

Fleqsuvy[™] (baclofen) – New drug approval

- On February 7, 2022, <u>Azurity Pharmaceuticals</u> announced the <u>FDA approval</u> of <u>Fleqsuvy (baclofen)</u> oral suspension, for the treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity.
 - Fleqsuvy may also be of some value in patients with spinal cord injuries and other spinal cord diseases.
 - Fleqsuvy is not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders.
- Baclofen is currently available orally as a generic <u>tablet</u> and as a brand oral solution (<u>Ozobax®</u>).
- The efficacy of Fleqsuvy is based upon a bioavailability study in healthy adults comparing baclofen oral tablets to Fleqsuvy.
- Warnings and precautions for Fleqsuvy include adverse reactions from abrupt withdrawal of Fleqsuvy; neonatal withdrawal symptoms; drowsiness and sedation; poor tolerability in stroke patients; exacerbation of psychotic disorders, schizophrenia, or confusional states; exacerbation of autonomic dysreflexia; exacerbation of epilepsy; posture and balance effects and ovarian cysts.
- The most common adverse reactions (up to 15% or more) with Fleqsuvy use were drowsiness, dizziness, and weakness.
- Fleqsuvy should be initiated with a low dosage, preferably in divided doses, administered orally. The following gradually increasing dosage regimen is suggested, but should be adjusted based on clinical response and tolerability:
 - 1 mL (5 mg) three times a day for three days
 - 2 mL (10 mg) three times a day for three days
 - 3 mL (15 mg) three times a day for three days
 - 4 mL (20 mg) three times a day for three days
 - Additional increases may be necessary up to the maximum recommended dosage of 80 mg daily (4 mL [20 mg] four times a day).
- Azurity Pharmaceuticals' launch plans for Fleqsuvy are pending. Fleqsuvy will be available as a 25 mg/5 mL oral suspension.



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