FDA Advisory Committee for Lotronex

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Side Effects while taking Lotronex

Constipation 25%

None 59%

Diarrhea 2%
Ischemic Colitis 1%
Nausea 3%
Abdominal Pain 6%
Sleep Disturb. 1%
Other 3%

Patients’ Perspective

Restrictions Willing to Accept

Risk Management

- Patients sign an *Informed Consent* form
- Patients participate in surveys about use and side effects in order to provide ongoing feedback
- IBS Self Help Group and IBS Association websites\(^1\) provide Lotronex education and signs and symptoms information to users and the IBS Community

Conclusion

- IBS sufferer’s quality of life was dramatically improved with access to Lotronex.
- IBS sufferers are prepared to accept the risks associated with its use.
- IBS sufferers will work with the FDA to reduce those risks.