This is a promotional meeting organised and funded by Tillotts Pharma UK.
Tillotts products will be discussed at this meeting

You are invited to attend:

Management of mild to moderate Ulcerative Colitis (UC) during the winter period: The role of Octasa (mesalazine)

Tues 15th Nov | 18:30 - 21:30

Manor of Grove, High Wych, Sawbridgeworth, CM21 0JU

Speaker: Monica Bose - Consultant Gastroenterologist Princess Alexandra Hospital

Agenda:

18:30 - 19:00	Registration	All
19:00 - 19:05	Welcome and Introduction	Bubacar Sawo Tillotts Pharma UK
19:05 - 19:35	Management of mild to moderate Ulcerative colitis (UC) during the winter period: The role of Octasa (Mesalazine)	Monica Bose
19:35 - 19:50	Q&A	All
19:50 - 20:00	Dose optimisation with Octasa 1600mg and Octasa 1g suppositories	Bubacar Sawo Tillotts Pharma UK
20:00 - 21:30	Round table discussion and dinner	All

To register to attend this event please contact your Tillotts Key Account Manager

You can also learn more about Octasa modified-release tablets at www.Tillotts.co.uk/Octasa

If you have any questions about Octasa modified-release tablets, please don't hesitate to contact your local Tillotts Key Account Manager who will be happy to schedule a call or appointment or alternatively email Enquiries@Tillotts.com

PU-00922 | September 2022

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OCTASA® 1600mg
modified release mesalazine

Octasa (mesalazine) 400mg, 800mg & 1600mg modified-release tablets – Prescribing Information.

Presentation: Modified Release tablets containing 400mg, 800mg or 1600mg mesalazine. **Indications:** All strengths: Ulcerative Colitis – Treatment of mild to moderate acute exacerbations. Maintenance of remission. 400mg & 800mg only: Crohn's ileocolitis – Maintenance of remission. **Dosage and administration:** 400mg & 800mg tablets – Adults: Mild acute disease: 2.4g once daily or in divided doses, with concomitant steroid therapy where indicated. Moderate acute disease: 2.4g – 4.8g daily. 2.4g may be taken once daily or in divided doses, higher doses should be taken in divided doses. Maintenance therapy: 1.2g – 2.4g once daily or in divided doses. 1600mg tablets – Adults: Acute exacerbations: up to 4.8g, once daily or in divided doses. Maintenance: 1600mg daily. Tablets must be swallowed whole. Elderly: 400mg & 800mg – normal adult dose may be used unless liver or renal function is severely impaired. 1600mg – no studies in elderly patients have been conducted. Children: 400mg & 800mg – limited documentation of efficacy in children >6 years old. Dose to be determined individually. Generally recommended that half the adult dose may be given to children up to a body weight of 40 kg; and the normal adult dose to those above 40 kg. 1600mg – safety and efficacy not established in children. **Contra-indications:** Hypersensitivity to salicylates, mesalazine or any of the excipients, severe impairment of hepatic or renal function (GFR less than 30 ml/min/1.73m2). **Warnings and Precautions:** Urinary status (dip sticks) should be determined prior to and during treatment, at discretion of treating physician. Caution in patients with raised serum creatinine or proteinuria. Stop treatment immediately if renal impairment is evident. Cases of nephrolithiasis have been reported with mesalazine treatment. Ensure adequate fluid intake during treatment. Severe cutaneous adverse reactions including Stevens-Johnson Syndrome and toxic epidermal necrolysis have been reported. Stop treatment immediately if signs and symptoms of severe skin reactions are seen. Haematological investigations are recommended prior to and during treatment, at discretion of treating physician. Stop treatment immediately if blood dyscrasias are suspected or evident. Caution in patients with impaired hepatic function. Liver function should be determined prior to and during treatment, at the discretion of the treating physician. Do not use in patients with previous mesalazine-induced cardiac hypersensitivity and use caution in patients with previous myo- or pericarditis of allergic background. Monitor patients with pulmonary disease, in particular asthma, very carefully. In patients with a history of adverse drug reactions to sulphasalazine, discontinue immediately if acute intolerance reactions occur (e.g. abdominal cramps, acute abdominal pain, fever, severe headache and rash). Use with caution in patients with gastric or duodenal ulcers. Intact 400mg & 800mg tablets in the stool may be largely empty shells. If this occurs repeatedly patients should consult their physician. Use with caution in the elderly, subject to patients having normal or non-severely impaired renal and liver function. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption, should not take the 400mg or 800mg tablets. **Interactions:** No interaction studies have been performed. May decrease the anticoagulant activity of warfarin. Caution when used with known nephrotoxic agents such as NSAIDs, methotrexate and azathioprine. May increase the myelosuppressive effects of azathioprine, 6-mercaptopurine or thioguanine. Monitoring of blood cell counts is recommended if these are used concomitantly. **Fertility, pregnancy and lactation:** Only to be used during pregnancy and lactation when the potential benefit outweighs the possible risk. No effects on fertility have been observed. **Adverse reactions:** Common: dyspepsia, rash. Uncommon: eosinophilia (as part of an allergic reaction), paraesthesia, urticaria, pruritus, pyrexia, chest pain. Rare: headache, dizziness, myocarditis, pericarditis, abdominal pain, diarrhoea, flatulence, nausea, vomiting, photosensitivity. Very rare: altered blood counts (aplastic anemia, agranulocytosis, pancytopenia, neutropenia, leucopenia, thrombocytopenia), blood dyscrasia, hypersensitivity reactions (such as allergic exanthema, drug fever, lupus erythematosus syndrome, pancolitis), peripheral neuropathy, allergic and fibrotic lung reactions (including dyspnoea, cough, bronchospasm, alveolitis, pulmonary eosinophilia, lung infiltration, pneumonitis), interstitial pneumonia, eosinophilic pneumonia, lung disorder, acute pancreatitis, changes in liver function parameters (increase in transaminases and cholestasis parameters), hepatitis, cholestatic hepatitis, alopecia, myalgia, arthralgia, impairment of renal function including acute and chronic interstitial nephritis and renal insufficiency, renal failure which may be reversible on withdrawal, nephrotic syndrome, oligospermia (reversible). Not known: Stevens-Johnson Syndrome, toxic epidermal necrolysis, pleurisy, lupus-like syndrome with pericarditis and pleuropericarditis as prominent symptoms as well as rash and arthralgia, nephrolithiasis, intolerance to mesalazine with C-reactive protein increased and/or exacerbation of symptoms of underlying disease, blood creatinine increased, weight decreased, creatinine clearance decreased, amylase increased, red blood cell sedimentation rate increased, lipase increased, BUN increased. Consult the Summary of Product Characteristics in relation to other adverse reactions. **Marketing Authorisation Numbers, Package Quantities and basic NHS price:** 400mg – PL36633/0002; packs of 90 tablets (£16.58) and 120 tablets (£22.10). 800mg – PL36633/0001; packs of 90 tablets (£40.38) and 180 tablets (£80.75). 1600mg – PL36633/0009; packs of 30 tablets (£30.08). **Legal category:** POM. **Marketing Authorisation Holder:** Tillotts Pharma UK Ltd, The Larbourne Suite, The Stables, Wellingore Hall, Wellingore, Lincolnshire, LN5 0HX, UK. Octasa is a trademark. Further Information is available from the Marketing Authorisation Holder. Date of preparation of PI: March 2021

Octasa 1g Suppositories (mesalazine) - Prescribing Information

Presentation: Suppository containing 1g mesalazine. Indications: Treatment of acute mild to moderate ulcerative proctitis. Maintenance of remission of ulcerative proctitis. **Dosage and administration:** Adults and older people: Acute treatment - one Octasa 1 g Suppository once daily (equivalent to 1 g mesalazine daily) inserted into the rectum. Maintenance treatment - one Octasa 1 g Suppository once daily (equivalent to 1 g mesalazine daily) inserted into the rectum. Children: Limited experience and data for use in children. **Method of administration:** for rectal use, preferably at bedtime. Duration of use to be determined by the physician. **Contra-indications:** Hypersensitivity to salicylates or any of the excipients, severe impairment of hepatic or renal function. **Warnings and Precautions:** Blood tests and urinary status (dip sticks) should be determined prior to and during treatment, at discretion of treating physician. Caution in patients with impaired hepatic function. Do not use in patients with impaired renal function. Consider renal toxicity if renal function deteriorates during treatment. Cases of nephrolithiasis have been reported with mesalazine treatment. Ensure adequate fluid intake during treatment. Monitor patients with pulmonary disease, in particular asthma, very carefully. Patients with a history of adverse drug reactions to sulphasalazine should be kept under close medical surveillance on commencement of therapy, discontinue immediately if acute intolerance reactions occur (e.g. abdominal cramps, acute abdominal pain, fever, severe headache and rash). Severe cutaneous adverse reactions including Stevens-Johnson Syndrome and toxic epidermal necrolysis have been reported. Stop treatment immediately if signs and symptoms of severe skin reactions are seen. **Interactions:** No interaction studies have been performed. May increase the myelosuppressive effects of azathioprine, 6-mercaptopurine or thioguanine. May decrease the anticoagulant activity of warfarin. **Fertility, pregnancy and lactation:** Only to be used during pregnancy and lactation when the potential benefit outweighs the possible risk. No effects on fertility have been observed. **Adverse reactions:** Rare: Headache, dizziness, myocarditis, pericarditis, abdominal pain, diarrhoea, flatulence, nausea, vomiting, constipation, photosensitivity, Very rare: Altered blood counts (aplastic anaemia, agranulocytosis, pancytopenia, neutropenia, leukopenia, thrombocytopenia), peripheral neuropathy, allergic and fibrotic lung reactions (including dyspnoea, cough, bronchospasm, alveolitis, pulmonary eosinophilia, lung infiltration, pneumonitis), acute pancreatitis, impairment of renal function including acute and chronic interstitial nephritis and renal insufficiency, alopecia, myalgia, arthraligia, hypersensitivity reactions (such as allergic exanthema, drug fever, lupus erythematosus syndrome, pancolitis), changes in liver function parameters (increase in transaminases and parameters of cholestasis), hepatitis, cholestatic hepatitis, oligospermia (reversible). Consult the Summary of Product Characteristics in relation to other adverse reactions. **Marketing Authorisation Numbers, Package Quantities and basic NHS price:** PL36633/0011; packs of 10 suppositories (£9.87) and 30 suppositories (£29.62). **Legal category:** POM. **Marketing Authorisation Holder:** Tillotts Pharma UK Ltd, The Larbourne Suite, The Stables, Wellingore Hall, Wellingore, Lincolnshire, LN5 0HX, UK. Octasa is a trademark. Further Information is available from EO-00316 Date of prep: February 2021 the Marketing Authorisation Holder. Date of preparation of PI: February 2021

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. (address as above) Tel: 01522 813500.

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