

the pooled indications do not allow a small increase in the risk of cholecystectomies to be excluded, they show the risk to be extremely small.

11 Overall Conclusions and Recommendation for Use

The consistency of the data for both the primary and the secondary efficacy variables obtained at multiple endpoints in the CC clinical program, indicates that Zelnorm is effective in relieving the multiple and varied symptoms reported by patients with chronic constipation.

Moreover, the safety profile in the chronic constipation clinical program was similar to that reported at the time of IBS-C approval in July 2002.

Therefore, the data strongly support approval of the use of Zelnorm for the treatment of patients with chronic constipation and relief of the associated symptoms of straining, hard or lumpy stools, and infrequent defecation. The recommended dose is 6mg b.i.d. for 12 weeks.

12 References

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