Takeda

Spring Meeting

Park Avenue Hotel, Belfast
Friday March 29th, 2019

usg Ulster Society of Gastroenterology

Life feels good when they're under control[1-8]

Entocort® CR
Budesonide 3mg capsules

CROHN'S DISEASE
Indicated for the induction of remission in patients with mild to moderate active Crohn's disease affecting the ileum and/or the ascending colon[9]

Entocort® CR
Budesonide 3mg capsules

MICROSCOPIC COLITIS
Indicated for the induction and maintenance of remission in patients with microscopic colitis[9]

Entocort® CR is the ONLY LICENSED TREATMENT for the induction and maintenance of remission in microscopic colitis[9]

Entocort® Enema
Budesonide

ULCERATIVE COLITIS
Indicated for ulcerative colitis involving rectal and recto-sigmoid disease[10]

ENTOCORT CR 3mg Capsules (budesonide) - Prescribing Information
Please consult the Summary of Product Characteristics (SmPC) for full prescribing Information
Presentation: Hard gelatin capsules for oral administration with an opaque, light grey body and an opaque, pink cap marked CIR 3mg in black radial print. Contains 3mg budesonide. **Indications:** Induction of remission in patients with mild to moderate Crohn's disease affecting the ileum and/or the ascending colon. Induction of remission in patients with active microscopic colitis. Maintenance of remission in patients with microscopic colitis. **Dosage and administration:** *Active Crohn's disease (Adults):* 9mg once daily in the morning for up to eight weeks. Full effect achieved in 2-4 weeks. When treatment is to be discontinued, dose should normally be reduced in final 2-4 weeks. *Active microscopic colitis (Adults):* 9mg once daily in the morning. *Maintenance of microscopic colitis (Adults):* 6mg once daily in the morning, or the lowest effective dose. *Paediatric population:* Not recommended. *Older people:* No special dose adjustment recommended. Swallow whole with water. Do not chew. **Contraindications:** Hypersensitivity to the active substance or any of the excipients. **Warnings and Precautions:** Side effects typical of corticosteroids may occur. Visual disturbances may occur. If a patient presents with symptoms such as blurred vision or other visual disturbances they should be considered for referral to an ophthalmologist for evaluation of the possible causes. Systemic effects may include glaucoma and when prescribed at high doses for prolonged periods, Cushing's syndrome, adrenal suppression, growth retardation, decreased bone mineral density and cataract. Caution in patients with infection, hypertension, diabetes mellitus, osteoporosis, peptic ulcer, glaucoma or cataracts or with a family history of diabetes or glaucoma. Particular care in patients with existing or previous history of severe affective disorders in them or their first degree relatives. Caution when transferring from glucocorticoid of high systemic effect to Entocort CR. Chicken pox and measles may have a more serious course in patients on oral steroids. They may also suppress the HPA axis and reduce the stress response. Reduced liver function may increase systemic exposure. When treatment is discontinued, reduce dose over last 2-4 weeks. Concomitant use of CYP3A inhibitors, such as ketoconazole and cobicistat-containing products, is expected to increase the risk of systemic side effects and should be avoided unless the benefits outweigh the risks. Excessive grapefruit juice may increase systemic exposure and should be avoided. Patients with fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take Entocort CR. Monitor height of children who use prolonged glucocorticoid therapy for risk of growth suppression. **Interactions:** Concomitant colestyramine may reduce Entocort CR uptake. Concomitant oestrogen and contraceptive steroids may increase effects. CYP3A4 inhibitors may increase systemic exposure. CYP3A4 inducers may reduce systemic exposure. May cause low values in ACTH stimulation test. **Fertility, pregnancy and lactation:** Only to be used during pregnancy when the potential benefits to the mother outweigh the risks for the foetus. May be used during breast feeding. **Adverse reactions:** *Common:* Cushingoid features, hypokalaemia, behavioural changes such as nervousness, insomnia, mood swings and depression, palpitations, dyspepsia, skin reactions (urticaria, exanthema), muscle cramps, menstrual disorders. *Uncommon:* anxiety, tremor, psychomotor hyperactivity. *Rare:* aggression, glaucoma, cataract, blurred vision, ecchymosis. *Very rare:* Anaphylactic reaction, growth retardation. Prescribers should consult the summary of product characteristics in relation to other adverse reactions. **Marketing Authorisation Numbers, Package Quantities and basic NHS price:** PL 36633/0006. Packs of 100 capsules: £84.15. **Legal category:** POM. **Marketing Authorisation Holder:** Tillotts Pharma UK Ltd, The Stables, Wellingore Hall, Wellingore, Lincoln, LN5 0HX. Date of preparation of PI: November 2018

ENTOCORT (budesonide) ENEMA - Prescribing Information
Please consult the Summary of Product Characteristics (SmPC) for full prescribing Information
Presentation: 0.02 mg/ml budesonide (2 mg budesonide/100 ml) solution for rectal suspension. Each Entocort Enema consists of 2 components: a 2.3 mg faintly yellow, circular biconvex tablet with the engraving BA1 on one side and 2.3 on the other side; a 115 ml clear colourless solution. **Indications:** Ulcerative colitis involving rectal and recto-sigmoid disease. **Dosage and administration:** Route of administration: rectal. *Adults:* One Entocort Enema nightly for 4 weeks. Full effect is usually achieved within 2–4 weeks. If the patient is not in remission after 4 weeks, treatment may be prolonged to 8 weeks. *Paediatric population:* Not recommended. *Older people:* Dosage as for adults. No dosage reduction in patients with reduced liver function. Instruct the patient to read the instructions for use. Reconstitute the enema immediately before use. Ensure the tablet is completely dissolved. Administer in the evening before bed. **Contraindications:** Hypersensitivity to the active substance or the excipients. **Warnings and Precautions:** Side effects typical of corticosteroids may occur, including glaucoma. Visual disturbances may occur. If a patient presents with symptoms such as blurred vision or other visual disturbances they should be considered for referral to an ophthalmologist for evaluation. When patients are transferred from steroids of higher systemic effect they may have adrenocortical suppression; monitoring may be considered and the dose of systemic steroid should be reduced cautiously. Replacement of high systemic effect steroid treatment with Entocort enema sometimes unmasks allergies which were previously controlled by the systemic drug. Reduced liver function affects the elimination of glucocorticosteroids, causing lower elimination rate and higher systemic exposure, with possible systemic side effects. Care when considering systemic corticosteroids in patients with existing or previous history of severe affective disorders in themselves or first degree relatives e.g. depressive or manic-depressive illness and previous steroid psychosis. Systemic effects of steroids may occur, particularly at high doses and for prolonged periods, including Cushing's syndrome, adrenal suppression, growth retardation, decreased bone mineral density, cataract, glaucoma and very rarely a wide range of psychiatric/behavioural effects. Contains lactose and methyl-, propyl-parahydroxybenzoate. Caution in patients with hypersensitivity to these. Some patients may feel unwell in a non-specific way during withdrawal. When Entocort Enema is used chronically in excessive doses, systemic glucocorticosteroid effects may appear. However, the dosage form and the route of administration make any prolonged overdosage unlikely. **Interactions:** Raised plasma concentrations and enhanced effects of corticosteroids have been reported in women also treated with oestrogens and contraceptive steroids. Inhibitors of CYP3A4 can increase systemic exposure to budesonide several times and the combination should be avoided. If this is not possible, the period between treatments should as long as possible, and a reduction of the budesonide dose could also be considered. Other potent inhibitors of CYP3A4 are also likely to markedly increase plasma levels of budesonide. Concomitant treatment with CYP3A4 inducers may reduce budesonide exposure and require a dose increase. Because adrenal function may be suppressed, an ACTH stimulation test for diagnosing pituitary insufficiency might show low values. **Fertility, pregnancy and lactation:** Only to be used during pregnancy when the potential benefits to the mother outweigh the risks for the foetus. May be used during breast feeding. **Adverse reactions:** *Common:* depression, gastrointestinal disturbances (flatulence, nausea, diarrhoea), skin reactions (urticaria, exanthema). *Uncommon:* agitation, insomnia, anxiety, psychomotor hyperactivity, duodenal or gastric ulcer. *Rare:* signs or symptoms of systemic glucocorticosteroid effects, aggression, glaucoma, cataract including subcapsular cataract, blurred vision, pancreatitis, ecchymosis, osteonecrosis. *Very rare:* anaphylactic reaction. Prescribers should consult the summary of product characteristics in relation to other adverse reactions. **Marketing Authorisation Numbers, Package Quantities and basic NHS price:** PL 36633/0007. Packs of 7 enemas: £33.66. **Legal category:** POM. **Marketing Authorisation Holder:** Tillotts Pharma UK Ltd, The Stables, Wellingore Hall, Wellingore, Lincoln, LN5 0HX. Date of preparation of PI: March 2018

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk. Adverse events should also be reported to Tillotts Pharma UK Ltd. Tel: 01522 813500.

References: **1.** Greenberg GR *et al.* N Engl J Med 1994;331:836-841. **2.** Rezaie A *et al.* Cochrane Database Syst Rev 2015;6:CD000296. **3.** Madisch A *et al.* Int J Colorectal Dis 2005;20(4):312-316. **4.** Hofer KN. Ann Pharmacother 2003;37:1457-1464. **5.** Miehlke S *et al.* Gastroenterology 2008;135:1510-1516. **6.** Gross V *et al.* Aliment Pharmacol Ther 2006;23:303-312. **7.** Hartmann F *et al.* Aliment Pharmacol Ther 2010;32(3):368-376. **8.** Danielsson A *et al.* Scand J Gastroenterol 1992;27(1):9-12. **9.** Entocort® CR 3mg Capsules – Summary of Product Characteristics. November 2018. **10.** Entocort® Enema – Summary of Product Characteristics. March 2018.

Date of preparation: December 2018.
PU-00225.

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Welcome to Spring USG 2019

Dear Gastroenterology enthusiast,

Welcome to the Spring USG meeting which follows the time honoured format of a half-day meeting. I am sure that you will find something of interest.

After a good lunch we start with Nigel Trudgill, who missed the Autumn meeting due to bad weather. It is great that he has agreed to come again so that we get to hear his important message about "Post OGD Upper Gastrointestinal Cancer"

We then have the ever popular "Hot Topics", which this time are Viral hepatitis, C difficile and faecal transplant, and Complications of pancreatic cancer. Each of these topics will be delivered in 10 minutes by local presenters who are renowned for these areas of special interest. Hot topics wonderfully concentrate the mind!

Our last session has two very eminent visitors: Profs Janusz Jankowski and Mark Hull to talk about their chemoprevention trials. Many gastroenterologists in Northern Ireland were involved in the AspECT trial. The results were published in the Lancet last Autumn so it is very timely to hear about the outcomes from the Chief Investigator himself. We are also fortunate to have the CI of the seafood Polyp Prevention trial to discuss the results of his trial. With the emphasis increasingly on prevention of disease this session should be a great opportunity to consider how the gastroenterology community can or should become involved in this approach to reducing morbidity and mortality of GI cancers.

Of course the meeting gives us a wonderful opportunity to catch up with friends, to network and learn about treatments and devices demonstrated by our pharma and industry colleagues. Please enjoy the meeting and as ever we welcome your feedback.

Peter Watson
President USG

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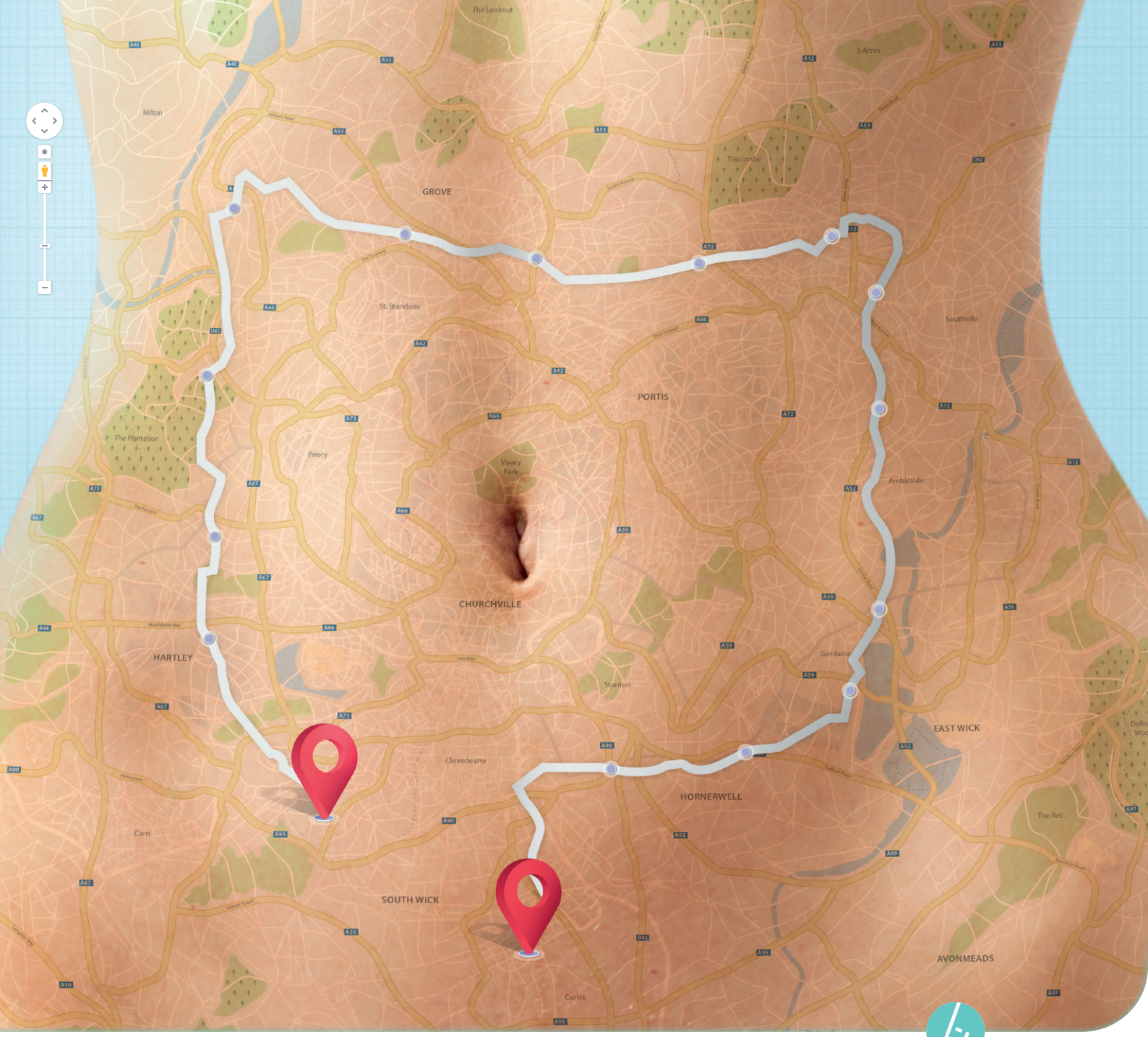
USG Spring Meeting
Friday 29th March 2019

Programme

12.00	**Registration**
12.30	**Lunch** **Meet-the-Industry**
13.20	**Welcome** **Dr Peter Watson,** USG President
	USG Bursaries 2019 **Dr Philip Hall,** USG Treasurer
SESSION 1	***Upper GI*** Chairs: **Mr Tim McAdam** and **Dr Shivaram Bhat**
13.30	***Post OGD Upper Gastrointestinal Cancer*** **Dr Nigel Trudgill,** Consultant Gastroenterologist, Sandwell and West Birmingham Hospitals
SESSION 2	***Hot topics in Gastroenterology*** Chairs: **Mr Tim McAdam** and **Dr Shivaram Bhat**
14.00	***Hot topics: Viral hepatitis*** **Dr Conor Braniff,** Consultant Hepatologist, Royal Victoria Hospital, Belfast
14.10	***Hot topics: C.diff/faecal transplant*** **Dr Andrew Murdock,** Consultant Gastroenterologist, Southern HSCT
14.20	***Hot topics: Complications of pancreatic surgery*** **Ms Claire Jones,** Consultant HPB and General Surgeon, Belfast HSCT
14.30	***Hot Topics Q&A***
14.40	**Tea and coffee break** **Meet-the-Industry**
SESSION 3	***Chemoprevention Trials*** Chairs: **Dr Peter Watson** and **Dr Helen Coleman**
15.10	***Esomeprazole and aspirin in Barrett's oesophagus (AspECT): a randomised factorial trial.*** **Prof Janusz Jankowski,** Health Policy Adviser and Senior Consultant Physician, University Hospitals Morecambe Bay and NICE.
15.40	***Eicosapentaenoic acid and aspirin, alone and in combination, for the prevention of colorectal adenomas (seAFOod Polyp Prevention trial): a multicentre, randomised, double-blind, placebo-controlled, 2 × 2 factorial trial.*** **Prof Mark Hull,** Clinical Scientist and Consultant Gastroenterologist, University of Leeds.
16:10	***Chemoprevention Trials Q&A***
16:25	***Summary of day & Closing remarks***



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For flaring mild to moderate UC patients

Prescribing Information: Cortiment® 9 mg, prolonged release tablets. **Please consult the full Summary of Product Characteristics before prescribing. Name of Product(s):** Cortiment® 9 mg, prolonged release tablets. **Composition:** One tablet contains 9 mg of budesonide. **Indication:** Induction of remission in patients with mild to moderate active ulcerative colitis where 5-ASA treatment is not sufficient. **Dosage:** *Adults:* The recommended daily dose for induction of remission is one 9 mg tablet in the morning, for up to 8 weeks. When treatment is discontinued, it may be useful to gradually reduce the dose. *Children:* No data are available, therefore the use in paediatric population is not recommended until further data become available. **Contraindications:** Hypersensitivity to the active substance, soya oil, peanut oil or to any of the excipients of the product. **Special Warnings and Precautions:** Caution is recommended in patients with infections, hypertension, diabetes mellitus, osteoporosis, peptic ulcer, glaucoma or cataracts or with a family history of diabetes or glaucoma or with any other condition where the use of glucocorticoids may have unwanted effects. Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare condition diseases such as Central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids. Reduced liver function may affect the elimination of glucocorticoids including budesonide, causing higher systemic exposure. Treatment with Cortiment tablets results in lower systemic steroid levels than conventional oral glucocorticoid therapy. As corticosteroids are known to have immunological effects the co-administration of Cortiment tablets is likely to reduce the immune response to vaccines. Concomitant administration of ketoconazole or other potent CYP3A4 inhibitors should be avoided. *Pregnancy:* Cortiment should only be used during pregnancy if the potential benefit justifies the potential risk to the foetus. **Side effects:** For the full list of side effects please consult the Summary of Product Characteristics. *Common:* nausea, abdominal pain upper, abdominal distension, abdominal pain, dry mouth, dyspepsia, headache, insomnia, acne, fatigue, myalgia, blood cortisol decreased. *Uncommon:* Flatulence, dizziness, mood altered, oedema peripheral, back pain, muscle spasms, influenza, leukocytosis. **Nature and Contents of Container:** The tablets are packaged in blister packs with aluminium push through foil, contained in a cardboard carton. **Marketing Authorisation Number:** *Tablets* 9 mg: 03194/0113. **Marketing Authorisation Holder:** Ferring Pharmaceuticals Ltd., Drayton Hall, Church Road, West Drayton, UB7 7PS, United Kingdom. **Legal Category:** POM. **Basic NHS Price:** £75.00 for 30 x 9 mg tablets. **Date of Preparation of Prescribing Information:** June 2017. Cortiment is a registered trademark. **COR/2152/2017/UK; Date of preparation:** August 2017.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Ferring Pharmaceuticals Ltd. Tel: 0844 931 0050. Email: medical@ferring.com

References: 1. Brunner M, *et al. Br J Clin Pharmacol.* 2006;61(1):31–8. **2.** Fiorino G, *et al. Curr Med Chem.* 2010;17(17):1851–7. **3.** Travis SPL, *et al. Gut.* 2014;63:433–41. doi:10.1136/gutjnl-2012-304258. **4.** Sandborn WJ, *et al. Gastroenterology.* 2012;143:1218–1226. **5.** Cortiment 9mg, Prolonged Release Tablets. SmPC. **6.** Entocort CR 3mg Capsules. SmPC. **7.** Budenofalk 3mg Gastro-resistant Capsules. SmPC.

Date of preparation: March 2018.
Job Code: COR/439/2018/UKa

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Mr Tim McAdam
Consultant Colorectal Surgeon
Belfast Trust

Organising Team

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Event Organiser USG

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Biographical Sketches

Dr Nigel Trudgill
Consultant Gastroenterologist,
Sandwell and West Birmingham Hospitals

Consultant Gastroenterologist, Deputy Medical Director and Responsible Officer at Sandwell and West Birmingham Hospitals NHS Trust, West Midlands, UK. Graduated Sheffield University in 1988. Chair of BSG oesophageal section committee and member BSG endoscopy committee.. Leads regional oesophageal manometry and reflux monitoring service. Screening Centre Director Sandwell and West Birmingham Bowel Cancer Screening Centre. Director of Royal College of Physicians Medical Workforce Unit. Current President of Midlands Gastroenterological Society. Current research interests in health informatics in gastroenterology and endoscopy quality.

Dr Conor Braniff
Consultant Hepatologist
Royal Victoria Hospital, Belfast.

Conor Braniff is a Hepatologist in the Royal Victoria Hospital, Belfast. He trained in Northern Ireland along with Perth and Dublin. He is interested in the management of viral hepatitis.

Ms Claire Jones
Consultant HPB and General Surgeon,
Belfast HSCT

Miss Claire Jones is a consultant HPB surgeon and clinical lead in the regional HPB unit in the Mater Hospital, Belfast. She completed her surgical training in Northern Ireland followed by an HPB fellowship in Queens Medical Centre, Nottingham. She has an interest in leadership, having had a role in AUGISt and completed the Lady Estelle Wolfson fellowship, RCSEng. Clinically Claire has a particular interest in pancreatic cancer and minimally invasive HPB surgery.

Prof Janusz Jankowski
Health Policy Adviser and Senior Consultant Physician, University Hospitals Morecambe Bay and NIC

Janusz is an expert in creating Collegiate Cultural Change, Successful Functional Teams and National Policy Impacts. Janusz has trained and taught in pre-eminent Universities e.g. Oxford, Cambridge, London, and San Francisco.
His research, including in Nature and Lancet series journals, is rated world-class (h-index>68).
He is currently a National Policy Adviser but previous senior leadership experience includes a range of Higher Education and Public roles including Charity CEO, Pro/Deputy Vice Chancellor Research and Innovation, Dean for Research & International Research Committee Chair.
He built successful Innovation Teams winning many National Prizes for Enterprise in the UK & EU. He has engaged in Knowledge Transfer winning awards for Education, Mentoring & Research.

Prof Mark Hull
Clinical Scientist and Consultant Gastroenterologist, University of Leeds

Professor Mark Hull PhD FRCP is a Clinician Scientist and Consultant Gastroenterologist with a research interest in the molecular basis of colorectal carcinogenesis and colorectal cancer prevention. He trained in Biochemistry at the University of Cambridge and Medicine at the University of Oxford. His PhD studies investigated NSAIDs and gastric ulcer healing at the University of Nottingham. He has previously been awarded MRC Clinician Scientist and Senior Clinical Fellowships. He has been awarded the Linacre Medal by the Royal College of Physicians of London and the President's Medal by the British Society of Gastroenterology. He is currently National Lead for Gastroenterology for the NIHR Clinical Research Network.

Dr Andrew Murdock
Consultant Gastroenterologist,
Southern HSCT

I Co Chair the Northern Ireland GI Small Working Group and represent the region on the IBD UK Standards Review Group.

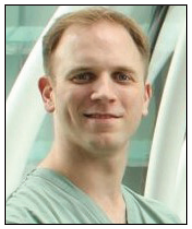
USG Committee Members

Dr Peter Watson,
President USG

Since 1991 Dr Watson has been consultant gastroenterologist at the Royal Victoria Hospital and senior lecturer in the Centre of Medical Education at Queen's University Belfast, where he is Academic Clinical Lead for Undergraduate Medicine. He was elected President of the Ulster Society of Gastroenterology in October 2016 .
His research interests have been in coeliac disease and more latterly Barrett's oesophagus and oesophageal cancer. He is on the Trials Management Group of AspECT (Aspirin and Esomeprazole Chemoprevention Trial of Oesophageal Cancer in Barrett's Oesophagus) and is co-lead of the recently formed Northern Ireland GI Research Network, which aims to promote research in gastroenterology in the clinical community.
He is serving a second term on the Oesophageal Committee of the British Society of Gastroeterology and has been an author on the BSG guidelines for Barrett's oesophagus and the forthcoming guidelines on oesophageal strictures.
He is an enthusiastic advocate of promoting excellence in medicine by means of shared experience and ideas with experts and peers at educational meetings such as BIG**Dr**

Dr Shivaram Bhat
Consultant Gastroenterologist
Hon Secretary USG

Dr Shivaram Bhat is a consultant Gastroenterologist at Craigavon Area Hospital in Northern Ireland. He graduated from Queens University Belfast medical school (2002) with subsequent postgraduate training in Northern Ireland and a clinical fellowship at the John Radcliffe Hospital in Oxford. During his postgraduate training he completed a PhD researching cancer progression in Barrett's oesophagus. His clinical and research interests include inflammatory bowel disease and early detection of GI cancer. He is a bowel cancer screening endoscopist and is the IBD lead for the Southern Health and Social Care Trust.



Dr Philip Hall
Consultant Gastroenterologist
Belfast Trust
Hon Treasurer USG

Dr Philip Hall has recently been appointed consultant gastroenterologist within the Belfast Trust. He graduated from Queens University Belfast in 2008 and completed gastroenterology training in Northern Ireland. He has a Masters degree in Clinical Education.
He completed an advanced therapeutic endoscopy fellowship in St Michael's Hospital, Toronto in 2017 and has interests in upper GI therapeutics, ERCP and quality improvement.

Dr Helen Coleman
Senior Lecturer
Queen's University Belfast

Dr Helen Coleman is a Senior Lecturer in Cancer Epidemiology at the Centre for Public Health at Queen's University Belfast, and previously studied there during her PhD and postdoctoral research projects. She has also spent time conducting research at Vanderbilt University, Nashville, TN, USA, Ulster University, and at the MRC-Human Nutrition Research centre in Cambridge, England. Dr Coleman's general research interests are in cancer epidemiology, particularly modifiable risk factors for progression from pre-cancerous conditions to cancer and factors associated with recurrence or survival after a cancer diagnosis. She is also involved in health services research projects that aim to optimise how individuals are treated and followed-up after a diagnosis of a pre-malignant condition or cancer, including analysis of Northern Ireland Bowel Cancer Screening data. Her strong interests are in cancers of the digestive tract, especially colorectal polyp/cancer, and oesophageal adenocarcinoma/ Barrett's oesophagus epidemiology.

Mr Tim McAdam
Consultant Colorectal Surgeon
Belfast Trust

I am a Consultant Colorectal Surgeon and clinical Lead in Belfast Trust having worked as a Consultant in Aberdeen for 6 years.
I was a medical student in QUB and trained in North of Scotland and England. My main interests are management of colorectal cancer, member of specialist endometriosis team and pelvic floor disorders. I am a faculty member for RCSEd surgical skills, NOTSS, RCSEng strategies in emergency surgery. I am a recognised national trainer for laparoscopic colorectal surgery.

Autumn Meeting 2018

Ellen Creegan

K. Diong with Mairead Guinness (Boston Scientific)

Mike Gibbons and William Dickey

Brian McLaughlin (MSD) and Seamus Murphy

Tony Tham with Karl Hogan and William Richards (Irish Hospitals Supplies Ltd)

Sarah-Jane Kelly (Cardic Service) with Mark McLoughlin

Julie Doyle and Rita McKee (Abbvie) with Eamon Mackle

USG Audience

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USG Committee

Dr Tracey Owen

Mr Alan Wilson (Speaker) with Paula Norris and Robin Perkins (Norgine)

Gary Dobson, Anna Isaac, Colin McIlmunn, Andrew McGuigan

Dr Tony Tham

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Asim El Shafie with Alison Brown (Mylan) and Rosalie Douglas

Niall Hopkins (Vifor Pharma), Shivaram Bhat and Sharon Parker (Vifor Pharma)

Gerard Rafferty, Mark McLoughlin, Ian Carl

Inder Mainie and Neil Patterson

Stacey O'Leary, Jennifer Doran, Elizabeth Kennedy

Sophie Semple (Tillotts Pharma) and Patricia Dunlop, Angela Lambe (Tillotts Pharma)

Lee Pryce (UK Medical) and Sudheer George Jacob

Una McMenamin and Peipei Liu (Queens)

Autumn Meeting 2018

Rebecca O'Kane

Helen Coleman and Philip Hall

Gary Morrison

Full House

USG Meeting
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Autumn Meeting

Friday 18th October, 2019

Park Avenue Hotel, Belfast.

usg Ulster Society of Gastroenterology

Autumn Meeting 2018

Catherine Larkin and Alex Rankin

Wendy Ward with Jim McManus (Kyowa Kirin)


Elaine McDonnell and Tanya Ridley


Jude Gallagher and Patricia Sinclair


Lisa McNeill, Leah Gilroy and Rachel Curran


Rebecca O'Kane and Rachel Rutherford

Dr John Anderson (Speaker), Dr John Morris (Speaker) and Philip Hall


Jenny Addley and Leanne Stratton

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OCALIVA is indicated for the treatment of primary biliary cholangitis (also known as primary biliary cirrhosis) in combination with UDCA in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA.[1] OCALIVA has a conditional licence.

*UDCA was withheld from patients intolerant to UDCA.[4]
†35 patients receiving OCALIVA 10 mg + UDCA (48%) and 46 patients receiving OCALIVA titration + UDCA (46%) achieved the primary composite endpoint of ALP <1.67 x ULN with a ≥15% reduction from baseline and total bilirubin ≤ULN compared with 7 patients on placebo + UDCA (10%).[4]

OCALIVA® ▼
obeticholic acid

Abbreviated Prescribing Information
OCALIVA ▼ (obeticholic acid)
Please refer to the Full Summary of Product Characteristics (SmPC) before prescribing

Presentation: OCALIVA supplied as film-coated tablets containing 5 mg and 10 mg obeticholic acid.
Indication: For the treatment of primary biliary cholangitis (also known as primary biliary cirrhosis) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA.
Dosage and administration: Oral administration. Hepatic status must be known before initiating treatment. In patients with normal or mildly impaired (Child Pugh Class A) hepatic function, the starting dose is 5 mg once daily. Based on an assessment of tolerability after 6 months, the dose should be increased to 10 mg once daily if adequate reduction of alkaline phosphatase (ALP) and/or total bilirubin have not been achieved. No dose adjustment of concomitant UDCA is required in patients receiving obeticholic acid. For cases of severe pruritus, dose management includes reduction, temporal interruption or discontinuation for persistent intolerable pruritus; use of bile acid binding agents or antihistamines (see SmPC).
Moderate to Severe Hepatic Impairment: In patients with Child-Pugh B or C hepatic impairment, a reduced starting dose of 5mg once weekly is required. After 3 months, depending on response and tolerability, the starting dose may be titrated to 5 mg twice weekly and subsequently to 10 mg twice weekly (at least 3 days between doses) if adequate reductions in ALP and/or total bilirubin have not been achieved. No dose adjustment required in Child Pugh Class A function. **Mild or moderate renal impairment:** No dose adjustments are required. **Paediatric population:** No data. **Elderly:** No dose adjustment required; limited data exists.
Contraindications: Hypersensitivity to the active substance or any excipients. Complete biliary obstruction.
Special warnings and precautions for use: After initiation, patients should be monitored for progression of PBC with frequent clinical and laboratory assessment of those at increased risk of hepatic decompensation. Dose frequency should be reduced in patients who progress from Child Pugh A to Child Pugh B or C Class disease. Serious liver injury and death have been reported in patients with moderate/severe impairment who did not receive appropriate dose reduction. Liver-related adverse events have been observed within the first month of treatment and have included elevations in alanine amino transferase (ALT), aspartate aminotransferase (AST) and hepatic decompensation.
Interactions: Following co-administration of warfarin and obeticholic acid, International Normalised Ratio (INR) should be monitored and the dose of warfarin adjusted, if needed, to maintain the target INR range. Therapeutic monitoring of CYP1A2 substrates with narrow therapeutic index (e.g. theophylline and tizanidine) is recommended. Obeticholic acid should be taken at least 4-6 hours before or after taking a bile acid binding resin, or at as great an interval as possible.
Fertility, pregnancy and lactation: Avoid use in pregnancy. Either discontinue breast-feeding or discontinue/abstain from obeticholic acid therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman. No clinical data on fertility effects.
Undesirable effects: Very common (≥1/10) adverse reactions were pruritus, fatigue, and abdominal pain and discomfort. The most common adverse reaction leading to discontinuation was pruritus. The majority of pruritus occurred within the first month of treatment and tended to resolve over time with continued dosing. Other commonly (≥ 1/100 to < 1/10) reported adverse reactions are, thyroid function abnormality, dizziness, palpitations, oropharyngeal pain, constipation, eczema, rash, arthralgia, peripheral oedema, and pyrexia. Please refer to the SmPC for a full list of undesirable effects.
Overdose: Liver-related adverse reactions were reported with higher than recommended doses of obeticholic acid. Patients should be carefully observed, and supportive care administered, as appropriate.
Legal category: POM
Marketing authorisation numbers: EU/1/16/1139/001 & 002
Marketing authorisation holder: Intercept Pharma Ltd, 2 Pancras Square, London, N1C 4AG, United Kingdom
Package Quantities and Basic NHS cost: OCALIVA 5 mg and 10 mg £2,384.04 per bottle of 30 tablets.
Date of revision: 11th April 2018

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Intercept Pharma Ltd on +44 (0)330 100 3694 or email: drugsafety@interceptpharma.com

Abbreviations. ALP, alkaline phosphatase; FXR, farnesoid X receptor; PBC, primary biliary cholangitis; UDCA, ursodeoxycholic acid.

References. 1. OCALIVA (obeticholic acid). Summary of Product Characteristics, 2018; **2. FDA Drug Approval Package: Urso (ursodiol) NDA# 020675. http://www.accessdata.fda.gov/drugsatfda_docs/nda/97/20675a.cfm [Last accessed March 2018]; 3. Ding L,** *et al.* **Bile acid nuclear receptor FXR and digestive system diseases.** *Acta Pharma Sin B* **2015;5:135–44; 4. Nevens F,** *et al.* **A Placebo-controlled trial of obeticholic acid in primary biliary cholangitis.** *N Engl J Med* **2016;375:631–43.**

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Autumn Meeting 2018


Stephen McCain


Andy Spence


Prof John O'Leary, TCD


Dr Myrtle Van der Wel


Dr John Anderson, Cheltenham General Hospital


Mr Alan Wilson


Nurses Meeting

Aidan Armstrong with Sarah-Jane Kelly (Cardic Service)

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