For infants and children with achondroplasia[1]

Approved from birth. Backed by experience.

The only treatment FDA approved from birth until growth plates close

Indicated to increase linear growth for children with achondroplasia.[1,2]

VOXZOGO®
(vosoritide) for injection

INDICATION AND IMPORTANT SAFETY INFORMATION

VOXZOGO® (vosoritide) is indicated to increase linear growth in pediatric patients with achondroplasia and open growth plates.

- This indication is approved under accelerated approval based on an improvement in annualized growth velocity. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Warnings and Precautions for Risk of Low Blood Pressure

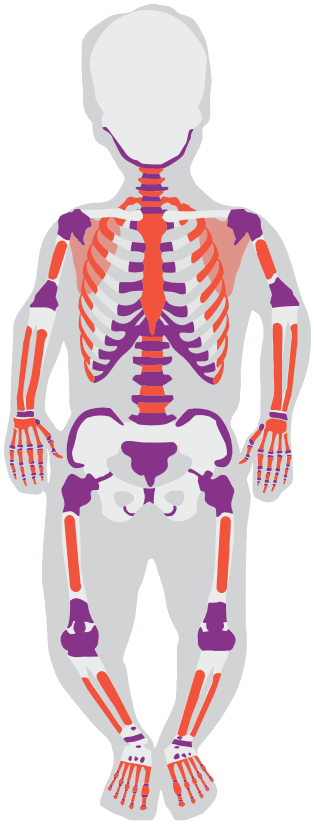
Transient decreases in blood pressure were observed in clinical studies. Patients with significant cardiac or vascular disease and patients on anti-hypertensive medicinal products were excluded from participation in VOXZOGO clinical trials. To reduce the risk of a decrease in blood pressure and associated symptoms (dizziness, fatigue, and/or nausea), patients should be well hydrated, have adequate food intake, and drink approximately 8-10 ounces of fluid in the hour prior to VOXZOGO administration.

Please see additional Important Safety Information presented throughout, and in the full Prescribing Information.

Endochondral bone growth is inhibited in achondroplasia[3,4]

Endochondral bone growth is the predominant process of bone development in which cartilage is replaced by bone at open growth plates. Most bones start to grow before birth and continue for as long as growth plates remain open.[5-7]

Achondroplasia affects endochondral bones, which make up **>90% of the bones in the body**[4,5,7-16]



Endochondral bones

Growth plates[5,9,17-25]

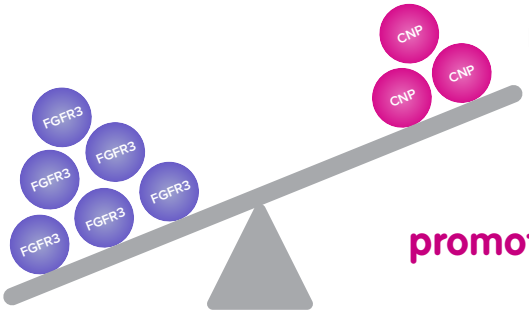
This image is for illustrative purposes only to show areas of endochondral bone growth.

Bone growth relies on a balance of signaling pathways[3]

In achondroplasia, this balance is disrupted[3]

Overactive FGFR3 signaling results in inhibited endochondral bone growth throughout the body.[3,4,7-16]

FGFR3 signaling slows bone growth.[3]



Endogenous CNP levels cannot adequately regulate overactive FGFR3 signaling.[3]

CNP signaling promotes bone growth.[3]

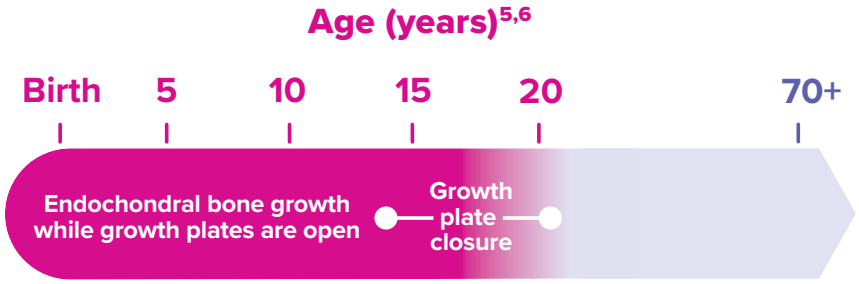
CNP, C-type natriuretic peptide; **FGFR3,** fibroblast growth factor receptor 3.

Please see additional Important Safety Information presented throughout, and in the full Prescribing Information.

VOXZOGO promotes endochondral bone growth as early as birth[1]

VOXZOGO targets overactive FGFR3 and works by mimicking the body's natural CNP to promote endochondral bone growth—only while growth plates remain open.[1]

By 2 years old, children with achondroplasia reach **more than half their adult height**[26]*



Maximize time on treatment by starting early and continuing until growth plates close[1,5,27]

International consensus guidelines support early initiation of VOXZOGO[27]

BioMarin provided funding for the *International consensus guidelines on the implementation and monitoring of vosoritide therapy in individuals with achondroplasia*, including honoraria to participants. BioMarin was not involved in the selection of the guidelines development group, defining the guidelines scope, the voting process, analysis of the results, or preparation of the submitted manuscript. Please see Acknowledgements section of publication for additional detail.[27]

SCAN THE QR CODE TO LEARN MORE

*Based on stature-for-age data (birth to 18 years old) from CLARITY, an achondroplasia natural history study, comprised of measurements from 549 males and 502 females with achondroplasia.[26]

IMPORTANT SAFETY INFORMATION

Warnings and Precautions for Risk of Low Blood Pressure (cont'd)

In a 52-week, randomized, double-blind, placebo-controlled trial in 121 subjects with achondroplasia, subjects aged from 5.1 to 14.9 years, (Study 1) eight (13%) of 60 patients treated with VOXZOGO had a total of 11 events of transient decrease in blood pressure, compared to 3 (5%) of 61 patients on placebo, over a 52-week treatment period. The median time to onset from injection was 31 (18 to 120) minutes, with resolution within 31 (5 to 90) minutes in VOXZOGO-treated subjects. Two out of 60 (3%) VOXZOGO-treated patients each had one symptomatic episode of decreased blood pressure with vomiting and/or dizziness compared to 0 of 61 (0%) patients on placebo.

Please see additional Important Safety Information presented throughout, and in the full Prescribing Information.

VOXZOGO has been studied in children aged 4 months to <18 years[1,28-30]

CANOPY ACH-OS (Study 901)
Ongoing Observational Study[29,31]

- Age: 0 months to <18 years
- Establish baseline growth*

CANOPY ACH-2I (Study 206)†
Phase 2 Infant and Toddler Study[30,31]

- Age: 0 months to <5 years
- 52-week, double-blind, randomized, placebo-controlled

CANOPY ACH-3 (Study 301)
Phase 3 Pivotal Study[28,31]

- Age: 5 to <18 years
- 52-week, double-blind, randomized, placebo-controlled

CANOPY ACH-EXT (Study 208)
Ongoing Open-label Extension Study[31,32]

- Duration: Near final adult height

CANOPY ACH-EXT (Study 302)
Ongoing Open-label Extension Study[28,31,33]

- Duration: Final adult height

10+ years of clinical trial experience in achondroplasia[2]

ACH, achondroplasia; **AGV,** annualized growth velocity; **CI,** confidence interval; **EXT,** extension; **LS,** least squares; **OS,** observational study; **SD,** standard deviation.

*Duration of ≥6 months if aged ≥3 months at study entry; duration of ≥3 months if aged <3 months at study entry.[29]
†Participants completed at least 3 or 6 months of an observational run-in growth study (either in CANOPY ACH-OS [Study 901] or CANOPY ACH-2I [Study 206]) to establish their baseline annualized growth velocity.[30,31]

IMPORTANT SAFETY INFORMATION

Adverse Reactions:

Adverse reactions that occurred in ≥5% of patients treated with VOXZOGO and at a rate greater than that of placebo in the phase 3 study are injection site reactions (including erythema, swelling, urticaria, pain, bruising, pruritus, hemorrhage, discoloration, and induration), vomiting, arthralgia, decrease in blood pressure, gastroenteritis, diarrhea, dizziness, ear pain, influenza, fatigue, seasonal allergy, and dry skin. VOXZOGO-treated patients had an increase in alkaline phosphatase levels (17%), and was noted as a laboratory abnormality.

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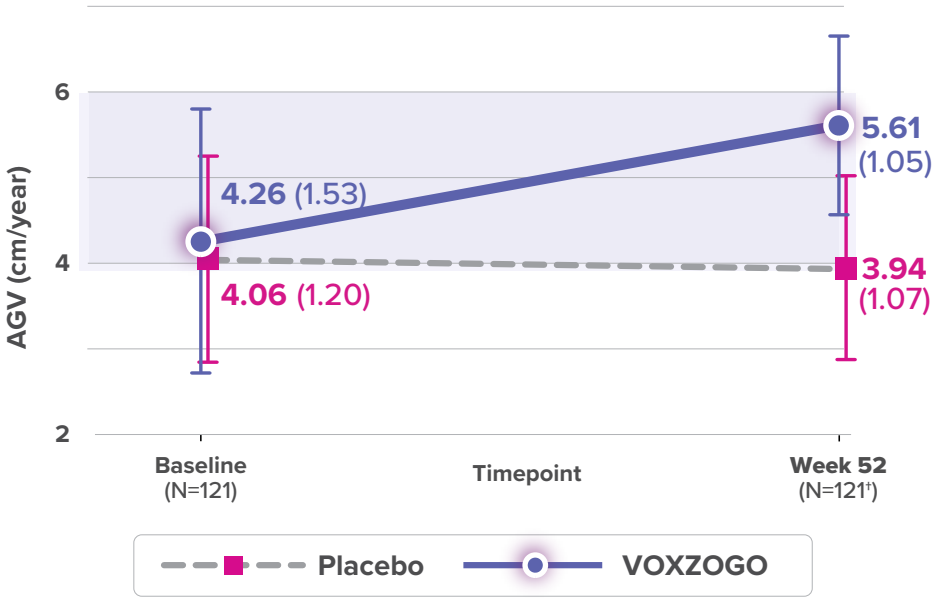
Children with achondroplasia grew faster on VOXZOGO than without treatment[1,34,35]

CANOPY ACH-3 (Study 301)

Phase 3 pivotal trial in children aged 5 to 15 years (N=121)[28,31]

Mean (±SD) AGV at week 52[34]



AGV difference from placebo at 1 year in the primary analysis:

+1.57 cm/yr[1*†‡]

P<0.0001 (95% CI: 1.22, 1.93)

AGV increase maintained over baseline at

4 years

in VOXZOGO-treated children from the open-label extension study (N=105)[35]

Mean (±SD) AGV at 4 years:
VOXZOGO (n=49): 4.77 (2.17)
Placebo to VOXZOGO (n=56): 4.43 (2.35)

Primary Endpoint (Study 301)

Change from baseline in AGV at Week 52 compared to placebo. AGV is a measure of linear growth expressed as the change in height or length units over 1 year.[1]

97% of children on VOXZOGO (58/60) in the phase 3 pivotal trial remained on treatment during the 1-year study[1]

*Improvement in AGV was consistent across all predefined subgroups, including sex, age, and Tanner stage.[1]
†All randomized subjects. Two patients in the VOXZOGO group discontinued from the study before Week 52; the values for these 2 patients were imputed assuming baseline growth rate for the period with missing data.[1]
‡Difference in LS mean change from baseline (VOXZOGO minus placebo; 2-sided *P*-value). LS means were estimated from the ANCOVA (analysis of covariance) model, which included treatment, stratum defined by sex and Tanner stage, baseline age, baseline AGV, and baseline height Z-score.[1]

Please see additional Important Safety Information presented throughout, and in the full Prescribing Information.

The VOXZOGO clinical trial program continues to evaluate multiple endpoints[1,2,32,36-38]

VOXZOGO is approved under accelerated approval based on an improvement in annualized growth velocity. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).[1]

As clinical trials are ongoing, the impact on final adult height has not been established and continues to be evaluated along with other pre-specified outcome measures. These endpoints are not included in the US Prescribing Information and do not establish a clinical benefit or conclusions on efficacy.[2,32,36-38]

CANOPY ACH-2I (Study 206) | **CANOPY ACH-EXT (Study 208)**

Secondary outcome measures include[31,32,36]*:

- Height change (over time from baseline)
- Functional measures (change from baseline)
- Tibial bowing
- Spine morphology (eg, spinal canal width)
- Spinal alignment (eg, angles)
- Skull morphology (eg, foramen magnum area)

CANOPY ACH-3 (Study 301) | **CANOPY ACH-EXT (Study 302)**

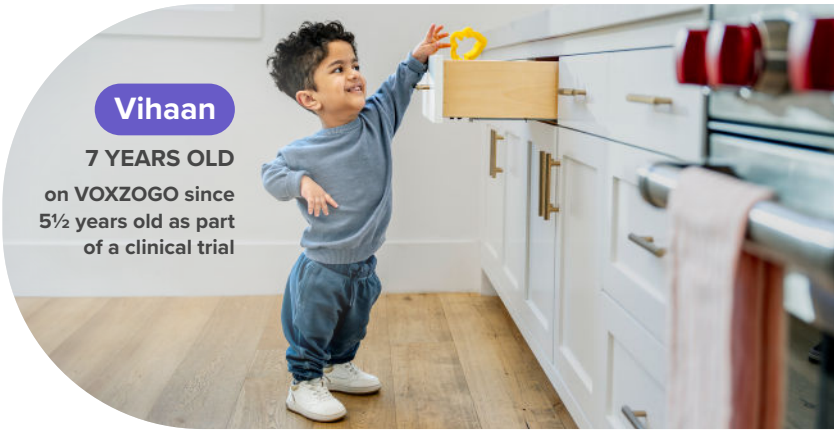
Secondary outcome measures include[31,37,38]*:

- AGV by age and sex
- Functional measures (change from baseline)
- Health-related quality of life (ie, QoLISSY)
- Body proportionality (eg, upper-to-lower body segment ratio)
- Bone morphology and quality
- Final adult height

ACH, achondroplasia; **AGV,** annualized growth velocity; **EXT,** extension; **QoLISSY,** Quality of Life in Short Stature Youth.

*Visit clinicaltrials.gov for the complete list of the trials' secondary outcome measures (NCT03583697, NCT03989947, NCT03197766, NCT03424018).[32,36-38]

Explore additional VOXZOGO data



IMPORTANT SAFETY INFORMATION

Adverse Reactions: (cont'd)

Injection site reactions: In Study 1, injection site reactions occurred in 51 (85%) subjects receiving VOXZOGO and 50 (82%) subjects receiving placebo over a 52-week period of treatment. Patients receiving VOXZOGO experienced a total of 6983 events of injection site reactions, while patients receiving placebo experienced a total of 1776 events of injection site reactions, over a 52-week period, representing 120.4 events per patient/year exposure and 29.2 events per patient/year exposure, respectively. Two patients in the VOXZOGO arm discontinued treatment due to adverse events of pain and anxiety with injections.

Please see additional Important Safety Information presented throughout, and in the full Prescribing Information.

Get to know the families who chose VOXZOGO

Annika

14 YEARS OLD

Started VOXZOGO: 9 years old as part of a clinical trial

Annika, 6 years old | Annika, 14 years old

For illustrative purposes only, image scale is not matched.

Hear more stories from families who started and stayed on treatment

Please see additional Important Safety Information presented throughout, and in the full Prescribing Information.

The safety profile of VOXZOGO has been carefully evaluated[1,39]

Children 5 to 15 years old

Over 1 year in the phase 3 pivotal trial (Study 301), adverse reactions that occurred in ≥5% of patients aged 5 to 15 years treated with VOXZOGO and at a percentage greater than placebo[1]:

ADVERSE REACTIONS[1]*	PLACEBO (n=61)	VOXZOGO (n=60)
Injection site erythema†	42 (69%)	45 (75%)
Injection site swelling†	22 (36%)	37 (62%)
Vomiting	12 (20%)	16 (27%)
Injection site urticaria†	6 (10%)	15 (25%)
Arthralgia	4 (7%)	9 (15%)
Decreased blood pressure	3 (5%)	8 (13%)
Gastroenteritis‡	5 (8%)	8 (13%)
Diarrhea	2 (3%)	6 (10%)
Dizziness§	2 (3%)	6 (10%)
Ear pain	3 (5%)	6 (10%)
Influenza	3 (5%)	6 (10%)
Fatigue‖	2 (3%)	5 (8%)
Seasonal allergy	1 (2%)	4 (7%)
Dry skin	0 (0%)	3 (5%)

In the long-term open-label extension study (Study 302), adverse reactions reported for up to 6 years of treatment are consistent with those seen in the 1-year pivotal trial.[39]

VOXZOGO may cause serious side effects including a temporary decrease in blood pressure in some patients; to reduce the risk of a decrease in blood pressure and associated symptoms (dizziness, feeling tired, or nausea), patients should be well fed and hydrated in the hour before receiving VOXZOGO.[1]

*Includes adverse reactions occurring more frequently in the VOXZOGO arm and with a risk difference of ≥5% (ie, difference of >2 subjects) between treatment arms.[1]
†Injection site reactions occurring more frequently in VOXZOGO-treated patients than placebo.[1]
‡Includes the preferred terms: gastroenteritis and gastroenteritis, viral.[1]
§Includes the preferred terms: dizziness, presyncope, procedural dizziness, and vertigo.[1]
‖Includes the preferred terms: fatigue, lethargy, and malaise.[1]

Please see additional Important Safety Information presented throughout, and in the full Prescribing Information.

Consistent safety profile from infancy through childhood[1,40]

Children under 5 years old

The overall safety profile of VOXZOGO in pediatric patients <5 years old was similar to that seen in older pediatric patients.[1]

- **Over 1 year in the phase 2 trial (Study 206),** the most common adverse reactions (>10%) reported in pediatric patients <5 years old were injection site reactions (86%) and rash (28%)[1]

Children under 2 years old

Adverse reactions reported in children 4 months to <2 years old were consistent with those seen in children aged 2 to <5 years old.[40]

In the long-term open label extension study (Study 208), adverse reactions reported for up to 4 years of treatment are consistent with those seen in the 1-year trial.[40]

Please see additional Important Safety Information presented throughout, and in the full Prescribing Information.

BioMarin is here to support you every step of the way

BioMarin Rare Connections™

Product access support from Case and Field Reimbursement Managers for:

- Helping with the insurance process and sharing coverage options
- Identifying financial programs, such as co-pay assistance
- Offering guidance on insurance changes
- Ensuring the specialty pharmacy receives the prescription
- Educating your patient's care team on coverage requirements for continued access to therapy

BioMarin Clinical Coordinators

One-to-one patient support for:

- Providing product education and support around the injection process
- Helping to find an injection routine that works for your patients and their family throughout their entire time on treatment
- Assisting through the specialty pharmacy process and sharing reminders for product refills
- Offering flexible meeting options including in person and/or virtually, by email, phone, or text

VOXZOGO

The Achondroplasia Doctor Finder

Help your patients take the next step and find specialized care near them

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Indication and Important Safety Information

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- This indication is approved under accelerated approval based on an improvement in annualized growth velocity. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Warnings and Precautions for Risk of Low Blood Pressure

Transient decreases in blood pressure were observed in clinical studies. Patients with significant cardiac or vascular disease and patients on anti-hypertensive medicinal products were excluded from participation in VOXZOGO clinical trials. To reduce the risk of a decrease in blood pressure and associated symptoms (dizziness, fatigue, and/or nausea), patients should be well hydrated, have adequate food intake, and drink approximately 8-10 ounces of fluid in the hour prior to VOXZOGO administration.

In a 52-week, randomized, double-blind, placebo-controlled trial in 121 subjects with achondroplasia, subjects aged from 5.1 to 14.9 years, (Study 1) eight (13%) of 60 patients treated with VOXZOGO had a total of 11 events of transient decrease in blood pressure, compared to 3 (5%) of 61 patients on placebo, over a 52-week treatment period. The median time to onset from injection was 31 (18 to 120) minutes, with resolution within 31 (5 to 90) minutes in VOXZOGO-treated subjects. Two out of 60 (3%) VOXZOGO-treated patients each had one symptomatic episode of decreased blood pressure with vomiting and/or dizziness compared to 0 of 61 (0%) patients on placebo.

Adverse Reactions:

Adverse reactions that occurred in ≥5% of patients treated with VOXZOGO and at a rate greater than that of placebo in the phase 3 study are injection site reactions (including erythema, swelling, urticaria, pain, bruising, pruritus, hemorrhage, discoloration, and induration), vomiting, arthralgia, decrease in blood pressure, gastroenteritis, diarrhea, dizziness, ear pain, influenza, fatigue, seasonal allergy, and dry skin. VOXZOGO-treated patients had an increase in alkaline phosphatase levels (17%), and was noted as a laboratory abnormality.

Injection site reactions: In Study 1, injection site reactions occurred in 51 (85%) subjects receiving VOXZOGO and 50 (82%) subjects receiving placebo over a 52-week period of treatment. Patients receiving VOXZOGO experienced a total of 6983 events of injection site reactions, while patients receiving placebo experienced a total of 1776 events of injection site reactions, over a 52-week period, representing 120.4 events per patient/year exposure and 29.2 events per patient/year exposure, respectively. Two patients in the VOXZOGO arm discontinued treatment due to adverse events of pain and anxiety with injections.

Pediatric Patients 0 to <5 Years:

The safety of VOXZOGO in pediatric patients 0 to <5 years with achondroplasia was evaluated in a 52-week randomized, double-blind, placebo-controlled study (Study 2). In this study, 64 patients from birth to <5 years of age were randomized to receive either a daily vosoritide dose with similar exposure to that characterized to be safe and effective in children with ACH aged ≥5 years old, or placebo. An additional 11 patients received open-label treatment as part of this study. The most common adverse reactions (>10%) reported in pediatric patients 0 to <5 years were injection site reactions (86%) and rash (28%). The overall safety profile of VOXZOGO in pediatric patients 0 to <5 years was similar to that seen in older pediatric patients.

Administration and Monitoring:

VOXZOGO is administered as a daily subcutaneous injection. Prior to use, instruct caregivers on proper preparation and administration of VOXZOGO, and ensure caregivers have demonstrated the ability to perform a subcutaneous injection.

Monitor and assess patient body weight, growth, and physical development regularly every 3-6 months. Adjust dosage according to the patient's actual body weight. Permanently discontinue treatment with VOXZOGO upon confirmation of no further growth potential, indicated by closure of epiphyses.

Special Populations:

- There are no available data on the use of VOXZOGO in pregnant women, or data on the presence of VOXZOGO in human milk, the effects on the breastfed infant, or the effects on milk production.
- The influence of renal impairment on the pharmacokinetics of VOXZOGO has not been evaluated. No dosage adjustment is needed for patients with eGFR ≥60 mL/min/1.73 m^2. VOXZOGO is not recommended for patients with eGFR <60 mL/min/1.73 m^2.

You may report side effects to the FDA at **1-800-FDA-1088** or **www.fda.gov/medwatch**. You may also report side effects to BioMarin at **1-866-906-6100**.

Please see additional safety information in the full Prescribing Information.

VOXZOGO®
(vosoritide) for injection

It's time to talk VOXZOGO

5,000+ infants and children with achondroplasia have been prescribed VOXZOGO worldwide[1,41]

VOXZOGO®
(vosoritide) for injection

The longest-studied medication for achondroplasia is backed by 10+ years of clinical trial experience.[2]

OVER 96% of insured patients have secured coverage for VOXZOGO[42]*

OVER 96% of eligible families with commercial insurance paid $0 out of pocket for VOXZOGO[43]*†

Connect with a Local BioMarin Representative

Learn more about VOXZOGO and how it can help your patients by connecting with a dedicated representative.

*BioMarin RareConnections™ Data on file. Patients included are eligible VOXZOGO patients who have enrolled in BioMarin RareConnections and are on commercial therapy.[42,43]

†With the BioMarin Co-Pay Assistance Program. Terms and Conditions apply. Valid only for patients with commercial prescription insurance coverage who have a valid prescription for an FDA-approved indication and who meet additional eligibility criteria. Not valid for prescriptions reimbursed, in whole or in part, by any federal, state, or government-funded insurance programs (for example, Medicare, Medicare Advantage, Medigap, Medicaid, VA, DoD, or TRICARE) or where prohibited by law or by the patient's health insurance provider. If at any time a patient begins receiving prescription drug coverage under any federal, state, or government-funded healthcare program, the patient will no longer be able to use the program and patient must notify BioMarin RareConnections at 1-866-906-6100 to stop participation. Patients residing in or receiving treatment in certain states may not be eligible for some or all of the program elements. Patients may not seek reimbursement for value received from the program from any third-party payers. Additional restrictions may apply. Offer subject to change or discontinuance without notice. This assistance offer is not health insurance. See BioMarin-copay-terms.com for full Terms and Conditions.

Please see additional Important Safety Information throughout, and in the full Prescribing Information.

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