## SUMMARY OF ASSESSMENT AND ITS FINDINGS

### BACKGROUND
A fatality was reported in which a patient took a significant overdose of flecainide following confusion in relation to the dose of the drug prescribed. We do not know if this treatment was initiated by the GP or under advice from a specialist. There is no particular suggestion that product packaging and presentation had a bearing here; the assessment tool was applied to help determine whether this could have been a factor and whether any actions should be pursued for the future in this regard.

### DETAILS OF PRODUCT ASSESSED
Various brand and generic flecainide products

### CONCLUSION FOLLOWING APPLICATION OF VALIDATED ASSESSMENT TOOL
There are some issues for how the products are presented both from the standardised livery use by some manufacturers and also from sound-alike names but they were unlikely to have been an issue in this case.

There are issues about the expertise to initiate this treatment, dosing and monitoring. It is evident that practice and recommendations vary although authoritative sources recommend that this treatment should only be initiated by specialists.

**BNF Dose.** By mouth (initiated under direction of hospital consultant), ventricular arrhythmias, initially 100 mg twice daily (max. 400 mg daily usually reserved for rapid control or in heavily built patients), reduced after 3–5 days to the lowest dose that controls arrhythmia. Supraventricular arrhythmias, 50 mg twice daily, increased if required to max. 300 mg daily.

**Tambocor SPC**
Treatment with oral Tambocor should be under direct hospital or specialist supervision for patients with:
- a) AV nodal reciprocating tachycardia; arrhythmias associated with Wolff-Parkinson-White Syndrome and similar conditions with accessory pathways
- b) Paroxysmal atrial fibrillation in patients with disabling symptoms.

Treatment for patients with other indications should continue to be initiated in hospital.

### POTENTIAL NEXT STEPS AND MITIGATION ACTIONS
Some ideas that may be considered to prevent repetition of this kind of incident with flecainide.
- Warnings on GP prescribing systems that specialist direction is required for initiation
- Warnings on community pharmacy systems to check patients initiated
- Consideration of more detailed information in BNF in line with MHRA guidance from 1989
- Consideration of local development and implementation of shared care protocols (which are in place in some areas)

This report was produced in January 2014 using photographic images (not physical products) available at the time of assessment. Images were obtained from pharmaceutical companies and also from the Commercial Medicines’ Unit PharmaQC database ([http://cmu.dh.gov.uk/medicines/pharmaqc-database/](http://cmu.dh.gov.uk/medicines/pharmaqc-database/)) and from various sources within the NHS.

This report summarises product assessments undertaken by: South West, North West and Trent

For comments email [swmi@uhbristol.nhs.uk](mailto:swmi@uhbristol.nhs.uk)

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