PharmaEssentia SOURCE™

Your resource for patient support & education

Supporting Your Patients' Access to BESREMi®

(ropeginterferon alfa-2b-njft)

INDICATION

BESREMi is indicated for the treatment of adults with polycythemia vera

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF SERIOUS DISORDERS

Interferon alfa products may cause or aggravate fatal or life-threatening neuropsychiatric, autoimmune, ischemic, and infectious disorders. Patients should be monitored closely with periodic clinical and laboratory evaluations. Therapy should be withdrawn in patients with persistently severe or worsening signs or symptoms of these conditions. In many, but not all cases, these disorders resolve after stopping therapy.

CONTRAINDICATIONS

- Existence of, or history of severe psychiatric disorders, particularly severe depression, suicidal ideation, or suicide attempt
- Hypersensitivity to interferons including interferon alfa-2b or any of the inactive ingredients of BESREMi.
- Moderate (Child-Pugh B) or severe (Child-Pugh C) hepatic impairment
- History or presence of active serious or untreated autoimmune disease
- Immunosuppressed transplant recipients

Please see additional Important Safety Information throughout and full Prescribing Information, including Boxed Warning.

Treat PV Where It Starts

BESREMi® (ropeginterferon alfa-2b-njft) INJECTION

BESREMi is the only FDA-approved agent for polycythemia vera (PV) that targets the source of the disease in the bone marrow.[1]

Helping Patients Access BESREMi Is Our Top Priority

PharmaEssentia SOURCE™ helps connect your appropriate patients to ongoing support, education, and resources throughout their treatment with BESREMi.

We provide personalized support, including:

- Partnering with you to make sure patients get BESREMi as quickly as possible
- Helping patients navigate insurance and financial hurdles
- Providing injection training and titration support

Upon enrolling in PharmaEssentia SOURCE, patients will receive a Welcome Kit that includes important information to get them started on BESREMi.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS

- Depression and Suicide: Life-threatening or fatal neuropsychiatric reactions have occurred in patients receiving interferon alfa-2b products, including BESREMi. These reactions may occur in patients with and without previous psychiatric illness.

  Other central nervous system effects, including suicidal ideation, attempted suicide, aggression, bipolar disorder, mania and confusion have been observed with other interferon alfa products.

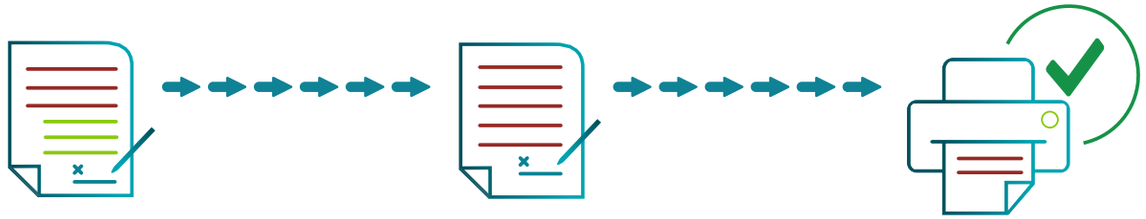
  Closely monitor patients for any symptoms of psychiatric disorders and consider psychiatric consultation and treatment if such symptoms emerge. If psychiatric symptoms worsen, it is recommended to discontinue BESREMi therapy.
- Endocrine Toxicity: These toxicities may include worsening hypothyroidism and hyperthyroidism. Do not use BESREMi in patients with active serious or untreated endocrine disorders associated with autoimmune disease. Evaluate thyroid function in patients who develop symptoms suggestive of thyroid disease during BESREMi therapy. Discontinue BESREMi in patients who develop endocrine disorders that cannot be adequately managed during treatment with BESREMi.
- Cardiovascular Toxicity: Toxicities may include cardiomyopathy, myocardial infarction, atrial fibrillation and coronary artery ischemia. Patients with a history of cardiovascular disorders should be closely monitored for cardiovascular toxicity during BESREMi therapy. Avoid use of BESREMi in patients with severe or unstable cardiovascular disease, (e.g., uncontrolled hypertension, congestive heart failure (≥ NYHA class 2), serious cardiac arrhythmia, significant coronary artery stenosis, unstable angina) or recent stroke or myocardial infarction.

Please see additional Important Safety Information throughout and full Prescribing Information, including Boxed Warning.

How to Enroll Your Patients

Enrolling Is Easy

Download the PharmaEssentia SOURCE™ Enrollment Form



Complete, sign, and date the healthcare professional portion.

Have your patient complete, sign, and date their portion.

Fax the completed form to 800-700-5065.

Please note: Your signature and your patient's signature are both required to enroll in PharmaEssentia SOURCE. If your patient is not available to sign, PharmaEssentia SOURCE can follow up with the patient by phone to obtain their consent once you've submitted the Enrollment Form.

Call us at **800-700-5053** to speak with one of our PharmaEssentia SOURCE Case Managers between 8:00 AM and 8:00 PM ET, Monday through Friday, or visit **PharmaEssentiaSOURCE.com**.

The completed PharmaEssentia SOURCE Enrollment Form can also serve as your patient's first prescription. If there is an insurance delay, this form also contains a prescription for a temporary supply of BESREMi®.

Options for Prescribing BESREMi

There are 3 options for prescribing BESREMi:

1. Complete and submit the PharmaEssentia SOURCE Enrollment Form. It includes a section that serves as your patient's first prescription.
2. Prescribe BESREMi for fulfillment through one of our specialty pharmacy partners, including Biologics or Onco360, and the medication will be shipped directly to your patient.
3. Dispense BESREMi in the office (for oncology GPO members).

The **Product Fact Sheet and Ordering Information** provides detailed product information and contacts for specialty pharmacies and distributors.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

- Decreased Peripheral Blood Counts: These toxicities may include thrombocytopenia (increasing the risk of bleeding), anemia, and leukopenia (increasing the risk of infection). Monitor complete blood counts at baseline, during titration and every 3-6 months during the maintenance phase. Monitor patients for signs and symptoms of infection or bleeding.

Please see additional Important Safety Information throughout and full Prescribing Information, including Boxed Warning.

We're Here to Help Navigate the Access and Reimbursement Process

Benefits Investigation

PharmaEssentia SOURCE™ Case Managers can help assess your patients' health insurance coverage and estimated out-of-pocket costs.

Prior Authorization Support

We'll coordinate with your patient's insurance company to determine if there are any prior authorization (PA) requirements. If a PA is required, we'll help determine what the submission process is, including if additional documentation is required. After your office submits the PA request, we're available to help you monitor the PA request status.

Appeals Support

We can work with you to identify the steps necessary to appeal the payer's decision. We also have templates available at **PharmaEssentiaSOURCE.com** to assist you with the process, including a letter of medical necessity, letter of appeal, and formulary exception letter.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

- Hypersensitivity Reactions: Toxicities may include serious, acute hypersensitivity reactions (e.g., urticaria, angioedema, bronchoconstriction, anaphylaxis). If such reactions occur, discontinue BESREMi and institute appropriate medical therapy immediately. Transient rashes may not necessitate interruption of treatment.
- Pancreatitis: Pancreatitis has occurred in 2.2% of patients receiving BESREMi. Symptoms may include nausea, vomiting, upper abdominal pain, bloating, and fever. Patients may experience elevated lipase, amylase, white blood cell count, or altered renal/hepatic function. Interrupt BESREMi treatment in patients with possible pancreatitis and evaluate promptly. Consider discontinuation of BESREMi in patients with confirmed pancreatitis.
- Colitis: Fatal and serious ulcerative or hemorrhagic/ischemic colitis have occurred in patients receiving interferon alfa products, some cases starting as early as 12 weeks after start of treatment. Symptoms may include abdominal pain, bloody diarrhea, and fever. Discontinue BESREMi in patients who develop these signs or symptoms. Colitis may resolve within 1 to 3 weeks of stopping treatment.
- Pulmonary Toxicity: Pulmonary toxicity may manifest as dyspnea, pulmonary infiltrates, pneumonia, bronchiolitis obliterans, interstitial pneumonitis, pulmonary hypertension, and sarcoidosis. Some events have resulted in respiratory failure or death. Discontinue BESREMi in patients who develop pulmonary infiltrates or pulmonary function impairment.
- Ophthalmologic Toxicity: These toxicities may include severe eye disorders such as retinopathy, retinal hemorrhage, retinal exudates, retinal detachment and retinal artery or vein occlusion which may result in blindness. During BESREMi therapy, 23% of patients were identified with an eye disorder. Eyes disorders ≥5% included cataract (6%) and dry eye (5%). Advise patients to have eye examinations before and during BESREMi therapy, specifically in those patients with a retinopathy-associated disease such as diabetes mellitus or hypertension. Evaluate eye symptoms promptly. Discontinue BESREMi in patients who develop new or worsening eye disorders.
- Hyperlipidemia: Elevated triglycerides may result in pancreatitis. Monitor serum triglycerides before BESREMi treatment and intermittently during therapy and manage when elevated. Consider discontinuation of BESREMi in patients with persistently, markedly elevated triglycerides.
- Hepatotoxicity: These toxicities may include increases in serum alanine aminotransferase (ALT), aspartate aminotransferase (AST), gamma-glutamyl transferase (GGT) and bilirubin. Liver enzyme elevations have also been reported in patients after long-term BESREMi therapy. Monitor liver enzymes and hepatic function at baseline and during BESREMi treatment. Discontinue BESREMi in patients who develop evidence of hepatic decompensation (characterized by jaundice, ascites, hepatic encephalopathy, hepatorenal syndrome or variceal hemorrhage) during treatment
- Renal Toxicity: Monitor serum creatinine at baseline and during therapy. Avoid use of BESREMi in patients with eGFR <30 mL/min. Discontinue BESREMi if severe renal impairment develops during treatment.
- Dental and Periodontal Toxicity: These toxicities may include dental and periodontal disorders, which may lead to loss of teeth. In addition, dry mouth could have a damaging effect on teeth and mucous membranes of the mouth during long-term treatment with BESREMi. Patients should have good oral hygiene and regular dental examinations.

Please see additional Important Safety Information throughout and full Prescribing Information, including Boxed Warning.

PharmaEssentia SOURCE™—Connecting Your Patients to Access Assistance Options

If your patients require assistance affording their medication, we are here to help. We have programs and referral services available to help patients with financial assistance options for BESREMi®, regardless of their insurance coverage.

Copay and Coinsurance Assistance Program: Eligible patients can receive BESREMi for as little as $0 per month.* This program covers copay, coinsurance, or deductible expenses for those who qualify.

Patients may be eligible if they meet requirements, such as:

- Having commercial (private) insurance that covers BESREMi
- Residing in the United States or a US territory
- Having a valid prescription for BESREMi from a US physician

Temporary Supply Program:
Provides a temporary supply of BESREMi to eligible patients experiencing insurance delays or gaps in coverage.†

Patient Assistance Program (PAP):
If your patient is uninsured or has limited coverage, they may be eligible to receive their medication at no cost through this program.†

Patients may be eligible if they meet requirements, such as:

- Not having prescription drug coverage or are rendered uninsured or underinsured
- Residing in the United States or a US territory
- Having a valid prescription from a US physician for BESREMi
- Meeting financial eligibility criteria

Referrals to Alternate Resources:
PharmaEssentia SOURCE will work with your patients to identify potential sources of insurance coverage and organizations that may help with various treatment-related needs, including the costs related to therapy.

*Restrictions apply and are subject to change. Not available to patients with prescription insurance plans through any federal or state healthcare programs, including but not limited to Medicare, Medicaid, TRICARE, and Veterans Health Administration. This offer is not valid for cash-paying patients, where BESREMi is not covered by the patient's commercial insurance, or where the plan reimburses patients for the entire cost of BESREMi.

†Restrictions apply and are subject to change.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

- Dermatologic Toxicity: These toxicities have included skin rash, pruritus, alopecia, erythema, psoriasis, xeroderma, dermatitis acneiform, hyperkeratosis, and hyperhidrosis. Consider discontinuation of BESREMi if clinically significant dermatologic toxicity occurs.
- Driving and Operating Machinery: BESREMi may impact the ability to drive and use machinery. Patients should not drive or use heavy machinery until they know how BESREMi affects their abilities. Patients who experience dizziness, somnolence or hallucination during BESREMi therapy should avoid driving or using machinery.
- Embryo-Fetal Toxicity: Based on the mechanism of action, BESREMi can cause fetal harm when administered to a pregnant woman. Pregnancy testing is recommended in females of reproductive potential prior to treatment with BESREMi. Advise females of reproductive potential to use an effective method of contraception during treatment with BESREMi and for at least 8 weeks after the final dose.

Please see additional Important Safety Information throughout and full Prescribing Information, including Boxed Warning.

IMPORTANT SAFETY INFORMATION (continued)

ADVERSE REACTIONS

The most common adverse reactions reported in > 40% of patients in the PEGINVERA study (n=51) were influenza-like illness, arthralgia, fatigue, pruritis, nasopharyngitis, and musculoskeletal pain. In the pooled safety population (n=178), the most common adverse reactions greater than 10%, were liver enzyme elevations (20%), leukopenia (20%), thrombocytopenia (19%), arthralgia (13%), fatigue (12%), myalgia (11%), and influenza-like illness (11%).

DRUG INTERACTIONS

Patients on BESREMi who are receiving concomitant drugs which are CYP450 substrates with a narrow therapeutic index should be monitored to inform the need for dosage modification for these concomitant drugs. Avoid use with myelosuppressive agents and monitor patients receiving the combination for effects of excessive myelosuppression. Avoid use with narcotics, hypnotics or sedatives and monitor patients receiving the combination for effects of excessive CNS toxicity.

USE IN SPECIFIC POPULATIONS

- Pregnancy: Based on mechanism of action and the role of interferon alfa in pregnancy and fetal development, BESREMi may cause fetal harm and should be assumed to have abortifacient potential when administered to a pregnant woman. There are adverse effects on maternal and fetal outcomes associated with polycythemia vera in pregnancy. Advise pregnant women of the potential risk to a fetus.
- Lactation: There are no data on the presence of BESREMi in human or animal milk, the effects on the breastfed child, or the effects on milk production. Because of the potential for serious adverse reactions in breastfed children from BESREMi, advise women not to breastfeed during treatment and for 8 weeks after the final dose.
- Females of Reproductive Potential: BESREMi may cause embryo-fetal harm when administered to a pregnant woman. Pregnancy testing prior to BESREMi treatment is recommended for females of reproductive potential. Advise female patients of reproductive potential to use effective contraception during treatment with BESREMi and for at least 8 weeks after the final dose.

PharmaEssentia SOURCE™
Your resource for patient support & education

Personalized Support to Help Your Patients Get Started on BESREMi

PharmaEssentia SOURCE can guide your patients through the access and reimbursement process and offer personalized support throughout their BESREMi treatment.

Information for your patients can be found in the **PharmaEssentia SOURCE Patient Guide**.

To learn more, call **800-700-5053** between 8:00 AM and 8:00 PM ET, Monday through Friday, or visit **PharmaEssentiaSOURCE.com**.

IMPORTANT SAFETY INFORMATION (continued)

USE IN SPECIFIC POPULATIONS (continued)

- Pediatric Use: Safety and effectiveness in pediatric patients have not been established.
- Geriatric Use: In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or other therapy.

Please see accompanying full Prescribing Information, including Boxed Warning.

Reference: 1. Besremi. Package insert. PharmaEssentia Corporation; 2021.

PharmaEssentia™

BESREMi® (ropeginterferon alfa-2b-njft) INJECTION