Remifentanil—
Addressing the challenges of ambulatory orthopedic procedures$^{1-3}$

INDICATIONS AND IMPORTANT RISK INFORMATION

INDICATIONS

ULTIVA® (remifentanil HCl) for Injection is indicated for intravenous administration:

- As an analgesic agent for use during the induction and maintenance of general anesthesia for inpatient and outpatient procedures
- For continuation as an analgesic into the immediate postoperative period in adult patients under the direct supervision of an anesthesia practitioner in a postoperative anesthesia care unit or intensive care setting
- As an analgesic component of monitored anesthesia care in adult patients

IMPORTANT RISK INFORMATION

Due to the presence of glycine in the formulation, ULTIVA is contraindicated for epidural or intrathecal administration. ULTIVA is also contraindicated in patients with known hypersensitivity to fentanyl analogs.

Please see Important Risk Information continued on pages 10-11, and accompanying full Prescribing Information in pocket for all precautions, warnings, contraindications, and adverse events.
Predictable control\textsuperscript{1-3}

**Rapid response**
- Allows for rapid titration to the desired depth of analgesia as required by varying levels of intraoperative stress\textsuperscript{1}

**Rapid recovery**
- Facilitates rapid recovery from outpatient and ambulatory surgery\textsuperscript{1,3,4,5,6}

**Added characteristics of Remifentanil**
- Well-established hemodynamic profile in inpatient and outpatient procedures\textsuperscript{1,6,7,9}
- No accumulation regardless of infusion duration\textsuperscript{1}
- Can be used in patients with renal or hepatic impairment\textsuperscript{1}

Remifentanil produces adverse events that are characteristic of \(\mu\)-opioids, such as respiratory depression, apnea, tachycardia, bradycardia, hypotension, hypertension, and skeletal muscle (including chest wall) rigidity.

1 Continuous infusions of Remi should be administered only by an infusion device and continuous monitoring is necessary. Interruption of infusion will result in rapid offset of effect.\textsuperscript{1}

2 Within 5 to 10 minutes after discontinuation of Remi, no residual analgesic activity will be present. However, respiratory depression may occur in some patients up to 30 minutes after termination of infusion due to residual effects of concomitant anesthetics. Other analgesics should be administered prior to discontinuation of Remi where postoperative pain is anticipated.\textsuperscript{1}

3 Study drugs were used in ordinary anesthetic functions to best reflect usual clinical practice.\textsuperscript{2}

4 Studies evaluated patients undergoing gynecological laparoscopy, varicose vein surgery, or arthroscopic surgery; outpatient laparoscopic tubal ligation procedures; day-case cystoscopies; and day-case rigid bronchoscopy.\textsuperscript{1}

5 Tachycardia, bradycardia, hypotension, and hypertension have been reported with Remi.\textsuperscript{1}

6 Remifentanil is commonly referred to as Remi by anesthesia providers.

Knee surgery (arthroscopy) case study

40-year-old male
6'3", 88.5 kg (195 lb)
BMI 24.4 kg/m\textsuperscript{2}

**Comorbidities**
- Hypertension
- History of delayed arousal following prior anesthetics

**Medication:** lisinopril

This case study is for illustrative and educational purposes only. The dosing regimen is specific to this case study and other regimens may vary depending on patient and procedure. Any use of this product is subject to the judgment of the practitioner in each case. Please consult the full Prescribing Information in the use of this product.

**Procedural considerations**
- Ambulatory anesthesia goals include rapid recovery, good quality analgesia, decreased duration of care, and prompt return to preoperative functional status with minimal side effects, such as postoperative nausea and vomiting (PONV).\textsuperscript{8}
- Management of hemodynamics and intraoperative stress responses is an important objective in short-procedure surgeries\textsuperscript{9}

**Patient considerations**
- Ambulatory patients expect to return to their preoperative functional state in the early postoperative period\textsuperscript{8}
- Minimizing patient discomfort and obtaining patient satisfaction in this setting are important objectives for anesthesia providers\textsuperscript{8}

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**Remifentanil case approach**

**Hypothetical total intravenous anesthesia (TIVA) plan**

<table>
<thead>
<tr>
<th>Stage of procedure</th>
<th>Action</th>
<th>Notes and safety considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperative</td>
<td>Acetaminophen 1000 mg po ~30 minutes prior to induction</td>
<td>• Remifentanil is commonly referred to as Remi by anesthesia providers.</td>
</tr>
<tr>
<td></td>
<td>Femoral nerve block</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hold ACE inhibitor on morning of surgery</td>
<td></td>
</tr>
<tr>
<td>Induction</td>
<td>Palonosetron 0.075 mg IV immediately prior to induction</td>
<td>• Remifentanil produces adverse events that are characteristic of μ-opioids, such as respiratory depression, apnea, tachycardia, bradycardia, hypotension, hypertension, and skeletal muscle (including chest wall) rigidity. Due to the presence of glycine in the formulation, Remi is contraindicated for epidural or intrathecal administration and in patients with known hypersensitivity to fentanyl analogs1</td>
</tr>
<tr>
<td></td>
<td>Dexamethasone 8 mg IV immediately prior to induction</td>
<td>• Remi has a synergistic effect with other anesthesia drugs and may reduce the dosage of propofol and other agents1</td>
</tr>
<tr>
<td></td>
<td>Propofol 1.5-2.5 mg/kg IV</td>
<td>• Administer Remi in port closest to patient to avoid accumulation in IV tubing. Titrated slowly in small increments until patient response is adequate to help minimize side effects, such as muscle rigidity or respiratory depression. Vital signs and oxygen saturation must be continuously monitored during Remi administration1</td>
</tr>
<tr>
<td></td>
<td>Remi* 1 mcg/kg IV over 30-60 seconds</td>
<td>• Intraoperative awareness has been reported with concomitant administration of Remi with propofol infusion ≤75 mcg/kg/min1</td>
</tr>
<tr>
<td>Maintenance</td>
<td>Remi 0.1-0.2 mcg/kg/min IV to start and adjusted to maintain heart rate within 20% of baseline</td>
<td>• Increase dose of Remi for painful or stimulating parts of procedure. Rapid response within 5-10 minutes of dose adjustment1</td>
</tr>
<tr>
<td></td>
<td>Propofol adjusted to maintain BIS between 40-60 (~120-175 mcg/kg/min IV)</td>
<td>• Maintain adequate amount of narcotic to prevent increase in blood pressure. Adjust dose of Remi to help provide hemodynamic stability1</td>
</tr>
<tr>
<td></td>
<td>Rocuronium to maintain 1 of 4 twitches</td>
<td></td>
</tr>
<tr>
<td>Emergence and postoperative</td>
<td>Discontinue propofol ~10 minutes prior to end of case</td>
<td>• Prepare for postoperative pain. Rapid offset of Remi results in rapid dissipation of analgesic effect within 5-10 minutes of discontinuation. Other analgesics should be administered prior to discontinuation where postoperative pain is anticipated1</td>
</tr>
<tr>
<td></td>
<td>Decrease Remi to 0.05 mcg/kg/min IV</td>
<td>• Rapid offset and rapid recovery regardless of infusion duration1</td>
</tr>
<tr>
<td></td>
<td>Surgeon to inject local anesthetic (typically 0.25% bupivacaine) into joint space</td>
<td>• Due to residual effects of concomitant anesthetics, respiratory depression may occur up to 30 minutes after discontinuation of Remi1</td>
</tr>
<tr>
<td></td>
<td>Discontinue all agents after wound closure</td>
<td>• In adult general anesthesia studies of 281 patients given Remi for postoperative analgesia, 61 (22%) experienced nausea, 22 (8%) experienced vomiting, 19 (7%) experienced respiratory depression, and 15 (5%) experienced shivering. After discontinuation in 929 patients, 339 (36%) experienced nausea, 150 (16%) experienced vomiting, 49 (5%) experienced shivering, and 44 (5%) experienced fever1</td>
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Please see Important Risk Information, starting on front page, for additional safety information.

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## Remifentanil case approach

### Hypothetical IV and inhalational (balanced) plan

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<td><strong>Maintenance</strong></td>
<td>Remi 0.1 mcg/kg/min IV to start and adjusted to maintain heart rate within 20% of baseline</td>
</tr>
<tr>
<td></td>
<td>Inhaled agent (sevoflurane or desflurane) adjusted to maintain BIS between 40-60 or MAC at 0.6-0.8</td>
</tr>
<tr>
<td></td>
<td>Rocuronium to maintain 1 of 4 twitches</td>
</tr>
<tr>
<td><strong>Emergence and postoperative</strong></td>
<td>Discontinue inhaled agent – 10 minutes prior to end of case</td>
</tr>
<tr>
<td></td>
<td>Initiate nitrous oxide at 50% to 60%</td>
</tr>
<tr>
<td></td>
<td>Decrease Remi to 0.05 mcg/kg/min IV</td>
</tr>
<tr>
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### Notes and safety considerations

*Remifentanil is commonly referred to as Remi by anesthesia providers.*

- Remi* produces adverse events that are characteristic of μ-opioids, such as respiratory depression, apnea, tachycardia, bradycardia, hypotension, hypertension, and skeletal muscle (including chest wall) rigidity. Due to the presence of glycine in the formulation, Remi is contraindicated for epidural or intrathecal administration and in patients with known hypersensitivity to fentanyl analogs.

- Remi has a synergistic effect with other anesthesia drugs and may reduce the dosage of propofol and other agents.

- Administer Remi in port closest to patient to avoid accumulation in IV tubing. Titrate slowly in small increments until patient response is adequate to help minimize side effects, such as muscle rigidity or respiratory depression. Vital signs and oxygen saturation must be continuously monitored during Remi administration.

- Intraoperative awareness has been reported with concomitant administration of Remi with propofol infusion ≤75 mcg/kg/min.

- Increase dose of Remi for painful or stimulating parts of procedure. Rapid response within 5-10 minutes of dose adjustment.

- Maintain adequate amount of narcotic to prevent increase in blood pressure. Adjust dose of Remi to help provide hemodynamic stability.

- Prepare for postoperative pain. Rapid offset of Remi results in rapid dissipation of analgesic effect within 5-10 minutes of discontinuation. Other analgesics should be administered prior to discontinuation where postoperative pain is anticipated.

- Rapid offset and rapid recovery regardless of infusion duration.

- Due to residual effects of concomitant anesthetics, respiratory depression may occur up to 30 minutes after discontinuation of Remi.

- In adult general anesthesia studies of 281 patients given Remi for postoperative analgesia, 61 (22%) experienced nausea, 22 (8%) experienced vomiting, 19 (7%) experienced respiratory depression, and 15 (5%) experienced shivering. After discontinuation in 929 patients, 339 (36%) experienced nausea, 150 (16%) experienced vomiting, 49 (5%) experienced shivering, and 44 (5%) experienced fever.

Please see full Prescribing Information in pocket for dosing and administration.
Goal: Predictable control

Intraoperative

- Significantly reduces intraoperative stress responses during outpatient and ambulatory procedures\(^{10,11}\)
- Well-established hemodynamic profile in inpatient and outpatient procedures\(^{1,6,7}\)

Respiratory depression, apnea, tachycardia, bradycardia, hypotension, hypertension, and skeletal muscle (including chest wall) rigidity have been reported with Remi.\(^1\)

- Provides a consistently stable intraoperative course for both inpatients and outpatients\(^9\)

Recovery

- Significantly reduces time to orientation in ambulatory orthopedic procedures\(^{12}\)
- Allows for early awakening when used with propofol-based TIVA in ambulatory procedures\(^{11}\)

- Provides earlier response to verbal command, discharge from the OR, and eligibility for discharge home compared to fentanyl in outpatient surgery\(^{11,12}\)

Recovery

- Study evaluated patients undergoing day-case cystoscopies\(^6\) and day-case rigid bronchoscopy.\(^7\)
- Within 5 to 10 minutes after discontinuation of Remi, no residual analgesic activity will be present. However, respiratory depression may occur in some patients up to 30 minutes after termination of infusion due to residual effects of concomitant anesthetics. Other analgesics should be administered prior to discontinuation of Remi where postoperative pain is anticipated.\(^1\)
- Median time to orientation was significantly faster in the Remi group: 6.0 min (5.0–8.5 min) compared with 8.0 min (5.0–12.8 min) in the N\(_2\)O group. No significant differences between groups were found in time to awakening to verbal stimulation, desflurane or fentanyl administration, neuropsychological testing, or any other outcome measure.\(^2\)

- Study evaluated patients undergoing day-case cystoscopies\(^6\) and day-case rigid bronchoscopy.\(^7\)
- Study evaluated 200 patients undergoing ambulatory laparoscopic surgery. Significantly fewer Remi patients than alfentanil patients had any intraoperative responses or responses to trocar insertion. Remi patients qualified for Phase 1 discharge later and were given postoperative analgesics sooner than alfentanil patients. Times to awakening and actual discharge times from the ambulatory center were similar between groups.\(^11\)

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\(^{1}\) Continuous infusions of Remi should be administered only by an infusion device and continuous monitoring is necessary. Interruption of infusion will result in rapid offset of effect.\(^1\)

\(^{10}\) In 201 outpatients, the Remi group experienced significantly fewer stress responses to surgical stimuli than the alfentanil group. Significantly fewer Remi patients responded to skin closure. Times to spontaneous respiration, adequate respiratory rate, and tracheal extubation were significantly shorter for alfentanil than Remi. Remi patients showed significantly better recovery of psychomotor and psychometric function between 30 and 90 min after surgery. Incidences of intraop hypotension and postop shivering were significantly higher with Remi.\(^10\)

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IMPORTANT RISK INFORMATION
(continued from front)

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Continuous infusions of ULTIVA should be administered only by an infusion device. IV bolus administration of ULTIVA should be used only during the maintenance of general anesthesia.

In nonintubated patients, single doses of ULTIVA should be administered over 30 to 60 seconds. Interruption of an infusion of ULTIVA will result in rapid offset of effect. Rapid clearance and lack of drug accumulation result in rapid dissipation of respiratory depressant and analgesic effects (within 5 to 10 min) upon discontinuation of ULTIVA at recommended doses. Discontinuation of an infusion of ULTIVA should be preceded by the establishment of adequate postoperative analgesia particularly where postoperative pain is anticipated.

ULTIVA should be used with caution in pediatric, geriatric, and morbidly obese patients due to high variability in pharmacodynamics and dose/response. Intraoperative awareness has been reported with concomitant administration with propofol infusion ≤75 mcg/kg/min.

Failure to adequately clear the IV tubing to remove residual ULTIVA has been associated with the appearance of respiratory depression, apnea, and muscle rigidity upon the administration of additional fluids or medications through the same IV tubing.

ULTIVA SHOULD BE USED IN CAREFULLY MONITORED SETTINGS BY SPECIFICALLY TRAINED PERSONS NOT INVOLVED IN THE SURGICAL OR DIAGNOSTIC PROCEDURE. OXYGEN SATURATION IS TO BE CONTINUOUSLY MONITORED. RESUSCITATIVE AND INTUBATION EQUIPMENT, OXYGEN, AND AN OPIOID ANTAGONIST MUST BE READILY AVAILABLE.

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The study by Philip and colleagues (reference 11) was supported in part by Glaxo Wellcome Inc.

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Remifentanil—
Addressing ambulatory orthopedic challenges from surgery to recovery1-3

FOR INJECTION
ULTIVA® (remifentanil HCl)

INDICATIONS AND IMPORTANT RISK INFORMATION

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Predictable control\textsuperscript{1-3}

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<td><strong>Facilitates rapid recovery</strong> from outpatient and ambulatory surgery\textsuperscript{2,4-5}</td>
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<tr>
<td><strong>Significantly reduces intraoperative stress responses</strong> during outpatient and ambulatory procedures\textsuperscript{6,7,9}</td>
</tr>
<tr>
<td><strong>Provides a consistently stable</strong> intraoperative course for both inpatients and outpatients\textsuperscript{8}</td>
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<tr>
<td><strong>Well-established hemodynamic profile</strong> in inpatient and outpatient procedures\textsuperscript{1,9,10}</td>
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**IMPORTANT RISK INFORMATION**

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