HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use OZOBAX® DS safely and effectively. See full prescribing information for OZOBAX DS.

OZOBAX DS (baclofen) oral solution
Initial U.S. Approval: 1977

---------- INDICATIONS AND USAGE----------

- OZOBAX DS is a gamma-aminobutyric acid (GABA-ergic) agonist indicated for the treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity. (1)
- OZOBAX DS may also be of some value in patients with spinal cord injuries and other spinal cord diseases. (1)

Limitations of Use

OZOBAX DS is not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders (1)

---------- DOSAGE AND ADMINISTRATION ----------

- Baclofen oral solution is available in multiple concentrations; include both the total dose in mg and the total dose in volume on prescriptions (2.1)
- Initiate OZOBAX DS with a low dosage, preferably in divided doses, administered orally. Increase gradually based on clinical response and tolerability. (2.2)
- The maximum dosage is 80 mg daily (20 mg four times a day). (2.2)
- When discontinuing, reduce the dosage slowly. (2.3)

---------- DOSAGE FORMS AND STRENGTHS----------

Oral Solution: 10 mg/5 mL (3)

---------- CONTRAINDICATIONS ----------

- Hypersensitivity to baclofen (4)

----------WARNINGS AND PRECAUTIONS ----------

- Abrupt discontinuation of baclofen has resulted in serious adverse reactions including death; therefore, reduce the dosage slowly when OZOBAX DS is discontinued. (5.1)
- Neonatal withdrawal symptoms can occur; gradually reduce the dosage and discontinue OZOBAX DS before delivery. (5.2)
- OZOBAX DS 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 OZOBAX DS may be additive to those of alcohol and other CNS depressants. (5.3)
- OZOBAX DS can cause exacerbation of the following: psychotic disorders, schizophrenia, or confusional states; autonomic dysreflexia; epilepsy. Use with caution in patients with these conditions (5.5, 5.6, 5.7)

----------ADVERSE REACTIONS----------

- The most common (up to 15% or more) adverse reactions in patients were drowsiness, dizziness, and weakness. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Metacel Pharmaceuticals, LLC at 1-833-469-6229 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------USE IN SPECIFIC POPULATIONS----------

- Pregnancy: Based on animal data, may cause fetal harm (8.1)
- Because baclofen is excreted unchanged through the kidneys it may be necessary to reduce the dosage in patients with impaired renal function. (8.6)

See 17 for PATIENT COUNSELING INFORMATION

Revised: 09/2023

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed