

MESSAGE FROM PROFESSOR ALASDAIR BRECKENRIDGE, CHAIRMAN,
COMMITTEE ON SAFETY OF MEDICINES

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Dear Healthcare Professional

Medicines containing phenylpropanolamine (PPA) and possible association with increased risk of stroke

You may have seen articles in the media over the past few days reporting that medicines containing phenylpropanolamine (PPA) are being withdrawn in the United States (US). This follows the results of a study that suggests use of PPA may be associated with haemorrhagic stroke, particularly when used in slimming treatments. This letter is to keep you informed of the current situation relating to the UK use of PPA containing products (a list of which is attached).

The Licensing Authority has previously taken action in 1984 and 1996 to introduce maximum daily dose limits and warnings for PPA containing products. Cough and cold remedies licensed in the UK thus contain a lower maximum daily dose of PPA (100mg) than in the US (150mg). No PPA containing slimming treatments are licensed in the UK.

The Committee on Safety of Medicines (CSM) has now conducted an initial review of the safety of UK products containing PPA and a possible link with haemorrhagic stroke. The CSM has advised that the evidence of a link is weak and mainly associated with indications which are not licensed in the UK.

There is a wide range of suitable alternative medicines available and all products containing PPA are clearly labelled. Patients should be reminded that products should be used as stated on their label or leaflet. In particular:

- The maximum daily dose should not be exceeded (100 mg per day).
- Patients with high blood pressure, hyperthyroidism, heart disease or who are receiving monoamine oxidase inhibitors should not take PPA-containing products.
- PPA may aggravate conditions such as diabetes, glaucoma, or prostatic enlargement.

Patients who are concerned about products containing PPA are being advised to contact their pharmacist who has access to prescribing and patient information, and can suggest alternative remedies.

Please continue to report suspected adverse drug reactions, including suspected reactions to medicines available over the counter, through the Yellow Card Scheme.

Attached is a sheet that you might find helpful in discussions with patients. For further information please call the MCA on 0207 273 0000.

Yours faithfully

Professor Alasdair Breckenridge, Chairman, Committee on Safety of Medicines
Marketed products containing phenylpropanolamine (PPA)

Eskornade capsules - 30 Spansule
Triogesic tablets
Triominic tablets
MU-CRON tablets
Aller-eze Plus
Day Nurse
Day Nurse capsules
Contac 400
Boots prolonged release cold capsules
Benylin day and night cold treatment
Sinutab
Dimotapp Elixir Paediatric
Dimotapp LA Tablets
Dimotapp Elixir

In addition to the products listed above, other products which have been discontinued recently, may still be in use. Therefore patients should check the product label or leaflet to be certain.

COUGH AND COLD REMEDIES CONTAINING PHENYLPROPANOLAMINE (PPA): INFORMATION FOR PATIENTS

What is phenylpropanolamine (PPA)?

Some cold and flu remedies contain the medicine phenylpropanolamine (PPA). This is added to treat sinus congestion and stuffy nose as a decongestant.

Why have medicines containing PPA been withdrawn in the USA?

In the USA, where the maximum daily dose of PPA is higher in cold remedies than in the UK, manufacturers have been asked to discontinue medicines containing PPA as a precaution. This advice is based on the results of a recent study performed in the US. This suggested that there could be an increased risk of brain haemorrhage whilst taking PPA, especially when in prolonged use as 'slimming aids'. No slimming products containing PPA are available in the UK.

Is it safe to take cold and flu remedies containing phenylpropanolamine?

No medicine is absolutely free of possible side-effects, but the Committee on Safety of Medicines has advised that PPA containing medicines may remain on the market for the symptomatic relief of colds and influenza. However, patients with high blood pressure, an overactive thyroid gland, heart disease or who are receiving monoamine oxidase inhibitors including Nardil, Isocarboxazid, Parnate, and Manerix, should not take phenylpropanolamine-containing products. The maximum stated dose should also not be exceeded. Phenylpropanolamine can sometimes aggravate conditions such as diabetes, glaucoma, or prostate symptoms.

What is the evidence about PPA and how great is the risk?

The US study did *not* find a risk of haemorrhagic stroke associated with the use of PPA in cold and flu remedies but suggested an increased risk when used in products as long-term slimming aids (appetite suppressants). The evidence was weak. No PPA-containing slimming aids are available in the UK.

Which remedies contain phenylpropanolamine?

Phenylpropanolamine is an ingredient of around a dozen marketed cold and flu remedies in the UK including many common brands. If your medicine contains phenylpropanolamine it will be stated on the list of ingredients on the label or leaflet. If you are not sure, ask your pharmacist.

What are the other possible side effects of PPA?

Sedation, high blood pressure, bladder problems, headache, agitation, rash, nausea or vomiting have occasionally been reported but are usually transient and not severe.

What are the alternative products?

There are many other cough and cold remedies available in pharmacies that do not contain PPA. Ask your pharmacist who can advise you on the choice available.