



Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Therapeutic Goods Act 1989

I, Dr Jane Cook, Acting Head, Office of Product Review, Therapeutic Goods Administration and delegate of the Secretary to the Department of Health and Ageing for the purposes of section 42DF(1) of the *Therapeutic Goods Act 1989*, give notice that the restricted representation described in paragraph (a) below has been approved for use in advertisements directed to consumers, for the products identified in paragraph (b), provided the conditions identified in paragraphs (c) and (d) are met:

- (a) Representations to the effect that advertisements to consumers for the goods described in paragraph (b) may refer to: “stroke”, “heart attack”, “cardiovascular disease” and “cerebrovascular disease” when used in the phrase “***When used as directed by your doctor, Astrix Capsules help to prevent heart attack and stroke in people with known cardiovascular or cerebrovascular disease***”.
- (b) Astrix 100mg Blister Pack (Aust R 29551) supplied as a medicine by Mayne Pharma International Pty Ltd.
- (c) The advertisements in which the representations are made must include:
 - i. A warning for the patient to “consult a medical practitioner prior to commencing use of Astrix Capsules” or words to that effect;
 - ii. A statement that “The use of low dose aspirin may be only one component of your medical practitioner’s management plan to prevent you having a further heart attack or stroke. You should discuss this plan with your medical practitioner” or words to that effect;
 - iii. A warning “Do not substitute other medicines containing aspirin, for this medicine, without first consulting your pharmacist or medical practitioner” or words to that effect; and
- (d) The advertisements in which the representations are made must give the same prominence to conditions (i) – (iii) above, as is required for *mandatory statements* by section 6 of the Therapeutic Goods Advertising Code.

Dated this 22nd day of December 2011

Dr Jane Cook
Delegate of the Secretary to the Department of Health and Ageing; and
A/g Head
Office of Product Review