

NEW DRUG SUPPLEMENT No 3

Produced by Tayside Medicines Information Service

This supplement to the Tayside Prescriber is produced in response to demand for early information on new drugs from a neutral source. The following is a summary of the evidence from published sources. It does not comment on the role, if any, that such drugs might have, nor does it endorse their use in practice. A system exists in Tayside whereby advice on new drugs for local prescribers will follow from the Area Drug & Therapeutics Committee after assessment by the Drug Evaluation Panel. Anyone wishing to introduce a new drug in hospital practice must first complete a Submission Form before any such assessment can take place. Copies of the Submission Form are available on request from the Secretary, Area Drug & Therapeutics Committee, Medicines Information Service, Department of Pharmacy, Ninewells Hospital. The situation regarding primary care is currently under consideration.

DESLORATADINE (Neoclarityn®)

The introduction of Neoclarityn® (Schering-Plough) comes at a time when loratadine (Clarityn®) is poised to 'go generic'. What, if any, are its advantages over loratadine? This review is published in response to an increasing number of questions received from GPs who have been 'advised' to prescribe treatment for patients referred to hospital. It is based on a New Product Evaluation produced by the Trent Medicines Information Service in May 2001.

Background

Loratadine has been a non-sedating antihistamine of choice in past editions of the Tayside Area Drug Formulary. It will shortly be available in generic form, no doubt at substantially reduced cost. Desloratadine is the major active metabolite (descarboxyethoxyl loratadine) which appears in the body within 2 hours of a dose of loratadine. Desloratadine may therefore be expected to have a similar efficacy/toxicity profile to that of loratadine.

Indications and dosage

Desloratidine is currently licensed for seasonal allergic rhinitis (SAR) in adults and adolescents over 12 years of age. Unlike loratadine, it is not (yet) licenced for perennial rhinitis or urticaria. The dose is 5 mg (one tablet) daily which is half the licensed dose of loratadine.

What then are the differences between these drugs?

Specific claims for desloratadine include enhanced potency and a more pronounced effect on the chronic inflammatory response to allergens. Such claims are related to increased H₁ receptor selectivity and binding potency and recognition that SAR is less likely to be a local response to inhaled allergens than a systemic condition with local tissue manifestations within which the drug is more active¹. In particular, desloratadine is reported to have a consistent decongestant effect that begins within a few hours of dosing and is sustained throughout the dosing interval^{1,2}. Its reportedly improved safety profile is related to a lack of effect on the QT_c interval and hence cardiac conduction³.

It is hard to imagine that loratadine, which is rapidly converted to desloratadine and which is given in twice the dosage, will not exert similar activity and efficacy. No head-to-head comparisons with loratadine or, indeed, other non-sedating antihistamines have been published. With regard to safety, terfenadine and astemizole remain the only antihistamines highlighted by the Committee on Safety of Medicines and reported in the BNF to cause clinically important cardiac side effects.

Apart from the restricted licence, desloratadine is a prescription only drug while loratidine can be purchased over-the-counter.

Cost of treatment

Both desloratidine 5 mg OD and loratadine 10 mg OD cost £7.06 per month. This is somewhat less than cetirizine (Zirtek®) at £8.15 but more than fexofenadine (Telfast®) at £6.90. It remains to be seen what the cost of generic loratadine will be.

In summary

The marketing of a new antihistamine which is an active metabolite of an established drug is not new (cetirizine/hydroxyzine, fexofenadine/ terfenadine) and the arrival of desloratadine should be seen in this context. New theories about SAR as a manifestation of systemic allergy and whether or not there are specific effects of antihistamines on the allergic cascade are interesting ... but require further investigation. Indeed such investigations are already underway in Tayside. Until convincing evidence is available and/or the results from meaningful head to head trials of non-sedating antihistamines are published, there seems little reason to change existing practice.

References

¹ Bachert C. Decongestant efficacy of desloratadine in patients with seasonal allergic rhinitis. *Allergy* 2001; **56** (Suppl 65): 14-20

² Meltzer E, Prenner B, Nayak A et al. Efficacy and tolerability of once daily 5 mg desloratadine, a H₁ receptor antagonist, in patients with seasonal allergic rhinitis. *Clin Drug Invest* 2001; **21**: 25-32

³ Henz BM. The pharmacologic profile of desloratadine: a review. *Allergy* 2001; **56** (Suppl 65): 7-13