

Steps taken after assessment

- On 2 May 2002 the European Commission approved a Type II variation to widen the specification limit for citric acid from that approved at the time of granting the Marketing Authorisation.
- On 5 November 2002 the European Commission adopted a Decision amending the Marketing Authorisation and approving a Type I variation to increase the shelf life of the finished product.
- On 10 March 2004, the EMEA accepted a change in the package insert (deletion of the list of local representatives). Amendments were made to the relevant sections of this EPAR.
- The European Commission renewed the Marketing Authorisation for Pruban on 17 November 2005; this decision was based on the favourable opinion and assessment report adopted by the CVMP on 7 September 2005.