

FDA Advisory Committee for Lotronex

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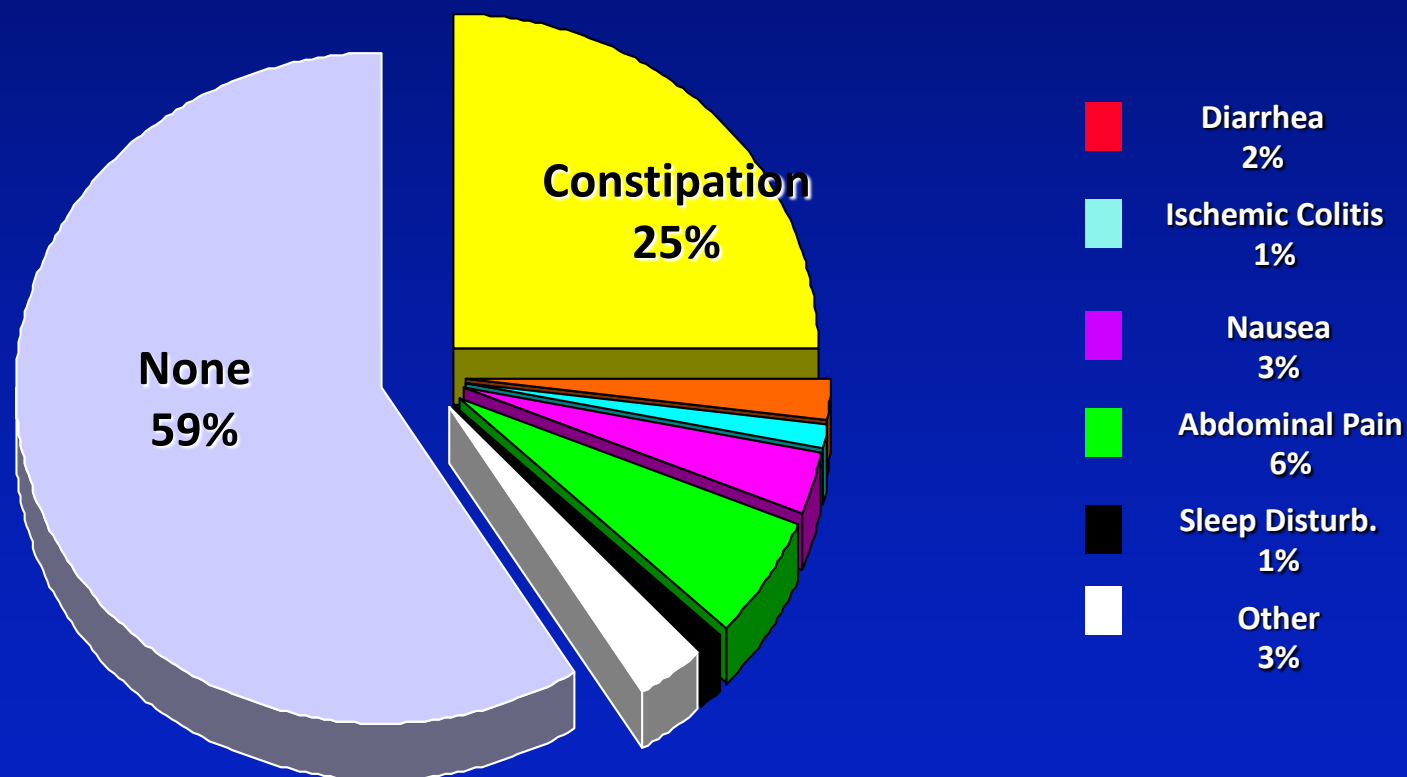
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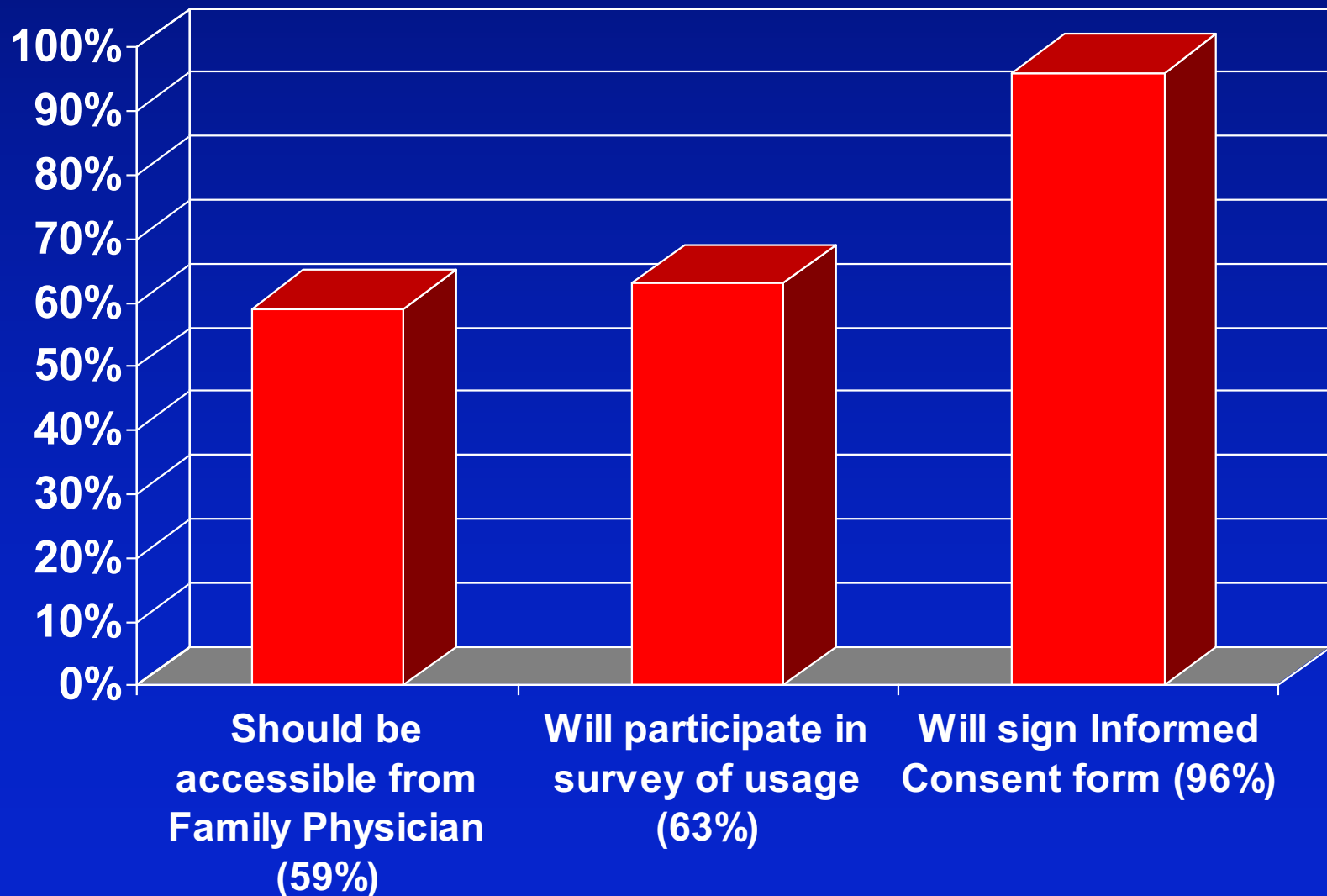
Side Effects while taking Lotronex



Patients' Perspective

References: Electronic survey conducted by the Irritable Bowel Syndrome Self Help Group December 2000 – March 2001 of 485 former and current Lotronex users.

Restrictions Willing to Accept



Reference: Electronic survey conducted by the Irritable Bowel Syndrome Self Help Group March 2002 – April 2002 of IBS sufferers.

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 websites¹ provide Lotronex education and signs and symptoms information to users and the IBS Community

Reference: 1. <http://www.ibsgroup.org> and <http://www.ibsassociation.org>

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.