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New Ursofalk 500mg reinforces Dr Falk philosophy of patient centred medicine.

Dr Falk Pharma has announced the launch of Ursofalk 500mg (active substance Ursodeoxycholic acid) in response to the growing awareness of the need to reduce patient medicine burden.

Ursodeoxycholic acid is the first line and only licensed treatment for Primary Biliary Cirrhosis (1) (PBC) a lifelong and potentially life threatening liver disease. Formerly only available as a 250mg capsule dose, the new 500mg strength will halve the number of tablets that patients are required to take. It will be of particular benefit to PBC sufferers who as well as often enduring a high medicine burden suffer from side effects such as dry mouth, which makes swallowing several tablets at once difficult.

The 500mg launch comes as a new survey of over 500 PBC patients (2) highlights this issue. Those surveyed took an average of between four and five different medications each day (2) with around 6% taking more than ten medications per day and 1% on more than 20 different medications per day. Perhaps not surprisingly, 79% of respondents would prefer a once daily dose of Urso compared to the 30% who are currently being offered it.

‘There is a significant issue with PBC patients passively or actively not taking tablets,’ says Professor David Jones, consultant hepatologist at Newcastle Hospitals NHS Trust and lead of the UK PBC Consortium. ‘Patients are human and although some of them will be organised others are not. They may struggle with brain fog or dry mouth or they may simply forget. However, we know that not taking the correct dosage of Urso has, for a number of patients, a direct link to a poorer long term outcome than if they took the optimum dosage of 15mg per kilo body weight.

‘On the standard 250mg tablet, an average weight PBC patient may be taking around four to six tablets of Urso per day or more. That is a lot of tablets to swallow, particularly when taken on top of other medications. If, with the 500mg tablet you halve their Urso burden to two to three tablets, especially as they can take them all at once, the patient is far more likely to comply with their regimen. In the long run this will save lives. ’

In addition, according to the independent survey, carried out by the charity The PBC Foundation many patients are currently being underprescribed ursodeoxycholic acid.

Whilst 31% of patients weighed more than 80kg only 12.4% of the patients surveyed were on a 1000 mg/day a dosage, the minimum dosage for that weight. Further whilst the dosage of Urso should be strictly weight related more than 33 % of survey respondents were weighed less than once a year.(2)

‘This survey shows that, in the UK, some PBC patients are being significantly underdosed with Urso,’ says Dr Riadh Jazrawi, Medical Director of Dr Falk Pharma. ‘This may be one reason why the PBC outcomes in Europe, where optimum dosage is more usual, are better than here in the UK. (4) However not only are the patients being underdosed, but often they are struggling to comply with the regimen they are given.

‘A central ethos of Dr Falk Pharma is to provide patient centred medicines. We strongly believe that, by making the dosage regimen easier for patients to follow in the short term, the Ursofalk 500mg will over the long term, lead to better patient outcomes.’

Ends

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- 1) GASTROENTEROLOGY 2005;128:297-303
- (2) The PBC Foundation: Living with PBC Survey 2013
- (3) HEPATOLOGY, 2007;p 963 - 965

Notes to Journalists.

Primary Biliary Cirrhosis is a slow-acting, chronic liver disease, which causes progressive destruction of the microscopic bile ducts in the liver. The body's own defence mechanisms attack the cells lining the bile ducts within the liver as if they are foreign invaders. There is no known cause of PBC.

The resulting damage impairs the drainage of bile, and the build up of bile acids causes inflammation and scarring which may after many years become extensive. This replacement of liver cells by fibrous tissue is called cirrhosis, and it may eventually obstruct the flow of blood through the liver so that it can no longer function normally. However, many people who have PBC never progress to the stage of cirrhosis.

Ursodeoxycholic Acid is the only current approached and licensed treatment for PBC and has been proven to slow down the progress of the disease. It has been suggested that it has modulatory effects on the immune system, reduces bile acid flow, and provides cytoprotection which reduces the overall damage caused to the liver.

Gut 1995;37;301-304 A G Lim, R P Jazrawi and T C Northfield

Ursofalk is coded DrF13/136