

SOLESTA (Dextranomer and hyaluronic acid)

Effective Date: 1/28/14

Date Developed: 1/28/14 by Robert Sterling, MD

Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19, 2/18/20,
2/2/21, 8/3/21, 2/1/22, 1/31/23, 2/13/24, 2/18/25

Solesta is administered submucosally in the anal canal as a bulking agent in the anal area for patients with fecal incontinence who have failed to respond to more conservative therapies (e.g. diet, fiber therapy, antimotility agents, other bulking agents, temporary rectal tubes). Dextranomer is a network of dextran-sucrose beads which swell upon application; hyaluronate provides viscosity and facilitates injection.

Authorization:

Adult patients who have failed conservative therapies for fecal incontinence

Pediatric patients with vesicoureteral reflux II to IV

Dosing:

Fecal incontinence (Adult):

Submucosal injection: 4 mL given as 4 x 1 mL injections in the anal canal in the following order: posterior, left lateral, anterior, and right lateral (maximum dose: 4 mL per treatment session); if inadequate response, may repeat ≥ 4 weeks after first injection with the point of injection made in between the initial injections, shifted one-eighth of a turn (eg, left posterolateral, left anterolateral, right anterolateral, and right posterolateral).

Vesicoureteral reflux (Pediatric): Infants ≥ 2 months, Children, and Adolescents: Submucosal injection: 0.5 to 1 mL single injection in the bladder near the ureteral orifice; if the ureteral orifice does not completely coapt with a single injection, a second more distal intra-ureteral injection or a sub-ureteral implantation can be performed

NOTE: Requires a person trained in its administration

PRECAUTIONS: hypersensitivity to hyaluronic acid; active inflammatory bowel disease; prior pelvic radiation; rectal prolapse; any active anorectal condition (e.g. abscess, fissure, hemorrhoids, bleeding);

DRUG INTERACTIONS: none known

REFERENCES

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Revision History:

Date Reviewed/No Updates: 1/13/15 by C. Sanders, MD

Date Approved by P&T Committee: 1/27/15

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Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
1/24/17	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/23/18	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
1/22/19	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
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2/1/22	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
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2/18/25	Yes	Howard Taekman, MD; Robert Sterling, MD	Updated dosing section