Pan Mersey
Area Prescribing Committee

Prescribing Support Information

URSODEOXYCHOLIC ACID

AMBER patient retained by specialist

Your patient has been identified as being suitable to receive ursodeoxycholic acid in accordance with the indications detailed below. They have been started on treatment and have been reviewed to assess the efficacy and adverse effects of the treatment by the specialist team.

Ursodeoxycholic acid has been considered as appropriate for prescribing in primary care and the information contained in this document has been provided to support you to prescribe it for your patient in the community. Your patient's dose is now stable and is detailed in the attached clinic letter.

Your patient will remain under the care of the specialist team whilst receiving this medicine.

Indications

- Primary biliary cholangitis
- Dissolution of gallstones
- Hepatobiliary disorders associated with cystic fibrosis in children aged 6-18 years
- Total parenteral nutrition (TPN) -induced cholestasis in children (off label use)

Drug, Form and Dose

Tablets 150 mg, 250mg, 300 mg, 500mg
Capsules 250 mg
Suspension 250mg in 5ml

Primary biliary cholangitis

The dose is 12-15mg/kg/day (Stages I-III of primary biliary cholangitis) which is equivalent to around 600-1000mg, taken in two or three divided doses daily.

Any dose titration will be carried out by the specialist.

Dissolution of gallstones

A daily dose of 8 to 12mg/kg/day will produce cholesterol desaturation in most cases. The specialist is responsible for establishing the minimum effective dose. The daily dose for most patients is 600-900mg, according to body weight. The dose should be taken as a single dose or divided into two, and taken after meals, with one dose always after the evening meal.

The duration of treatment needed to achieve dissolution will not usually exceed 2 years. Treatment should be continued for 3-4 months after the radiological disappearance of gallstones. In some cases, stones may recur after successful treatment.

Hepatobiliary disorders associated with cystic fibrosis

The dose is 10-15mg/kg twice daily. Alternatively, the total daily dose can be given in 3 divided doses. It is licensed for children aged 6-18 years and hepatobiliary disorders normally become an issue in teenagers. At 18 years, patients transfer to adult services and will remain under specialist care with life-long 6-8 weekly reviews. No monitoring is required in primary care; it is all carried out in the hospital. Ursodeoxycholic acid may be used under the age of 6 under the direction of the specialist CF consultant only.

TPN-induced cholestasis in children

For all ages, including neonates, the dose is 10mg/kg 3 times a day. Cholestasis is reversible when TPN is discontinued, provided enteral feeding is started before irreversible liver damage has occurred.

Monitoring recommendations

Primary biliary cholangitis: the SPC recommends that liver function should be monitored every 4 weeks for 3 months, then every 3 months. This is to monitor disease progress and not drug toxicity. However, the local expert view is that monitoring every 6-12 months is appropriate. The specialist will determine the exact frequency of monitoring and notify the GP.

Gallstones: the specialist is responsible for determining the frequency of ultrasound monitoring and will provide the patient with the necessary appointments.

Cystic fibrosis: patients will be followed up regularly in secondary care.

TPN-induced cholestasis: patients will be followed up in secondary care. For patients who are clinically unstable, the trust would continue to prescribe.

How long the medicine should be prescribed for

The specialist will determine the duration of treatment and this will be communicated to the GP. For dissolution of gallstones, duration of treatment does not usually exceed 2 years. For patients with primary biliary cholangitis and cystic fibrosis, treatment is lifelong, if tolerated. For patients with TPN – induced cholestasis, the specialist would stop ursodeoxycholic acid once the Gamma GT level normalises.

Contra-indications

Acute inflammation of the gall bladder; frequent episodes of biliary colic; inflammatory diseases and other conditions of the colon, liver or small intestine which interfere with enterohepatic circulation of bile salts; non-functioning gall bladder; radio-opaque stones.

Unsuccessful portoenterostomy or without recovery of good bile flow in children with biliary atresia

Adverse effects

For a comprehensive list consult the BNF or Summary of Product Characteristics.

Special warnings/cautions

Use with caution in liver disease. The manufacturers advise to avoid in pregnancy and lactation.

In patients with advanced primary biliary cholangitis: If diarrhoea occurs, the dose must be reduced and in cases of persistent diarrhoea, the therapy should be discontinued.

For a comprehensive list consult the BNF or Summary of Product Characteristics.

Interaction with other medicines

For a comprehensive list consult the BNF or Summary of Product Characteristics.
Seek advice from the initiating Specialist if there are any concerns about interactions.

Please contact the specialist team if any of the following occur:

- If the patient suffers any adverse reactions
- If the patient decides to discontinue treatment for any reason
- Any deterioration in symptoms should be reported to the specialist team, particularly an increase in fatigue or itch[3].

Contact details for advice

Please refer to the contact details included in the clinic letter issued by the specialist.

Additional Information

Patients with gallstones should be given dietary advice (including avoidance of excessive cholesterol and calories). Although ursodeoxycholic acid is licensed for the treatment of gallstones, it is not recommended in CKS[4] or NICE[5] guidance.

There is a greater risk of osteoporosis in patients with primary biliary cholangitis so general lifestyle advice to prevent loss of bone density (weight-bearing exercise, smoking cessation, minimising alcohol intake, etc) should be provided.

References

1. Summary of Product Characteristics. Accessed 16/01/2020 SPC
2. British National Formulary. Accessed 16/01/2020 BNF
3. The British Society of Gastroenterology/UK-PSC primary biliary cholangitis treatment and management guidelines 2019. BSG and UK-PSC guidelines
4. NICE CG 188. Gallstone disease: diagnosis and management. October 2014. NICE
5. NICE Clinical Knowledge Summary. Gallstones. June 2019. Gallstones - NICE CKS