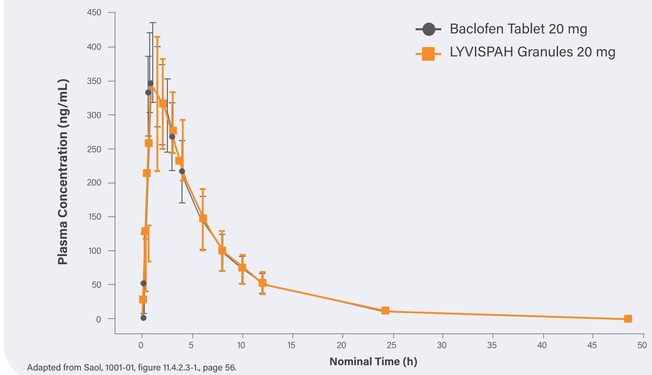
Baclofen is now available in a dissolvable form

LYVISPAH™ provides the clinical benefits of baclofen in a convenient, rapidly dissolvable granule formulation[1]

- Baclofen has been well established for the treatment of spasticity[2]
- LYVISPAH is bioequivalent to oral baclofen tablets[1,3]

Mean (±SD) Baclofen Plasma Concentration



Adapted from Saol, 1001-01, figure 11.4.2.3-1., page 56.

IMPORTANT SAFETY INFORMATION

Indication

- LYVISPAH™ (baclofen) oral granules is indicated for the treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity.
- LYVISPAH may also be of some value in patients with spinal cord injuries and other spinal cord diseases.

Limitations of Use:
LYVISPAH is not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders.

Contraindication

LYVISPAH is contraindicated in patients with hypersensitivity to baclofen.

Warnings and Precautions

- Abrupt discontinuation of baclofen, regardless of the cause, has resulted in adverse reactions that include hallucinations, seizures, high fever, altered mental status, exaggerated rebound spasticity, and muscle rigidity, that in rare cases has advanced to rhabdomyolysis, multiple organ-system failure, and death. Therefore, reduce the dosage slowly when LYVISPAH is discontinued, unless the clinical situation justifies a rapid withdrawal.
- Neonatal withdrawal can occur; gradually reduce the dosage and discontinue LYVISPAH before delivery.

Customized dosing for individual patient needs

LYVISPAH provides flexible dosing as it comes in 5 mg, 10 mg, and 20 mg single-dose packets of flavored granules[4]

- **Rapidly dissolving** strawberry-flavored granules provide an **alternative** for patients with spasticity who also have **difficulty swallowing pills**[1]
- **Conveniently stored** at room temperature providing an added benefit to patients **on-the-go**[4]
- **Samples** are available in the **5 mg and 10 mg** dosage strengths

Commercially insured patients may pay as little as $10 for their prescription*

*Up to maximum benefit of $100. Subject to eligibility. Individual out-of-pocket costs may vary. Not valid for patients covered under Medicare, Medicaid, or other federal or state programs. Please see full Terms, Conditions and Eligibility Criteria at LyvispahHCP.com/savings.

IMPORTANT SAFETY INFORMATION *(continued)*

Warnings and Precautions *(continued)*

- LYVISPAH can cause drowsiness and sedation. Patients should avoid the operation of automobiles or other dangerous machinery until they know how the drug affects them. Advise patients that the central nervous system effects of LYVISPAH may be additive to those of alcohol and other CNS depressants.
- LYVISPAH can cause exacerbation of the following: psychotic disorders, schizophrenia, or confusional states; autonomic dysreflexia; epilepsy. Use with caution in patients with these conditions.
- LYVISPAH should be used with caution in patients who have had a stroke.

Adverse Reactions

- The most common adverse reactions (>1%) in patients treated with baclofen for spasticity are drowsiness, dizziness, weakness, nausea, confusion, hypotension, headache, insomnia, constipation, urinary frequency, and fatigue.

Drug Interactions

- LYVISPAH can cause CNS depression, including drowsiness and sedation, which may be an additive when used concomitantly with other CNS depressants or alcohol.

Use in Specific Populations

- Pregnancy: There are no adequate data on the developmental risks associated with the use of LYVISPAH in pregnant women. LYVISPAH should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- Lactation: Nursing mothers should exercise caution, as oral baclofen has been shown to pass into milk at therapeutic doses. Withdrawal symptoms can occur in breastfed infants when maternal administration of LYVISPAH is stopped, or when breastfeeding is stopped.

Flexibility of administration

LYVISPAH can be administered in 3 ways[4]

1. Poured directly into the patient's mouth, with or without water
2. Mixed with liquids or soft foods, such as apple sauce, yogurt, or pudding*
3. Via enteral feeding tube†

Visit LyvispahHCP.com/admin or scan the QR code to view a short video detailing the 3 modes of administration

*Must be taken within 2 hours.

†**Feeding tubes may become blocked when medications that are not specifically indicated for enteral administration are used. LYVISPAH is the only oral baclofen FDA approved for both oral and enteral feeding-tube administration.**

IMPORTANT SAFETY INFORMATION *(continued)*

Use in Specific Populations *(continued)*

- Pediatrics: Safety and effectiveness in pediatric patients below the age of 12 have not been established.
- Elderly Patients: 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 of other drug therapy.
- Renal Impairment: Because baclofen is primarily excreted unchanged through the kidneys, LYVISPAH should be given with caution to patients with renal impairment, and it may be necessary to reduce the dosage.

Please see the full Important Safety Information throughout.

References: 1. Office of Clinical Pharmacology Review (Lyvispah®). NDA number 215422. Link to EDR: \\CDSESUB1\evsprod\NDA215422\0001. Submission date 1/22/2021. Submission type: Original NDA (505(b)(2)). **2.** Ghanavatian S, Derian A. Baclofen. [Updated 2021 Dec 17]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK526037/ **3.** Data on file [Amneal]. **4.** LYVISPAH (baclofen) oral granules [Prescribing Information]. Roswell, GA: Saol Therapeutics; 2021.

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PP-CON-LYVI-US-0015 03/2023

LYVISPAH™ (baclofen) oral granules

Baclofen. Now dissolvable.