

# Gamolenic Acid

- The UK marketing authorisations for the licensed gamolenic acid products, Epogam and Efamast, were withdrawn some time ago.
- Improved reporting by the Prescription Pricing Division of unlicensed "specials" and natural products not in the BNF has indicated that 80 patients in Guernsey are still being prescribed gamolenic acid.
- The cost per prescription item ranged from £ 107 to £11 in the 3/12 ending June 2011 and the estimated annual cost is nearly £50,000.
- Gamolenic acid capsules are available to buy from several outlets on the islands for very reasonable prices.
- Like all withdrawn products, gamolenic acid will be removed from the local prescribing list at the end of this year.
- This bulletin revises the advice given by the MHRA at the time and the cost of supplying it as a special.

## What is the background to this?

Epogam and Efamast contained gamolenic acid, which was derived from evening primrose oil. Epogam was licensed for the symptomatic relief of atopic eczema in children and adults and Efamast was licensed to treat mastalgia (breast pain). The MHRA reviewed all of the relevant information, which included clinical studies and statistical analyses, and advised that this did not support their use as a medicine.

### Were there any safety concerns?

There were no safety concerns associated with these products, and the MHRA advised that gamolenic acid should be considered a dietary supplement, rather than a medicine suitable for prescribing. During it's use in clinical practice there have been reports of mostly mild reactions like diarrhoea and nausea. The MRHA advised that patients who wished to remain on evening primrose oil buy it from a health food store or a pharmacy.

#### How much is being prescribed locally and what is the cost?

Until recently the Prescription Pricing Division listed items without a BNF entry as "unspecified drug code" on various reports. Without manually checking over one million prescription forms it was impossible to establish exactly what was being prescribed.

However this has now greatly improved, enabling us to scrutinise prescribing of these products in detail. PPD data indicate that approximately eighty patients on the islands are prescribed gamolenic acid every month. The cost of each item varies depending on the dose and strength used, and crucially also the supplies available to our community pharmacists. The most expensive prescription cost £ 107 and the least expensive £11 in the quarter ending June 2011. Epogam cost just over £20 per month in 2001, so the cost has effectively increased by 400%.

Prescribing by primary care organisations in the quarter ending June 2011 is as follows.

Practice	Total Items	Cost per Item excluding fees and grants	Estimated annual cost excluding fees and grants
Healthcare	118	£44.53	£21,012
QRMP	99	£51.19	£20,268
L'Aumone	31	£69.10	£8,568
and St Sampsons			
Dr Cooper	14	£14.69	£820
Dr Lyons	0	0	0

Also attached is a table of island-wide prescribing at individual doctor level in the Guernsey practices.

#### So what?

You will be aware that the prescribing list is reviewed when the Social Security Department board approves new treatments, having considered the advice of the Pharmaceutical Benefits Advisory Committee. This is usually done every two months.

On a bi-annual basis treatments that have been withdrawn from the UK market are also removed. The next scheduled date for this exercise is December 2011 and after that date gamolenic acid will no longer be prescribable on States prescriptions in Guernsey and Alderney.

#### Doctors are therefore requested to

- Review any patients on prescribed gamolenic acid in the coming weeks and months.
- Please advise them that the recommendations on it's use changed some time ago and that it is no longer considered a medicine but is now regarded as a food supplement.
- Recommend that it be bought from a pharmacy or a healthfood store if the patient wishes to continue.

A message to this effect is being added to the islands' Scriptswitch profile, and the sooner this is done the better for our patients.

The increasing cost of unlicensed treatments became a major cost burden relatively quickly, both here and in the UK. Many special formulations are helpful for patients with complex medical needs and will need to be available in the long term.

But some older and /or "natural" products that might be expected to be very good value are not as they are often only available as extremely expensive specials. Where their use is specifically not recommended in high quality evidence based guidelines, it is important that patients receiving them on prescription are reviewed and that no new patients are commenced on them. Doing so will mean that scarce financial resources will be freed up to fund those treatments that we all want to be available i.e. those that have been shown to enable our patients to live longer and/ or better lives.

If you have any queries, comments or observations on the above bulletin, or if you have ideas for future bulletins please contact.

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