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Tegaserod Dosage

Applies to the following strengths: 2 mg; 6 mg

Usual Adult Dose for:

- Irritable Bowel Syndrome
- Constipation Chronic

Additional dosage information:

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Usual Adult Dose for Irritable Bowel Syndrome

Tegaserod was voluntary withdrawn from the US market by the manufacturer in March, 2007 due to increased reports of serious cardiovascular adverse events, including angina, heart attacks, and stroke. However, the FDA announced on July 27, 2007 that it is allowing the restricted use of tegaserod under a treatment investigational new drug (IND) protocol to treat IBS-C and CIC in women younger than 55 who meet specific guidelines. These patients must meet strict criteria and have no known or preexisting heart complications and be in critical need of this therapy. Tegaserod will stay off the market for general use. Prescribers with IBS-C or CIC patients who meet the IND criteria should contact Novartis at 888-669-6682 or 800-QUI-NTILE. Those patients who do not qualify for the tegaserod treatment protocol may contact FDA's Division for Drug Information regarding other options at 888-463-6332.

Women:

Initial dose: 6 mg orally twice a day before meals for 4 to 6 weeks.

Maintenance dose: If patients respond to therapy after 4 to 6 weeks, an additional 4 to 6 week course may be prescribed. Efficacy beyond 12 weeks has not been established.

Men: Safety and efficacy have not been established.

Usual Adult Dose for Constipation - Chronic

Tegaserod was voluntary withdrawn from the US market by the manufacturer in March, 2007 due to increased reports of serious cardiovascular adverse events, including angina, heart attacks, and stroke. However, the FDA announced on July 27, 2007 that it is allowing the restricted use of tegaserod under a treatment investigational new drug (IND) protocol to treat IBS-C and CIC in women younger than 55 who meet specific guidelines. These patients must meet strict criteria and have no known or preexisting heart complications and be in critical need of this therapy. Tegaserod will stay off the market for general use. Prescribers with IBS-C or CIC patients who meet the IND criteria should contact Novartis at 888-669-6682 or 800-QUI-NTILE. Those patients who do not qualify for the tegaserod treatment protocol may contact FDA's Division for Drug Information regarding other options at 888-463-6332.

6 mg orally twice a day before meals. Efficacy beyond 12 weeks has not been established.

Renal Dose Adjustments

Contraindicated in patients with severe renal impairment (CrCl 15 mL/min or less)

Liver Dose Adjustments

Contraindicated in patients with moderate or severe hepatic impairment. No dosage adjustments are required in mild hepatic impairment.

Dose Adjustments

Patients should stop therapy and consult a physician in the presence of new or worsening abdominal pain (with or without rectal bleeding).

Precautions

Contraindicated in patients with history of bowel obstruction, symptomatic gallbladder disease, sphincter of Oddi dysfunction, or abdominal adhesions.

Therapy should not be initiated in patients with diarrhea. Discontinue immediately if syncope or hypotension associated with diarrhea occur.

Discontinue immediately if symptoms of ischemic colitis such as rectal bleeding, bloody diarrhea, or new/worsened abdominal pain occur. Treatment with tegaserod should not be resumed if ischemic colitis is confirmed.

Patients should be advised discontinue tegaserod and to notify their physician promptly if they experience severe diarrhea, lightheadedness, dizziness, fainting, bloody stools, or new or increased stomach pain.

Dialysis

Data not available

Other Comments

Tegaserod should be taken before meals.

If the patient is unable to swallow whole tablets, tegaserod tablets may be crushed and mixed with water or apple juice to make a suspension. Apple juice may be preferable because it masks the taste of tegaserod, forms a homogenous suspension, and the drug's dissolution profile is like that of whole tablets. Tegaserod is stable in apple juice for 1 hour at room temperature and for 3 days at 5 degrees C. Milk, applesauce, yogurt, orange juice, and chocolate-hazelnut spread are not recommended because they do not form homogenous suspensions and/or dissolution is not comparable to the tablets which could adversely affect bioavailability.

Frequently asked questions

• Is Zelnorm back on the market?

More about tegaserod

- Check interactions
- Compare alternatives
- Reviews (45)
- Side effects
- During pregnancy
- Drug class: serotoninergic neuroenteric modulators
- Breastfeeding

Patient resources

Other brands

Zelnorm

Professional resources

Other brands

Zelnorm

Related treatment guides

- Constipation, Chronic
- Irritable Bowel Syndrome with Constipation

Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

Medical Disclaimer

DRUG STATUS

Availability

Rx Prescription only

Pregnancy & Lactation

& Risk data available

CSA Schedule*

N/A Not a controlled drug

Approval History

The Drug history at FDA

User Reviews & Ratings

8.8 / 10

45 Reviews

Related Drugs

MiraLAX, Linzess, Amitiza, Trulance, Ibsrela, GlycoLax, tenapanor, plecanatide, linaclotide, lubiprostone

Images

Zelnorm (tegaserod) 6 mg (NVR E H)



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