue are immediately free-to-all online, including abstracts and tables of contents, Inside Blood commentaries, How I Treat articles, and 5 clinically relevant research articles or Review Articles per issue selected by the Editor-in-Chief. In addition, Blood ensures that patients looking for pertinent information can access any article without charge by contacting the Journal.

Any author (including, but not limited to, those supported by the Howard Hughes Medical Institute or Wellcome Trust) wishing immediate public access for their accepted paper may pay an additional Public Access manuscript fee of $2,000. Upon receipt of payment, Blood will also deposit on behalf of the author the final edition of the published paper into PubMed Central. This fee does not apply to research funded by the National Institutes of Health.
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The individual depicted is not a hemophilia patient. For illustrative purposes only.

*BeneFix was approved February 11, 1997.³

Indication for BeneFix
BeneFix® Coagulation Factor IX (Recombinant) is indicated for the control and prevention of bleeding episodes in adult and pediatric patients with hemophilia B (congenital factor IX deficiency or Christmas disease), including peri-operative management.

BeneFix is NOT indicated for the treatment of other factor deficiencies (eg, factors II, VII, VIII and X), hemophilia A patients with inhibitors to factor VIII, reversal of coumarin-induced anticoagulation, or bleeding due to low levels of liver-dependent coagulation factors.

Important Safety Information for BeneFix
• BeneFix is contraindicated in patients who have manifested life-threatening, immediate hypersensitivity reactions, including anaphylaxis, to the product or its components, including hamster protein.
• Anaphylaxis and severe hypersensitivity reactions are possible. Should symptoms occur, treatment with the product should be discontinued, and emergency treatment should be sought.
• BeneFix has been associated with the development of thromboembolic complications, including patients receiving continuous infusion through a central venous catheter. The safety and efficacy of BeneFix administration by continuous infusion have not been established.
• Development of activity-neutralizing antibodies has been detected in patients receiving factor IX products. If expected plasma factor IX activity levels are not attained, or if patient presents with allergic reaction, or if bleeding is not controlled with an expected dose, an assay that measures factor IX inhibitor concentration should be performed.
• Patients may develop hypersensitivity to hamster (CHO) protein as BeneFix contains trace amounts.
• The most common adverse reactions (>5%) from clinical trials were nausea, injection site reaction, injection site pain, headache, dizziness and rash.


Please see brief summary of full Prescribing Information for BeneFix on reverse side.
**INDICATIONS AND USAGE**

Control and Prevention of Bleeding Episodes in Hemophilia B

BeneFxa Coagulation Factor IX (Recombinant) is indicated for the control and prevention of bleeding episodes in adult and pediatric patients with hemophilia B (congenital factor IX deficiency or Christmas disease).

BeneFxa is NOT indicated for treatment of other factor deficiencies (e.g., factors II, VII, VIII, and X), hemophilia A patients with inhibitors to factor VIII, reversal of coumarin-induced anticoagulation, or bleeding due to low levels of liver-dependent coagulation factors.

**Peri-operative Management in Patients with Hemophilia B**

BeneFxa is indicated for peri-operative management in adult and pediatric patients with hemophilia B.

**CONTRAINDICATIONS**

BeneFxa is contraindicated in patients who have manifested life-threatening, immediate hypersensitivity reactions, including anaphylaxis, to the product or its components, including hamster protein.

**WARNINGS AND PRECAUTIONS**

**Anaphylaxis and Severe Hypersensitivity Reactions**

Allergic type hypersensitivity reactions, including anaphylaxis, have been reported with BeneFxa and have manifested as pruritus, rash, urticaria, hives, facial swelling, dizziness, hypotension, nausea, chest discomfort, cough, dyspnea, wheezing, flushing, discomfort (generalized) and fatigue. Frequently, these events have occurred in close temporal association with the development of factor IX inhibitors. Advise patients to discontinue use of the product and contact their physician and/or seek immediate emergency care. Patients may develop hypersensitivity to hamster (CHO) protein as BeneFxa contains trace amounts.

**Thromboembolic Complications**

The safety and efficacy of BeneFxa administration by continuous infusion have not been established. There have been post-marketing reports of thrombotic events in patients receiving continuous-infusion BeneFxa through a central venous catheter, including life-threatening superior vena cava (SVC) syndrome in critically ill neonates.

**Nephrotic Syndrome**

Nephrotic syndrome has been reported following immune tolerance induction with factor IX products in hemophilia B patients with factor IX inhibitors and a history of allergic reactions to factor IX. The safety and efficacy of using BeneFxa for immune tolerance induction have not been established.

**Neutralizing Antibodies (Immunogenicity)**

Patients using BeneFxa should be monitored for the development of factor IX inhibitors by appropriate clinical observations and laboratory tests. Inhibitors have been reported following administration of BeneFxa. If expected plasma factor IX activity levels are not attained, or if bleeding is not controlled with an expected dose, an assay that measures factor IX inhibitor concentration should be performed.

Patients with factor IX inhibitors may be at an increased risk of anaphylaxis upon subsequent challenge with factor IX. Patients experiencing allergic reactions should be evaluated for the presence of an inhibitor. Patients should be observed closely for signs and symptoms of acute hypersensitivity reactions, particularly during the early phases of initial exposure to product.

Because of the potential for allergic reactions with factor IX concentrates, the initial (approximately 10 - 20) administrations of factor IX should be performed under medical supervision where proper medical care for allergic reactions could be provided.

**Monitoring Laboratory Tests**

Patients should be monitored for factor IX activity levels by the one-stage clotting assay to confirm that adequate factor IX levels have been achieved and maintained, when clinically indicated.

Patients should be monitored for the development of inhibitors if expected factor IX activity plasma levels are not attained, or if bleeding is not controlled with the recommended dose of BeneFxa. Assays used to determine if factor IX inhibitor is present should be titered in Bethesda Units (BU's).

**ADVERSE REACTIONS**

The most serious adverse reactions are systemic hypersensitivity reactions, including bronchospastic reactions and/or hypotension and anaphylaxis and the development of high-titer inhibitors necessitating alternative treatments to factor IX replacement therapy.

The most common adverse reactions observed in clinical trials (frequency >5% of PTPs or PUPs) were headaches, dizziness, nausea, injections site reaction, injection site pain and skin-related hypersensitivity reactions (e.g., rash, hives).

**Clinical Trials Experience**—Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

During uncontrolled open-label clinical studies with BeneFxa conducted in previously treated patients (PTPs), 113 adverse reactions with known or unknown relation to BeneFxa therapy were reported among 38.5% (25 of 66) of subjects (with some subjects reporting more than one event) who received a total of 7,573 infusions. The most frequently reported treatment-emergent adverse reactions were headache (10.8%), dizziness (7.7%), injection site reaction (7.7%), nausea (6.2%), and injection site pain (6.2%).

In the 63 previously untreated patients (PUPs), who received a total of 5,538 infusions, 10 adverse reactions were reported among 9.5% of the patients (6 out of 63) having known or unknown relationship to BeneFxa. Adverse reactions reported in 25% of subjects were: hives (4.8%), factor IX inhibition (3.2%), dyspnea (3.2%), injection site reaction (1.6%), chills (1.6%), and rash (1.6%).

**Immunogenicity**

In clinical studies with 65 PTPs (defined as having more than 50 exposure days), a low-titer inhibitor was observed in one patient. The inhibitor was transient, the patient continued on study and had normal factor IX recovery pharmacokinetics at study completion (approximately 15 months after inhibitor detection).

In clinical studies with pediatric PUPs, inhibitor development was observed in 2 out of 63 patients (3.2%), both were high-titer (>5 BU) inhibitors detected after 7 and 15 exposure days, respectively. Both patients were withdrawn from the study.

**DRUG INTERACTIONS**—None known.

**USE IN SPECIFIC POPULATIONS**

**Pregnancy**

Pregnancy Category C—Animal reproduction and lactation studies have not been conducted with BeneFxa. It is not known whether BeneFxa can affect reproductive capacity or cause fetal harm when given to pregnant women. BeneFxa should be administered to pregnant women only if needed.

**Labor and Delivery**

There is no information available on the effect of factor IX replacement therapy on labor and delivery. Use only if needed.

**Nursing Mothers**

It is not known whether this drug is excreted into human milk. Because many drugs are excreted into human milk, caution should be exercised if BeneFxa is administered to nursing mothers. Use only if needed.

**Pediatric Use**

Safety, efficacy, and pharmacokinetics of BeneFxa have been evaluated in previously treated (PTP) and previously untreated pediatric patients (PUP). On average, lower recovery has been observed in pediatric patients (<15 years). A dose adjustment may be needed.

**Geriatric Use**

Clinical studies of BeneFxa did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Dose selection for an elderly patient should be individualized.

**STORAGE AND HANDLING**

Product kept at temperature or under refrigeration, at a temperature of 2 to 30°C (36 to 86°F). Do not leave BeneFxa after the expiration date on the label. Do not freeze to prevent damage to the diluent syringe.

**Product after reconstitution:** The product does not contain a preservative and should be used within 3 hours.

This brief summary is based on the BeneFxa Coagulation Factor IX (Recombinant) Prescribing Information LAB-0464-8.0, revised 11/2011.

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