

**CHENODAL
(chenodiol)****RATIONALE FOR INCLUSION IN PA PROGRAM****Background**

Chenodiol is the non-proprietary name for chenodeoxycholic acid, a naturally occurring human bile acid. At therapeutic doses, Chenodal (chenodiol) suppresses hepatic synthesis of cholesterol and cholic acid, and inhibit biliary cholesterol secretion, which leads to increased production of cholesterol unsaturated bile thereby allowing for dissolution of gallstones (1-2).

Regulatory Status

FDA-approved indication: Chenodal is indicated for patients with radiolucent stones in well-opacifying gallbladders, in whom selective surgery would be undertaken except for the presence of increased surgical risk due to systemic disease or age. The likelihood of successful dissolution is far greater if the stones are floatable or small. For patients with nonfloatable stones, dissolution is less likely and added weight should be given to the risk that more emergent surgery might result from a delay due to unsuccessful treatment. Safety of use beyond 24 months is not established. Chenodal will not dissolve calcified (radiopaque) or radiolucent bile pigment stones (2).

If partial dissolution is not seen by 9 to 12 months, the likelihood of success of treating longer is greatly reduced; Chenodal should be discontinued if there is no response by 18 months (2).

Because of the potential hepatotoxicity of Chenodal, poor response rate in some subgroups of Chenodal treated patients, and an increased rate of a need for cholecystectomy in other Chenodal treated subgroups, Chenodal is not an appropriate treatment for many patients with gallstones. Chenodal should be reserved for carefully selected patients and treatment must be accompanied by systematic monitoring for liver function alterations (2).

The optimal frequency of monitoring liver function tests is not known. It is suggested that serum aminotransferase levels should be monitored monthly for the first three months and every three months thereafter during Chenodal administration (2).

Serum cholesterol should be monitored at six months intervals. It may be advisable to discontinue Chenodal if cholesterol rises above the acceptable age-adjusted limit for given patient (2).

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Chenodal may cause fetal harm when administered to a pregnant woman. Chenodal is contraindicated in women who are or may become pregnant (2).

The safety and effectiveness of Chenodal in patients less than 18 years of age have not been established (2).

Summary

Chenodal (chenodiol) is indicated for patients with radiolucent stones in well-opacifying gallbladders, in whom selective surgery would be undertaken except for the presence of increased surgical risk due to systemic disease or age. The likelihood of successful dissolution is far greater if the stones are floatable or small. For patients with nonfloatable stones, dissolution is less likely and added weight should be given to the risk that more emergent surgery might result from a delay due to unsuccessful treatment. Safety of use beyond 24 months is not established. Chenodal will not dissolve calcified (radiopaque) or radiolucent bile pigment stones. Chenodal may cause fetal harm when administered to a pregnant woman. Chenodal is contraindicated in women who are or may become pregnant. The safety and effectiveness of Chenodal in pediatric patients have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Chenodal while maintaining optimal therapeutic outcomes.

References

1. Chenodal. Drug Facts and Comparisons. eFacts [online]. 2021. Available from Wolters Kluwer Health, Inc.
2. Chenodal [package insert]. San Diego, CA. Travere Therapeutics; July 2023.