NORTHERN IRELAND MEDICINES MANAGEMENT NEWSLETTER

August 2013

Volume 4, Issue 4

Health and Social Care Board

SOUVENAID®— WHAT IS THE EVIDENCE? [6-11]

What is it?

Souvenaid® was launched earlier this year as a medical food for use in the early stages of Alzheimer's disease. It is a multi-nutrient drink containing omega-3 polyunsaturated fatty acids. It is taken on a daily basis.

What is the evidence for it?

In two small scale studies (225 and 259 patients), Souvenaid® was reported to increase memory function after 12 and 24 weeks in drug naive patients with mild Alzheimer's Disease (i.e. MMSE score of 20 to 26). To date there is no evidence that Souvenaid® has any effect on other symptoms such as activities of daily living or Behavioural and Psychological Symptoms of Dementia. Benefits of Souvenaid® in patients who are receiving treatment for Alzheimer's disease, or with moderate and severe Alzheimer's disease have not been established.

The product has not been approved though the Advisory Council for Borderline Substances (ACBS) process.

In this issue:

The **Alzheimer's Society** issued a statement to say that, while the studies showed some benefits for memory, there is no evidence it has any effect on other symptoms of dementia. Furthermore, patients would be better spending the money on regular exercise as this is a far more effective way of reducing cognitive decline and NHS money would be better spent on other treatments for Alzheimer's disease.
NICE are due to publish an Evidence Summary on Souvenaid® in September 2013.

What is the cost?

Souvenaid® costs £3.49 per 125mL bottle, or £1,273 per patient per year.

Action

Clinicians are asked not to prescribe Souvenaid® on the basis that there is no evidence to suggest it provides benefit to patients who are receiving treatment for Alzheimer's disease.

Did you see? CODEINE — NEW WARNINGS: CHILDREN AND BREASTFEEDING [1]

The MHRA has updated safety advice regarding codeine with regards to use in children and breastfeeding mothers. Codeine should only be used to relieve acute moderate pain in children older than 12 years and only if it cannot be relieved by other painkillers such as paracetamol or ibuprofen alone. Furthermore, a significant risk of serious and life-threatening adverse reactions has been identified in children with obstructive sleep apnoea who received codeine after tonsillectomy or adenoidectomy (or both). Codeine is now contraindicated in all children younger than 18 years who undergo these procedures for obstructive sleep apnoea.
Codeine should not be used by breastfeeding mothers because it can pass to the baby through breast milk and potentially cause harm. Further information can be found on the MHRA website:
http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON296400

TOP 10 MISSED GENERICS ACROSS NORTHERN IRELAND

Based on January to March 2013 data, the top ten missed generics across Northern Ireland have the potential to release in excess of £1.6 million annually if generic switches are fully implemented. Practices are encouraged to check if they have any patients on the following brands and consider making the switch to generic.

Brand		*Generic*	*Potential Savings Annually*
Xalatan® 2.5mL eye drops	→	Latanaprost 50mcg/ml eye drops	£250,340
Nexium® (all strengths)	→	Esomeprazole	£244,928
Aricept® 10mg tablet	→	Donepezil 10mg tablet	£210,452
Arimidex® 1mg tablet	→	Anastrozole 1mg tablet	£181,196
Lipitor® (all strengths)	→	Atorvastatin tablets	£173,580
Losec® 20mg	→	Omeprazole 20mg	£153,380
Seroquel®	→	Quetiapine	£135,948
Plavix®	→	Clopidogrel	£115,100
Ventolin® Evohaler	→	Salbutamol inhaler	£102,844
Actonel® Once a Week 35mg tablet	→	Risedronate 35mg tablet	£83,016
TOTAL			**£1,650,784**

Action
Most practices have already implemented the Departmental policy of prescribing items generically from initiation, however it is still worth checking that all products coming off patent in 2012/2013 are being prescribed as the generic form of the drug e.g. latanaprost (above). The list of recent/imminent patent expiries is readily available in the April 2013 generics bulletin at the link: http://primarycare.hscni.net/pdf/Generics_Bulletin_April_13.pdf

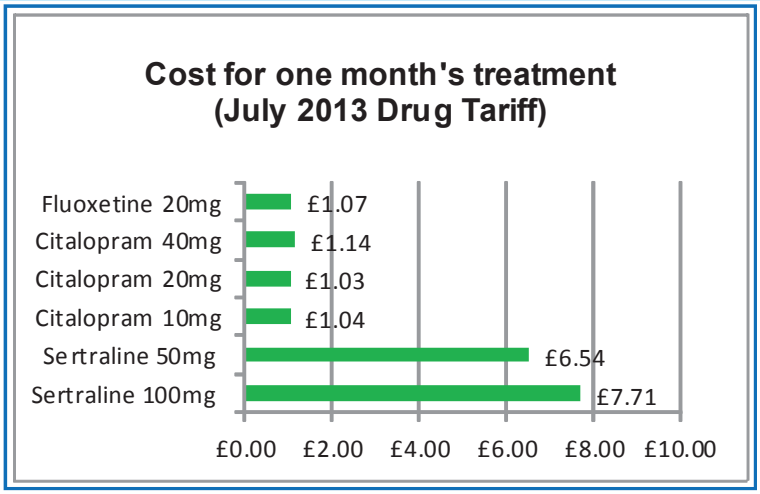
SSRI PRICE DIFFERENTIAL: SERTRALINE [4,5]

The NHS cost of sertraline has been fluctuating over recent months. This fluctuation is due to shortage problems with sertraline. It is anticipated to continue for the foreseeable future.

Prescribing of sertraline has risen by 2% in the last year, further adding to this pressure.

The Northern Ireland Formulary recommends citalopram or fluoxetine or sertraline as first line drug treatment options of major depression.

Action
Clinicians are asked to consider citalopram or fluoxetine as alternative SSRIs for *new* patients, where clinically possible.



Did you see? FENTANYL: RISK OF SEROTONIN SYNDROME WITH SEROTONERGIC DRUGS [14]

Product information for fentanyl patches and sublingual tablets has been updated to include a warning on potentially life-threatening serotonin syndrome when serotonergic drugs are administered concomitantly with fentanyl. Serotonin syndrome may occur with the concomitant use of serotonergic drugs such as SSRIs, SNRIs and drugs which impair the metabolism of serotonin (including MAOIs). This may occur within the recommended dose. See SPCs for full details: www.medicines.org.uk.

Action
Caution in prescribing fentanyl to patients taking serotonergic drugs.
If serotonin syndrome is suspected, rapid discontinuation of fentanyl should be considered.
Report any suspected adverse reactions to the MHRA through Yellow Card Scheme: www.mhra.gov.uk/yellowcard.

NEW RESOURCE FOR MENTAL HEALTH: CHOICE AND MEDICATION WEBSITE

What is it?
Choice and Medication is a website that provides up-to-date information on a range of mental health conditions as well as information on medicines used in mental health. The information is maintained on a central server by Mistura Enterprise Ltd. (an independent organisation run by professionals and specialists in mental health and mental health medicines).

Who is it aimed at?
It is suitable for both healthcare professionals and patients. Patient information leaflets suitable for different levels of reading ability are available for all mental health medicines. Patients may be directed to this website for a reliable source of information.

How to access the website?
The website is commercially available on subscription to NHS Trusts, specialist interest pharmacy groups, community pharmacies, independent healthcare providers and charitable mental health organisations.
It has now been purchased and is available for Northern Ireland, as part of the on-going Mental Health Medicines Management pilot.
The Northern Ireland site is freely available at the link: http://www.choiceandmedication.org/hscni. This link will shortly be available on the HSCB website (Medicines Management section) and on the BSO website (community pharmacists).

Did you see? STRONTIUM RANELATE — NEW CARDIOVASCULAR RISKS [3]

In addition to the known risks of venous thromboembolism with strontium ranelate, new information has highlighted the increased risk of serious cardiac disorders, including myocardial infarction, in patients receiving strontium. As such, the MHRA has imposed new restricted indications, new contraindications, and warnings on its use. Further details can be found on the MHRA website and SPC: http://www.mhra.gov.uk; http://www.medicines.org.uk.

Action
Clinicians are asked to review patients currently receiving strontium ranelate at a routine appointment and consider whether or not to continue treatment. Strontium ranelate should not be used in patients with:

- Ischaemic heart disease
- Peripheral arterial disease
- Cerebrovascular disease
- A history of these conditions
- Uncontrolled hypertension

A decision to prescribe strontium ranelate for new patients should be based on an assessment of the individual patient's overall risks.

Did you see? DICLOFENAC — NEW WARNINGS IN PATIENTS WITH HEART CONDITIONS [2]

The MHRA now advises that patients with serious underlying heart conditions, such as heart failure, heart disease, cerebrovascular disease, circulatory problems or a previous heart attack or stroke should no longer use diclofenac. This follows completion of a European review which found a small increased risk of heart attack and stroke. Further details can be found on the MHRA website:
http://www.mhra.gov.uk/home/groups/dsu/documents/publication/con287041.pdf

Action
Patients with these conditions should be switched to an alternative treatment at their next routine appointment. Diclofenac treatment should only be initiated after careful consideration for patients with significant risk factors for cardiovascular events.

NON-BENZODIAZEPINE HYPNOTICS — ANY BETTER THAN PLACEBO?[12,13]

A recent study (reported in the BMJ) used FDA data to determine the effectiveness of non-benzodiazepine hypnotics in the treatment of adult insomnia. Non-benzodiazepine hypnotics included in this study were eszopiclone (not available in UK), zaleplon and zolpidem. Sleep latency (time to fall asleep) was assessed both objectively (using polysomnography) and subjectively (from the patient's perspective).
It was found that these agents allow people to fall asleep faster, however not strikingly faster, than placebo.
When monitored using polysomnography, patients taking placebo fell asleep on average 20 minutes faster than before treatment, and patients taking active treatment fell asleep on average 42 minutes faster (i.e. 22 minutes faster than placebo). When patients were asked, the difference in perceived sleep onset was only seven minutes faster with the hyptnotic compared to placebo.
The size of this effect is small and needs to be balanced with concerns about adverse effects, tolerance, and potential addiction.

Action
The placebo response accounted for about half of the drug response. This suggests that increased attention should be directed at psychological interventions for insomnia.

References

1. MHRA. Codeine for analgesia: restricted use in children because of reports of morphine toxicity. MHRA Drug Safety Update, Volume 6, Issue 12 July 2013. http://www.mhra.gov.uk
2. MHRA. Press release: MHRA confirms advice on the use of diclofenac. MHRA, 28 June 2013. http://www.mhra.gov.uk
3. MHRA. Strontium ranelate (Protelos): risk of serious cardiac disorders—restricted indications, new contraindications, and warnings. Drug Safety Update, Volume 6, Issue 9 April 2013. http://www.mhra.gov.uk
4. HSCB. Chapter 4 Central Nervous System, Northern Ireland Formulary http://www.hscboard.hscni.net/NIFormulary/Chapter4_CNS_summary.pdf
5. HSCB. Drug Tariff, July 2013. http://www.hscbusiness.hscni.net/services/2034.htm
6. Sijben J et al. A multi nutrient concept to enhance synapse formation and function: science behind a medical food for Alzheimer's disease. OCL, 2011;18:5.
7. Scheltens P et al. Efficacy of a medical food in mild Alzheimer's disease: A randomised, controlled trial. Alzheimers & Dementia, 2010;6:1 -10.
8. Scheltens P et al. Efficacy of Souvenaid in Mild Alzheimers Disease: Results from a Randomised Controlled Trial. Journal of Alzheimers Disease: 2012; 31:225 – 236.
9. Alzheimer's Society. Nutritional drink could have memory benefits for people with Alzheimer's, study claims. July 2012. http://www.alzheimers.org.uk
10. Thaipisuttikul P and Galvin JE. Use of medical foods and nutritional approaches in the treatment of Alzheimer's disease. Clin Pract (Lond) 2012; 9(2):199–209.
11. Nutricia. Accessed 30/7/2013 [http://www.nutricia.co.uk/souvenaid].
12. Huedo-Medina TB et al. Effectiveness of non-benzodiazepine hypnotics in treatment of adult insomnia: meta-analysis of data submitted to the Food and Drug Administration. BMJ, 2012;345:e8343.
13. POEMS. Placebo almost as effective as non benzodiazepine hypnotics in adults. Prescriber, 2013;24(11)42.
14. MHRA. Janssen Dear Healthcare Provider Letters, June and July 2013. http://www.mhra.gov.uk

This newsletter has been produced for GPs and pharmacists by the Regional Pharmacy and Medicines Management Team. If you have any queries or require further information on the contents of this newsletter, please contact one of the Medicines Management pharmacists in your local HSCB office.

Eastern Area Office: 028 9055 3784 Southern Area Office: 028 3741 4622

Northern Area Office: 028 2531 1049 Western Area Office: 028 7186 0086