It is not known whether this drug is excreted in human milk. As a general rule, nursing should not be undertaken while a patient is on a drug since many drugs are excreted in human milk.

A dose-related increase in incidence of ovarian cysts and a less marked increase in enlarged and/or hamartomatic adrenal glands was observed in female rats treated chronically with baclofen.

Ovarian cysts have been found by palpation in about 4% of the multiple sclerosis patients that were treated with baclofen for up to one year. In most cases these cysts disappeared spontaneously while patients continued to receive the drug. Ovarian cysts are estimated to occur spontaneously in approximately 1% to 5% of the normal female population.

ADVERSE REACTIONS

The most common is transient drowsiness (10-63%). In one controlled study of 175 patients, transient drowsiness was observed in 63% of those receiving baclofen compared to 36% of those in the placebo group. Other common adverse reactions are dizziness (5-15%), weakness (5-15%) and fatigue (2-4%). Others reported:

Neuropsychiatric: Confusion (1-11%), headache (4-8%), insomnia (2-7%); and, rarely, euphoria, excitement, depression, hallucinations, paraesthesia, muscle pain, tinnitus, slurred speech, coordination disorder, tremor, rigidity, dystonia, ataxia, blurred vision, nystagmus, strabismus, myosis, mydriasis, diplopia, dysarthria, epileptic seizure.

Cardiovascular: Hypotension (0-9%). Rare instances of dyspnea, palpitation, chest pain, syncope.

Gastrointestinal: Nausea (4-12%); constipation (2-6%); and, rarely, dry mouth, anorexia, taste disorder, abdominal pain, vomiting, diarrhea, and positive test for occult blood in stool.

Genitourinary: Urinary frequency (2-6%); and, rarely, enuresis, urinary retention, dysuria, impotence, inability to ejaculate, nocturia, hematuria.

Other: Instances of rash, pruritus, ankle edema, excessive proliferation, weight gain, nasal congestion.

Some of the CNS and genitourinary symptoms may be related to the underlying disease rather than to drug therapy. The following laboratory tests have been found to be abnormal in a few patients receiving baclofen: increased SGOT, elevated alkaline phosphatase, and elevation of blood sugar.

OVERDOSE

Signs and symptoms: Vomiting, muscular hypotonia, drowsiness, accommodation disorders, coma, respiratory depression and seizures.

Treatment: In the alert patient, empty the stomach promptly by induced emesis followed by lavage. In the comatose patient, secure the airway with a cuffed endotracheal tube before beginning lavage (do not induce emesis). Maintain adequate respiratory exchange, do not use respiratory stimulants.

DOSAGE AND ADMINISTRATION

The determination of optimal dosage requires individual titration. Start therapy at a low dosage and increase gradually until optimum effect is achieved (usually between 40-80 mg daily).

The following dosage titration schedule is suggested:

5 mg t.i.d. for 3 days
10 mg t.i.d. for 3 days
15 mg t.i.d. for 3 days
20 mg t.i.d. for 3 days

Thereafter additional increases may be necessary but the total daily dose should not exceed a maximum of 80 mg daily (20 mg q.i.d.).

The lowest dose compatible with an optimal response is recommended. It benefits are not evident after a reasonable trial period, patients should be slowly withdrawn from the drug (see WARNINGS: Abrupt Drug Withdrawal).

HOW SUPPLIED

Baclofen Tablets, USP 10 mg are off-white, scored, oval-shaped tablets debossed “22 66” on one side and debossed “V” on the reverse side; and supplied as follows:

• Bottles of 10: NDC 0603-2406-10
• Bottles of 30: NDC 0603-2406-16
• Bottles of 90: NDC 0603-2406-02
• Bottles of 100: NDC 0603-2406-21
• Bottles of 500: NDC 0603-2406-29
• Bottles of 1000: NDC 0603-2406-32
• Bottles of 2500: NDC 0603-2406-30

Baclofen Tablets, USP 20 mg are off-white, scored, capsule-shaped tablets debossed “2268” on one side and debossed “V” on the reverse side; and are supplied as follows:

• Bottles of 10: NDC 0603-2407-10
• Bottles of 30: NDC 0603-2407-16
• Bottles of 90: NDC 0603-2407-21
• Bottles of 100: NDC 0603-2407-29
• Bottles of 500: NDC 0603-2407-32
• Bottles of 1000: NDC 0603-2407-30

Dispense in a tight container with child-resistant closure. Store at 20°-25°C (68°-77°F) (see USP Controlled Room Temperature).