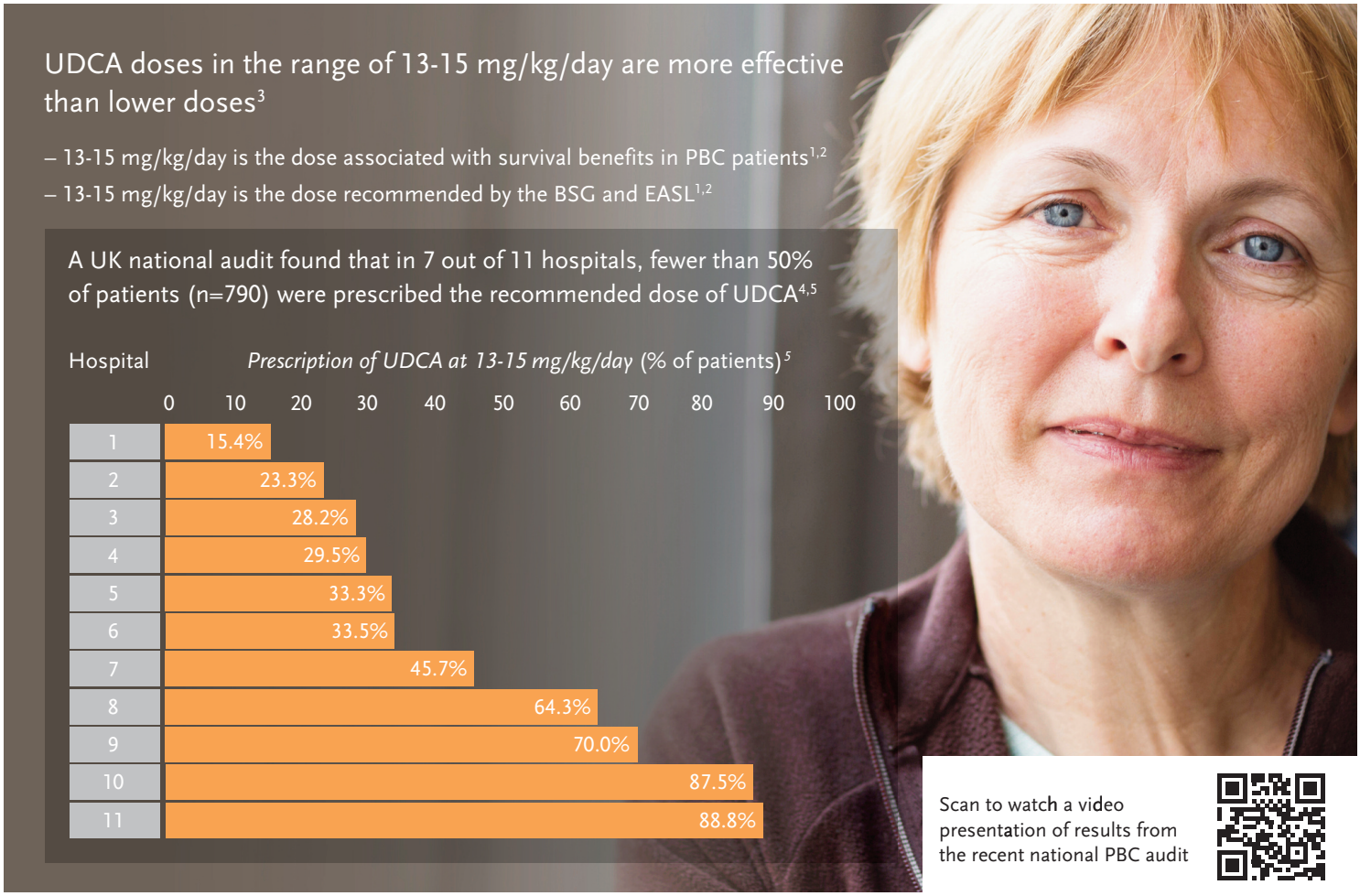
UDCA is a life-long treatment for PBC

The length of that life may depend on the UDCA dose[1-3]



UDCA doses in the range of 13-15 mg/kg/day are more effective than lower doses[3]

– 13-15 mg/kg/day is the dose associated with survival benefits in PBC patients[1,2]
– 13-15 mg/kg/day is the dose recommended by the BSG and EASL[1,2]

A UK national audit found that in 7 out of 11 hospitals, fewer than 50% of patients (n=790) were prescribed the recommended dose of UDCA[4,5]

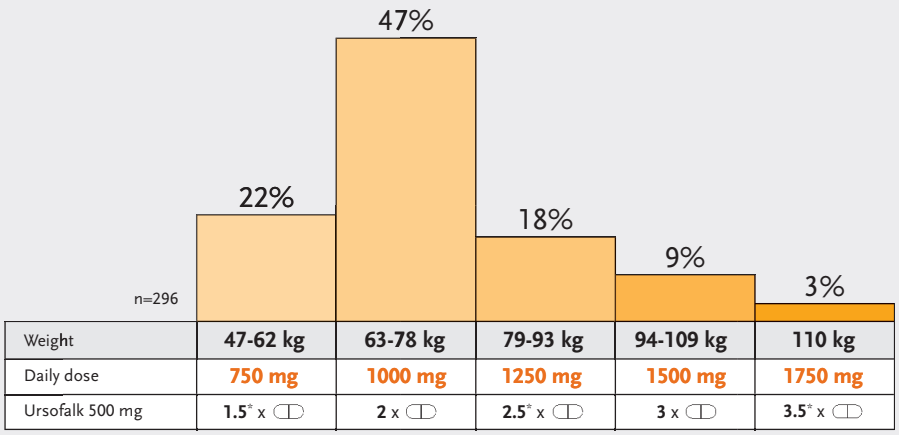
Scan to watch a video presentation of results from the recent national PBC audit

Weight monitoring should be part of regular patient review[6]

Pill burden should also be considered[7]

97% of patients would be adequately dosed on three or fewer Ursofalk 500 mg tablets per day[8,9]

Weight distribution of UK PBC patients with correct dosing options[8,9]



Weight	47-62 kg	63-78 kg	79-93 kg	94-109 kg	110 kg
Daily dose	750 mg	1000 mg	1250 mg	1500 mg	1750 mg
Ursofalk 500 mg	1.5* x	2 x	2.5* x	3 x	3.5* x

*the 500 mg pill is scored so it can be split into 2 x 250 mg half tablets

Prescribing information is available on page 2

Ursofalk®
ursodeoxycholic acid

Together we *know more.*
Together we *do more.*

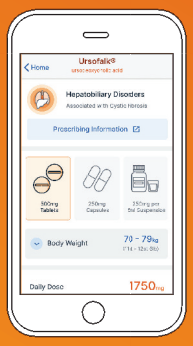
Want a simple way to check that dose is weight appropriate?

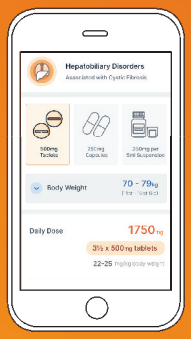
Check out our smartphone apps available in the App Store or Google Play

For you

Search for 'Ursofalk HCP App'

Check if your patient is on the right UDCA dose for their weight whether they're on tablets, capsules or oral suspension





For your patients

Search for 'UDCA Dosing App for Patients'

Makes it simple for patients to check their own dose, whatever formulation of UDCA they take

Prescribing Information (Refer to full SPC before prescribing).
Presentations: Ursofalk 250mg hard capsules containing 250mg ursodeoxycholic acid (UDCA), Ursofalk 250mg/5ml suspension, containing 250mg UDCA per 5ml suspension, Ursofalk 500mg film-coated tablets containing 500mg UDCA. **Indications:** Treatment of primary biliary cirrhosis (cholangitis) (PBC) where there is no decompensated hepatic cirrhosis; stages I-III. Dissolution of radiolucent cholesterol gallstones of less than 15mm, in patients with a functioning gall bladder. Paediatric population: hepatobiliary disorders associated with cystic fibrosis in children aged 6 to 18 years (capsules and tablets) or 1 month to 18 years (suspension). **Dosage:** For PBC - adults and elderly: 12-16mg UDCA/kg/day in 3 divided doses during the first three months and once daily in the evening when liver values improve. For gallstones: approximately 10mg UDCA/kg/day taken in the evening. Follow up cholecystograms may be useful. Children: PBC and gallstones are rare in children and adolescents. Data are limited. Dose should be related to body weight and condition. For hepatobiliary disorders associated with cystic fibrosis in children aged 1 month to 18 years: 20 mg/kg/day in 2-3 divided doses, with a further increase to 30 mg/kg/day if necessary. **Contra-indications:** Acute inflammation of the gall bladder or biliary tract. Occlusion of the biliary tract. Radio opaque gall bladder. Frequent episodes of biliary colic. Radio-opaque calcified gallstones. Impaired contractility of the gall bladder. Hypersensitivity to bile acids or any excipient of the formulation. When used for hepatobiliary disorders associated with cystic fibrosis in children aged 1 month to 18 years - unsuccessful portoenterostomy or without recovery of good bile flow in children with biliary atresia. **Warnings/Precautions:** Carry out liver function tests every 4 weeks in the first 3 months of treatment, then every 3 months. Decompensation of hepatic cirrhosis may occur when used for advanced PBC, which partially regresses on discontinuation of treatment. Rarely, in PBC, clinical symptoms may worsen. Reduce dose to 250mg daily and gradually increase to recommended dose. Monitor gallstone dissolution with oral cholecystography, ultrasound control, at 6 - 10 months after starting treatment. Stop treatment in cases of persistent diarrhoea. 5ml suspension contains 11 mg sodium, equivalent to 0.6 % of the WHO recommended maximum daily intake of 2 g sodium for an adult. 5ml suspension also contains 7.5 mg benzoic acid which may increase jaundice in neonates and 50 mg propylene glycol which may induce serious adverse effects in neonates. **Interactions:** Cholestyramine, colestipol and certain antacids (e.g. aluminium hydroxide, aluminium oxide) bind bile acids and may interfere with absorption/efficacy. Leave a 2-hour gap between taking these substances and Ursofalk. The absorption of ciclosporin may be affected and absorption of ciprofloxacin and nitrendipine reduced. Concomitant UDCA and rosuvastatin resulted in slightly elevated plasma levels of rosuvastatin. Therapeutic effect of dapsone may also be affected. Oestrogenic hormones and cholesterol lowering agents e.g. clofibrate, increase biliary lithiasis. **Use in pregnancy:** There are no adequate data. Use only in pregnancy if clearly necessary. When treating women of childbearing potential non-hormonal or low oestrogen oral contraceptive measures are recommended.
If used for gallstone dissolution, then effective non-hormonal contraception should be used. No adverse reactions are expected in breastfed infants. **Undesirable effects:** Pasty stools, diarrhea (common). Upper abdominal pain (in PBC treatment), calcification of gallstones, decompensation of hepatic cirrhosis, urticaria (very rarely). **Legal category:** POM. Cost: Ursofalk 250mg capsules, 100-capsule pack: £31.88; €23.69. 60-capsule pack: £30.17. Ursofalk 250mg/5ml suspension, 250ml bottle: £26.98, €26.66. Ursofalk 500mg tablet, 100-tablet pack: £80; €51.51. **Product licence holder:** In the UK: Dr Falk Pharma UK Ltd; Unit K, Bourne End Business Park, Cores End Road, Bourne End, SL8 5AS. In Ireland: Dr. Falk Pharma GmbH, Leinenweberstrasse 5, 79108 Freiburg, Germany. **Product licence number:** Ursofalk capsules: PL10341/0006; PA573/5/1. Ursofalk suspension: PL10341/0007; PA573/5/2. Ursofalk tablets: PL10341/0010; PA573/5/3. Date of preparation: January 2023

Further information is available on request.

Adverse events should be reported. In the UK, visit www.mhra.gov.uk/yellowcard. In Ireland, visit https://www.hpra.ie/homepage/about-us/report-an-issue/human-adverse-reaction-form Adverse events should also be reported to Dr Falk Pharma UK Ltd at PV@drfalkpharma.co.uk

Abbreviations:
BSG: British Society of Gastroenterology
EASL: European Association for the Study of the Liver
PBC: primary biliary cholangitis
UDCA: ursodeoxycholic acid

References

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5. Sivakumar M *et al.* Presented at BSG Campus, January 2021. Available at: www.youtube.com/watch?v=MnRW6x4umEc Accessed on: 24.02.21
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Date of preparation: March 2023
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To download your copy of the Ursofalk 500mg tablet leaflet please scan here:

www.drfalk.co.uk
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ursodeoxycholic acid