Medical exception template

Orilissa® elagolix tablets 150 mg 200 mg

Full-form letter

This functionality contains additional fields for you to complete, based on your clinical judgment for your specific patient, and creates a full-form letter.

Based on your selections, the tool will generate pre-populated information consistent with the approved U.S. full Prescribing Information.

Your details:

First full name:

Last full name:

Your contact number:

Payer details:

Payer's full name:

Department:

Street address:

Zip code:

Fax number (Optional):

Denial date (MM/DD/YYYY):

Denial reason:

Medical exception template

Orilissa® elagolix tablets 150 mg 200 mg

Full-form letter continued

Patient details:

Patient's full name:

Patient's contact number:

Date of birth (Optional) (MM/DD/YYYY):

Member ID:

Date diagnosed (Optional) (MM/DD/YYYY):

Description of patient's medical history:

Medical exception template

Full-form letter continued

Orilissa® elagolix tablets 150 mg 200 mg

My patient:

Please select all that apply.

☐ **Prior treatment intolerance or failure in the management of moderate to severe pain associated with endometriosis with no or mild hepatic impairment**

Medical exception

Clinical Consideration: Prior treatment intolerance or failure in the management of moderate to severe pain associated with endometriosis with no or mild hepatic impairment

- ORILISSA is indicated for the management of moderate to severe pain associated with endometriosis.
- Use the lowest effective dose, taking into account the severity of symptoms and treatment objectives.
- In Study EM-1 and EM-2, 46% and 43% of women treated with ORILISSA 150 mg once daily and 76% and 72% of women treated with ORILISSA 200 mg twice daily were responders* for dysmenorrhea compared to 20% and 23% of women on placebo, respectively, at Month 3.
- In Study EM-1 and EM-2, 50% of women treated with ORILISSA 150 mg once daily and 55% and 58%, respectively, of women treated with ORILISSA 200 mg twice daily were responders* for non-menstrual pelvic pain compared to 36% and 37% of women on placebo, respectively, at Month 3.
- Women taking ORILISSA 150 mg once daily and 200 mg twice daily reported a statistically ($p < 0.001$) significant reduction from baseline in numeric rating scale (NRS) scores compared to placebo at Month 3 in both Studies EM-1 and EM-2 (Study EM-1: 0.7 points for ORILISSA 150 mg once daily and 1.3 points for ORILISSA 200 mg twice daily; Study EM-2: 0.6 points for ORILISSA 150 mg once daily and 1.2 points for ORILISSA 200 mg twice daily).
- For additional information on this topic, please contact AbbVie Medical Information (www.abbviemedinfo.com).

☐ **Prior treatment intolerance or failure in the management of moderate to severe pain associated with endometriosis with moderate hepatic impairment**

Medical exception

Clinical Consideration: Prior treatment intolerance or failure in the management of moderate to severe pain associated with endometriosis with moderate hepatic impairment

- ORILISSA is indicated for the management of moderate to severe pain associated with endometriosis.
- Initiate treatment with ORILISSA 150 mg once daily for up to 6 months in patients with moderate hepatic impairment.
- In Study EM-1 and EM-2, 46% and 43% of women treated with ORILISSA 150 mg once daily and 76% and 72% of women treated with ORILISSA 200 mg twice daily were responders* for dysmenorrhea compared to 20% and 23% of women on placebo, respectively, at Month 3.
- In Study EM-1 and EM-2, 50% of women treated with ORILISSA 150 mg once daily and 55% and 58%, respectively, of women treated with ORILISSA 200 mg twice daily were responders* for non-menstrual pelvic pain compared to 36% and 37% of women on placebo, respectively, at Month 3.
- Women taking ORILISSA 150 mg once daily and 200 mg twice daily reported a statistically ($p < 0.001$) significant reduction from baseline in numeric rating scale (NRS) scores compared to placebo at Month 3 in both Studies EM-1 and EM-2 (Study EM-1: 0.7 points for ORILISSA 150 mg once daily and 1.3 points for ORILISSA 200 mg twice daily; Study EM-2: 0.6 points for ORILISSA 150 mg once daily and 1.2 points for ORILISSA 200 mg twice daily).
- For additional information on this topic, please contact AbbVie Medical Information (www.abbviemedinfo.com).

Medical exception template

Full-form letter continued

Orilissa® elagolix tablets 150 mg 200 mg

My patient:

Please select all that apply.

☐ **Dyspareunia is a predominant symptom**

Medical exception

Clinical Consideration: Dyspareunia is a predominant symptom

- ORILISSA is indicated for the management of moderate to severe pain associated with endometriosis.
- Initiate treatment with ORILISSA 200 mg twice a day for up to 6 months in patients in whom dyspareunia is a co-existing condition.
- In both Studies EM-1 and EM-2, women treated with ORILISSA 200 mg twice daily showed statistically significantly greater reduction in dyspareunia from baseline to Month 3 than women given placebo (Study EM-1: 0.2; Study EM-2: 0.3).
- For additional information on this topic, please contact AbbVie Medical Information (www.abbviemedinfo.com).

Please note:

The guidance presented here is for informational purposes only and is not intended to provide reimbursement or legal advice. AbbVie does not guarantee that the use of any information provided will result in coverage or payment by any third-party payer. (You are responsible for the submission based on your clinical judgment.)
This information is provided for use by United States health care professionals only.
It is not intended for patients.