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Use of Fludara (fludarabine) in combination with cyclophosphamide for the treatment of chronic lymphatic leukaemia

Although, we do not consider that the current marketing authorisations for oral and IV Fludara (PLs 00053/0239 & /0290) provide a recommendation that fludarabine and cyclophosphamide can be used concurrently for the treatment of chronic lymphocytic leukaemia, it does not preclude concurrent use. Malignancies very often require multiple drugs (and other therapies) and clinicians, expert groups, formulary committees etc are entitled to use/recommend drugs in combination as they see fit. An analogous situation is an SmPC for an antihypertensive would not necessarily contain all possible BP lowering regimens.

Vigilance & Risk Management of Medicines