

# Editor's Briefing

## OCTASA 400mg MR Tablets (mesalazine) and OCTASA 800mg MR Tablets (mesalazine) – Prescribing Information.

Please consult the Summaries of Product Characteristics (SmpCs) for full prescribing information. **Presentation:** Modified Release tablets containing 400mg mesalazine or 800mg mesalazine. **Indications:** *Ulcerative Colitis* – Treatment of mild to moderate acute exacerbations. Maintenance of remission. *Crohn's ileocolitis* – Maintenance of remission.

**Dosage and administration:** *400mg tablets* – Adults: Acute disease: Six tablets a day in divided doses, with concomitant steroid therapy where indicated. Maintenance therapy: Three to six tablets a day in divided doses. *800mg tablets* – Adults: Mild Acute Disease: 3 tablets (2.4g) once daily or in divided doses. Moderate Acute Disease: 3 to 6 tablets (2.4g-4.8g) daily. 2.4g may be taken once daily, higher doses should be taken in divided doses. Maintenance therapy: 2 to 3 tablets (1.6g to 2.4g) once daily or in divided doses. Not more than 3 tablets should be taken together. *400mg and 800mg tablets* – Tablets must be swallowed whole. **Elderly:** Normal adult dose may be used unless renal function is impaired. **Children:** Limited documentation of efficacy. 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. **Contra-indications:** Hypersensitivity to salicylates or any of the excipients, severe impairment of hepatic or renal function (GFR less than 20 ml/min), gastric or duodenal ulcer, haemorrhagic tendency. **Warnings and Precautions:** Blood tests (differential blood count; creatinine) and urinary status (dip sticks) should be determined prior to and during treatment, at discretion of treating physician. Follow-up tests are recommended 14 days after start of treatment, then a further two to three tests at intervals of 4 weeks. If findings are normal, carry out follow-up tests every 3 months. If additional symptoms occur, perform these tests immediately. Best avoided in patients with mild-moderate renal impairment; if necessary, use with extreme caution. Caution in patients with impaired hepatic function. If dehydration occurs, correct as soon as possible. Discontinue treatment if renal function deteriorates. Monitor patients with pulmonary disease, in particular asthma, very carefully. Discontinue immediately if acute intolerance reactions occur (e.g. abdominal cramps, acute abdominal pain, fever, severe headache and rash). Very rarely serious blood dyscrasia has been reported. Perform haematological investigations including a complete blood count especially if a patient develops signs and symptoms suggestive of blood dyscrasia during treatment, such as unexplained bleeding, haematoma, purpura, anaemia, persistent fever, or a sore throat. Stop treatment immediately if there is suspicion or evidence of blood dyscrasia and patients should seek immediate medical advice. Use with caution in the elderly subject to patients having normal renal function. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption, should not take this medicine. **Interactions:** Nephrotoxic agents (e.g. NSAIDs and azathioprine), digoxin, warfarin, azathioprine, 6-mercaptopurine or thioguanine. **Pregnancy and lactation:** Only to be used when the potential benefit outweighs the possible hazards. **Adverse reactions:** *Rarely:* Dizziness, headache myocarditis, pericarditis, abdominal pain, diarrhoea, flatulence, nausea, vomiting, bloating. *Very rarely:* Altered blood counts (aplastic anaemia, granulocytosis, pancytopenia, neutropenia, leucopenia, thrombocytopenia), bone marrow depression, anaemia, peripheral neuropathy, vertigo, allergic and fibrotic lung reactions (including dyspnoea, cough, bronchospasm, alveolitis, pulmonary eosinophilia, lung infiltration, pneumonitis), eosinophilic pneumonia, pancreatitis, exacerbation of disease, changes in liver function parameters (increase in transaminases and cholestasis parameters), hepatitis, cholestatic hepatitis, hepatic function abnormal / abnormal liver function tests, alopecia, Stevens Johnson syndrome, erythema multiforme, bulbous skin reactions, urticaria, rash, myalgia, arthralgia, lupus-like syndrome with pericarditis and pleuropericarditis as prominent symptoms as well as rash and arthralgia, impairment of renal function including acute and chronic interstitial nephritis and renal insufficiency, renal failure, which may be reversible on withdrawal, nephrotic syndrome, hypersensitivity reactions such as allergic exanthema, drug fever, lupus erythematosus syndrome, pancolitis, oligospermia (reversible). **Marketing Authorisation Numbers, Package Quantities and basic NHS price:** 400mg – PL36633/0002; packs of 90 tablets (£19.50) and 120 tablets (£26.00). 800mg – PL36633/0001; packs of 90 tablets (£47.50) and 180 tablets (£95.00). **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. ©2010 Tillotts Pharma UK Ltd. Further information is available from the Marketing Authorisation Holder. Date of preparation of API: October 2013.

**References:** 1. MIMS. Accessed online, May 2014. 2. Data on file. Tillotts Pharma UK Limited. [Dissolution profiles]. 3. Data on file, Tillotts Pharma UK Limited. [Patient years]. 4. British National Formulary. Mesalazine. Available at <http://www.medicinescomplete.com/mc/bnf/current/PHP493-mesalazine.htm> accessed May 2014. UK/OC/0023/0514. Date of preparation: June 2014.

Adverse events should be reported. Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). Adverse events should also be reported to Tillotts Pharma UK Ltd. (address as above) Tel: 0845 034 4476.



www.tillotts.com

## SCREENSAVERS

Screening is often held up to the general population as 'a good thing', rivalled only by apple pie and motherhood, but many GPs will, as Mant alludes to in his editorial this month on health checks and screening, have reservations at some level. Screening and cardiovascular health feature strongly in the *BJGP* this month and we present research that will inform debate on the best approaches. NHS Health Checks are explored further in the Debate & Analysis article by Dalton and colleagues but Mant suggests that 'this NHS preventive flagship merits scuttling because it's unfit for purpose.'

Perhaps some GPs feel in their bones, without being able to name it, the pull of 'quaternary prevention'. This is defined by WONCA as 'action taken to identify patients at risk of overmedicalisation, to protect him from new medical invasion, and to suggest to him interventions, which are ethically acceptable'.<sup>1</sup> It's a concept whose time may have come and, of course, it's not just patients who suffer harm from overmedicalisation. The editorial by Dobbin on burnout draws this out and it is implicit in Nigel Mathers' perceptive James Mackenzie Lecture, recognising the pressures on the system and the individual, and offering GPs the 'Tao of family medicine', an approach that might just help keep burnout at bay.

Communication is key, as ever, and research by Korhonen and colleagues recognises the importance of a patients' self-rating of their health to pick up disease that is otherwise missed in screening processes. We also publish a systematic review looking at screening for cardiometabolic risk in primary care (Koekkoek *et al*), and research on the prevalence and cost of treating uncomplicated stage 1 hypertension (McManus *et al*). Research showing the marked variation in cardiovascular risk prediction tools exposes the need for doctors and patients to have these discussions. Julia Langan Martin and colleagues present evidence of how physical health indicators are not being recorded in major mental illness.

Baby boomers may wince, but the editorial on the future funding of health and social care in England by Stephen Gillam is a clear-eyed appraisal of the enormous challenges that lie ahead. Lim and colleagues report on delays in diagnosis in symptomatic cervical

cancer (not to be confused with screening) and the accompanying editorial by Fiona Walter *et al* teases out practical measures practices can adopt.

Elsewhere in the *BJGP* we cover sight-threatening diabetic disease (Symes *et al*), use of non-contact infrared thermometers (Wang *et al*), and we have a Research into Practice article on the management of atrial fibrillation (Fitzmaurice and Hobbs). The importance of clinical intuition has been shown in areas such as serious childhood illness,<sup>2</sup> but doctors may have a blind spot when it comes to alcohol. Research in the *BJGP* this month (Saeyes and Cammu) suggests that doctors smoke less but, in line with the old saw, drink more than their patients. Our relationship with alcohol is complex but this fits with evidence showing GPs are poor at picking up problem alcohol drinking unless it lurches into full-blown dependence.<sup>3</sup> Moscrop and MacPherson present the case, in a Debate & Analysis article, that if we are really going to address health inequities we should consider recording patients' incomes. It is, as they acknowledge themselves, an uncomfortable proposal but one with huge potential.

Finally, you will notice that further improvements to the *BJGP* website have now been rolled out. You'll find all our content – from the current issue to the first publication in 1953 – is now easier to access on desktops and mobile devices, with new mechanisms to comment and engage in debate.

Euan Lawson  
Deputy Editor

## REFERENCES

1. PH3C Primary Health Care Classification Classification Consortium. *Quaternary prevention*. <http://www.ph3c.org/PH3C/docs/27/000103/0000261.pdf> [accessed 15 Sep 2014].
2. Van Den Briel A, Thompson M, Buntinx F, Mant D. Clinicians' gut feeling about serious infections in children: observational study. *BMJ* 2012; **345**: e6144.
3. Paul C, Yoong SL, Sanson-Fisher R, *et al*. Under the radar: a cross-sectional study of the challenge of identifying at-risk alcohol consumption in the general practice setting. *BMC Fam Pract* 2014; **15**: 74.

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