

## **6 ADVERSE REACTIONS**

### **6.2 Post-marketing Surveillance**

Since 2001, in an estimated population of over 200,000 people consuming SBI, the mild AE rate is less than 0.1%. Common AEs are mild nausea and constipation. There has been one report of mild, itchy skin rash in a patient consuming a product containing SBI. No serious AEs (SAEs) have been reported to the manufacturer or the FDA. Some patients have taken SBI for up to 4 years without experiencing AEs.