Informed consent

Key words: Duty of care, informed consent, negligence.

Although this column has discussed the necessity for informed consent before, there have been some changes in the law which suggest that this subject is becoming even more difficult to understand. The legal principles behind informed consent are clear. Legally, any unauthorized use of force on another person constitutes a "battery," and the threat of unauthorized use of force is an "assault." (Black's Law Dictionary)

Most surgical operations involve some use of force. Therefore, there must be consent. Because the nature of surgery is outside the experience of most patients, the consent must be granted only after the patient is properly informed. The most famous description of informed consent is a quote from Justice Benjamin Cardozo who, in 1914, stated that: "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages." (Schloendorff v Society of New York Hospital, 105 N.E. 92 (N.Y., 1914); overruled on other grounds (Bing v Thunig, 143 N.E. 2d 3, N.Y.))

If a nurse anesthetist and surgeon were walking down the street and decided that someone standing on the corner would look better with a less prominent chin, grabbed the person, anesthetized him, restructured his chin, bandaged him up and left him in front of a hospital, they could be indicted for assault and battery. In terms of legal principles, something which is illegal on the street does not become any more legal when performed in an operating room.

Like many other things in malpractice cases, attitude is very important. Patients want to know that their healthcare providers respect them and treat them as important. Healthcare providers who do not respect their patients, who treat their patients and their patients' bodies with arrogance should not expect much sympathy or forgiveness from their patients when things go wrong, even if it is not the provider's fault. The healthcare provider who is so arrogant that he or she does not seek the consent of an informed patient for a procedure which he or she is about to perform had better have a perfect result. The provider who carefully explains the risks to a patient and shows a concern for the patient, will be in far less trouble if things go wrong because the provider allowed the patient to participate in the decision.

What are the issues an anesthetist must discuss with a patient? In general, there are certain subjects which have to be explained to a patient for informed consent. Four are relevant to anesthesia:

1. The general nature of the contemplated procedure.
2. The risks involved.
3. The prospects of success.

The remaining required topics that are not relevant to anesthesia are:

June 1998/ Vol. 66/ No. 3
1. The patient's diagnosis.
2. The prognosis if the procedure is not performed.

**Significant, foreseeable risks**

Not every conceivable risk must be disclosed. Overwhelming the patient with information does not allow the patient to make an informed consent. The law recognizes that the patient will never know as much about anesthesia as the anesthetist. What is required is disclosure of the significant, foreseeable risks. However, what is significant is relative. Less frequent or less debilitating reactions may be more significant the more elective is the procedure or when there are other alternatives. In addition, if the healthcare provider knows that a patient is susceptible to a certain risk, there may be an obligation to disclose it even if it is remote to most people.

How does the healthcare provider determine what risks are significant, foreseeable risks? Usually the courts say that what a CRNA is supposed to do (the standard of care) is what another CRNA in similar circumstances would do. This is also the "traditional view" of informed consent. The healthcare practitioner discloses what other healthcare practitioners disclose as the significant, foreseeable risks. But this viewpoint has been criticized as "medical paternalism." It is part of the arrogance that many patients feel they encounter when they deal with the healthcare system. The healthcare provider has so much more education, knows so much more than the patient, and it is really inconvenient to have to explain these unlikely risks to someone when the healthcare provider already knows what is best for the patient.

This view does not recognize, as Justice Cardozo required, that the patient has the right to make the final choice, no matter how inconvenient or ill-advised the healthcare practitioner finds the decision. The same arrogance is also found when a healthcare provider decides that the patient is too nervous or "cannot handle" informed consent. A healthcare provider who fails to respect the patient's ultimate right to make decisions on the patient's own body had better be sure nothing goes wrong, because if the outcome is less than perfect, the patient will "get even."

**The modern view of informed consent**

Justice Cardozo's statement has led to a so-called "modern view" of informed consent. In the modern view, what other providers disclose is irrelevant. What should be disclosed to patients are the risks a reasonable person in the patient's shoes would want to know. States are more or less evenly divided between the traditional view and the modern view in determining what significant, foreseeable risks must be disclosed to patients.

Even the modern view has been criticized because it requires disclosure of only what a reasonable patient should hear rather than what this patient needs and wants to hear. Ideally, informed consent is a process in which the healthcare provider presents information and answers the patient's questions. However, such a disclosure requirement would probably prove too difficult for the courts who are looking for the same easy-to-apply tests as healthcare practitioners.

**Helpful advice**

Here are some practical points to keep in mind:

- **The process is important.** It is best if there is a cooperative process. The healthcare practitioner should answer questions and should preserve written evidence of the discussion between patient and provider. Because many drugs used in anesthesia cause amnesia, without either a written document or a witness, it will be the practitioner's word against the patient's. If something has gone wrong, the jury or fact-finder will be very sympathetic to the patient. By the way, the discussion is more important than the written evidence of it. However, like so many other things, it will be hard to prove that a discussion took place without something in writing. The writing may not be enough if the patient did not understand the document or had reasonable questions which were not answered.

- **Think about when in the process to get informed consent.** For example, informed consent from a woman in active labor may be insufficient because the patient is in too much pain to make an informed decision. I am not suggesting that informed consent is unnecessary in obstetrical cases. I am merely pointing out that in practically every labor case, there was a period of at least 6 months when many people knew that one day this patient was going to be in pain. Therefore, there should have been a lot of opportunity to get a proper consent prior to the day when she presents for delivery.

- **Do not make statements you may not be able to keep.** If you promise a patient you are going to do a regional, what happens if you have to change your mind? In *Lugenbuhl v Dowling*, 1997 La. LEXIS 2498 (Oct. 10), a surgeon promised he would use surgical mesh when he obtained the consent. The surgeon changed his mind during the operation. As it turned out, things did not go well and his patient sued him based on the lack of informed consent. Patients should not be misled that unanticipated circumstances cannot arise. A healthcare practitioner cannot rely on a change in circumstances to
negate his or her conversation with the patient if the change was foreseeable.

- Do not make statements you know to be untrue. Some anesthesia departments have informed consent forms which state that an anesthesiologist is going to administer the anesthetic. Should something go wrong after the patient was incorrectly told an anesthesiologist would administer the anesthetic, the form has "plaintiff's exhibit" written all over it.

- Avoid omissions. Keep in mind that virtually every informed consent case is based on a failure to disclose something. If you have doubts about whether to disclose a risk, err on the side of disclosure. If you are afraid to disclose something because the patient might not consent to the operation, go back and re-read the quote from Justice Cardozo at the beginning of this article.

- Beware of variations from state to state. There are important variations in state law. In Pennsylvania, the law provides that informed consent is only necessary when performing a "surgical or operative" procedure, but not a "non-surgical" procedure. Unfortunately, there is no definition of either surgical or non-surgical. Because the distinction is largely arbitrary (non-surgical procedures can still constitute a use of force and be "batteries" and can still do as much harm as surgical procedures), Pennsylvania law on informed consent can be complicated and illogical. See Morgan v MacPhail, 704 A. 2d 617, (Penna., 1997) where the Pennsylvania Supreme Court, in a 5 to 1 decision, held that informed consent was not required in a case involving an intercostal nerve block. The dissent criticized the decision for "perpetuat[ing] an unfounded distinction in the law of informed consent [in Pennsylvania] between surgical and non-surgical distinctions." The case reports a recent Pennsylvania statute making significant changes in the Pennsylvania requirements for informed consent.

Statutory enactments

Like Pennsylvania, other states have adopted a number of statutory enactments designed to protect healthcare providers against frivolous suits. Unfortunately, not all new statutes are moving in the same direction. Some healthcare reform laws deal specifically with informed consent and spell out, with specificity, what must be disclosed. Some statutes now limit the requirement of informed consent to only certain kinds of procedures. In some of the new statutes, the legislature has abandoned both the traditional view and modern view in favor of disclosure of only those risks listed in the statute. While this legislation may reduce the number of frivolous suits, it does nothing to foster the type of discussion which should be at the core of informed consent. As long as the healthcare provider has disclosed these identified risks, the patient cannot bring suit, whether or not the patient understood the risk and whether or not there may have been other risks more appropriate to the patient which were not explained.

Shift in legal principles

The other area of change has been a shift in the legal principles which require informed consent. As stated at the opening of this article, informed consent was originally seen as necessary to obtain permission to apply force to someone's body. It had nothing to do with negligence, which is the failure to meet a standard of practice. A provider who was not negligent could still be liable if the provider failed to respect the patient's ultimate right to make decisions about his or her body. In some states, the "consent to battery" aspect of informed consent has become displaced by a theory of negligence. Informed consent has become such a common healthcare procedure that, in some states, the courts have held or the legislature has determined that it is a part of the standard of care. A healthcare practitioner's obligation to obtain informed consent, in these states, is not based on avoiding a battery, it is part of the standard of practice expected of the practitioner. Failure to obtain informed consent would be negligence.

Informed consent has generally required a description of risks that were foreseeable without negligence. Because informed consent only gives permission to the practitioner to use force in the conduct of the operation, disclosing that the practitioner might be negligent was useless. A patient does not consent to negligence, and a practitioner who is negligent does not avoid liability no matter what is disclosed. Disclosure of information about the healthcare practitioner is rarely required. But, there are exceptions.

In Faya v Almarez, 620 A.2d 327 (Md. 1993), the Supreme Court of Maryland overruled the trial court which had dismissed a claim that a physician had an obligation to disclose his human immunodeficiency virus (HIV) status to his patients as part of the informed consent process. The trial court had ruled that because the patients were not, in fact, infected by the physician, they were in no position to complain that the physician had not informed them of his HIV status. The Appellate Court (relying, at least in part, on the position of the American Medical Association that physicians infected with HIV should confer with a public health officer and refrain from performing procedures that posed a significant risk of HIV transmission) ruled that
whether or not a physician had an obligation to disclose his HIV status was a question of fact to be determined by a jury. There have now been two more cases which consider whether healthcare workers have an obligation to disclose their HIV status as part of the informed consent process. Courts in California and Minnesota have ruled that if the patient is not, in fact, infected with HIV, there can be no recovery. Ironically, in both cases a trial court threw out the charges, only to have them reinstated by an intermediate court and then to have the cases dismissed again.

In Kerins v Hartley, 27 Cal. App. 4th 1062, 33 Cal. Rptr. 2d 172 (1994), a patient brought suit seeking to recover damages for emotional distress for fear of contracting acquired immune deficiency syndrome (AIDS) after a procedure conducted by an HIV-infected surgeon. The trial court entered summary judgment in favor of defendants. The Court of Appeals reversed. Shortly thereafter, the Supreme Court of California ruled, in Potter v Firestone, that plaintiffs could not sue for negligent infliction of emotional distress in California unless it accompanied another tort. “Unless a defendant assumes a duty to the plaintiff in which the emotional condition of the plaintiff is the object, recovery for negligent infliction of emotional distress is ordinarily available only if the defendant breaches some other legal duty which threatens physical injury, and the emotional distress is proximately caused by that breach of duty.” (6 Cal.4th at pp. 984-985, 25 Cal. Rptr.2d 550, 863 P.2d 795) Because of the California Supreme Court’s decision in Potter, the Appellate Court reconsidered the Kerins v Hartley case and held that the statistically insignificant chance that a plaintiff could contract AIDS from a surgeon precluded recovery of damages for emotional distress merely for creating the fear of contracting AIDS.

Similarly, in K.A.C. v Benson, 527 N.W. 2d 553 (Minn., 1995), a patient brought an action against a physician who performed a gynecological examination at a time when the physician suffered from AIDS and had running sores on his hands and arms. The trial court granted the physician’s motion for summary judgment. The patient appealed and the Court of Appeals reversed. The physician appealed, and the Supreme Court of Minnesota reversed the Court of Appeals. The Minnesota Supreme Court ruled that a patient who did not allege that she was actually exposed to HIV was not, as a matter of law, in the zone of danger and could not recover for negligent infliction of emotional distress. Discussing informed consent, the court said that because the doctor’s conduct did not significantly increase the risk that the patient would contract HIV, the doctor’s failure to disclose his HIV status was not material.

These rulings, especially the California decision, introduce more uncertainty into informed consent. The California court did not rule, as the Minnesota court did, that there was no obligation to disclose the practitioner’s HIV status. The court merely ruled that the type of injury which resulted, emotional distress, could not be the basis of a lawsuit without some other type of damage.

Requirements that practitioners disclose information about themselves have remained unusual. However, in 1996, the Wisconsin Supreme Court ruled in Johnson v Kokemoor (545 NW 2d 495) that a physician had an obligation to disclose his own inexperience in performing a fairly rare procedure. How does this compare to my assertion that informed consent does not require disclosure that a practitioner may be negligent? There is a difference between a practitioner who is inexperienced and a practitioner who may commit negligence. Johnson v Kokemoor and the AIDS cases, nonetheless, suggest that courts may impose a duty on practitioners to disclose information about themselves in some circumstances.

Disclosure of information about a practitioner
While I am unaware of any case which has yet dealt with it, an issue calling for disclosure of information about a practitioner could arise under some managed care contracts. Does a healthcare practitioner have an obligation to disclose that, under a managed care contract, his economic incentives may be contrary to the patient’s interest? For example, a practitioner under a capitated managed care contract could be paid more by not providing certain procedures than if the procedure were performed. Must this be disclosed? On the other hand, in the days before managed care, nobody thought healthcare practitioners were under an obligation to disclose that they made substantial sums for performing operations which also might not have been in their patient’s interest.
What are Your Anesthesia Services Worth?

MedProvider Scenario™
Anesthesia Practice Evaluation Software

• Regardless of your employment arrangement, **Do you know how much revenue you generate for your practice?** In today's competitive marketplace CRNAs nationwide need to be able to **Identify Their Worth**.

• **BCS, Incorporated's MedProvider Scenario™** software can assist you to do just that... **Identify Your Worth**. It's like having your own private consultant right at your fingertips. MedProvider Scenario™ is your anesthesia practice evaluation software, simple, yet comprehensive enough to use at your next administrative meeting.

• **$899.99 - Order and realize your worth today.** Call Toll Free 800-433-1439 or visit our web site at BCSconsult.com

**BCS, Incorporated**
Healthcare Practice Management and Consulting Services

---

**Now that you made plans for Nationals in August, 1998, plan to attend the American Academy of Pain Management's 9th Annual Clinical Meeting:**

**Pain Management:**

10 Years of Unity Among Disciplines

• 90+ speakers
• Continuing Education Credits

September 10 - 13, 1998
Atlanta Hilton & Towers • Atlanta, Georgia

For registration or information, call: (209) 533-9744, fax (209) 533-9750 or e-mail: aapm@aapainmanage.org
Introducing a 5-HT₃ receptor antagonist with a *value* difference
New Anzemet®
dolasetron mesylate injection/tablets

Proven performance in emesis control

**ANZEMET®** Excellent efficacy and well-defined safety profile

- Significantly greater efficacy vs placebo in the prevention and treatment of postoperative nausea and vomiting\(^3\,^6\)
- Clinically proven 24-hour control\(^1\,^6\,^7\)

**ANZEMET®** Outstanding dosing convenience*

- A single IV (12.5-mg) dose for either prevention or treatment of PONV\(^1\,^2\,^5\)
- A single oral (100-mg) dose for prevention of PONV\(^6\)
- Proven for a wide patient range without dosage adjustment—including the elderly and those with renal or hepatic impairment\(^5\,^6\)

**ANZEMET®** Outstanding price\(^1\,^8\)

The most common adverse events in postoperative patients are headache, dizziness, and hypotension.\(^5\,^6\)

ANZEMET\(^\circledR\) can cause ECG interval changes; it should be administered with caution in patients who have or may develop prolongation of cardiac conduction intervals. The recommended dose should not be exceeded.

A 5-HT\(_3\) receptor antagonist with a value\(^\circledR\) difference

*Adult dosing. See prescribing information for pediatric dosing
†More affordable than other injectable 5-HT\(_3\) receptor antagonists.
Based on average wholesale price (AWP), which is a published list price and may not reflect actual price paid by pharmacists or consumers
\(^\circledR\)Value equals outstanding price

Please see brief summaries of prescribing information on following pages.
Please visit us at the AANA Annual Meeting in Nashville, August 1-3, Booth #s 201/300
ANZEMET® Injection

(dolasetron mesylate injection)

WARNING

ANZEMET® (dolasetron mesylate) Injection is a 5% dextrose 0.9% sodium chloride (dextrose injection) solution that contains 0.2 mg/mL dolasetron mesylate with added sodium hydroxide to adjust pH to between 7.0 and 7.3.

INDICATIONS AND USAGE

ANZEMET® administration has been shown to decrease the incidence of postoperative nausea and vomiting (PONV) in patients undergoing various surgical procedures.

ANZEMET® is contraindicated in patients with known hypersensitivity to dolasetron mesylate, to the glucose polymer (dextrose injection), or to the sodium chloride injection.

ANZEMET® is not recommended for use in patients with QTc syndrome or those receiving antiarrhythmic drugs or other drugs with the potential for clinically significant drug interactions.

GENERAL

ANZEMET® should be used with caution in patients who have had cardiac conduction abnormalities or those who are receiving antiarrhythmic drugs or other drugs with the potential for clinically significant drug interactions.

WARNINGS

ANZEMET® is contraindicated in patients with known hypersensitivity to dolasetron mesylate, to the glucose polymer (dextrose injection), or to the sodium chloride injection.

WARNINGS

ANZEMET® Injection and ANZEMET® Tablets are contraindicated in patients with known hypersensitivity to dolasetron mesylate, to the glucose polymer (dextrose injection), or to the sodium chloride injection.

ADVERSE REACTIONS

In clinical trials, the following adverse events were reported in >2% of patients receiving either ANZEMET 25 mg or ANZEMET 100 mg: headache, dizziness, nausea, vomiting, hyperemesis, somnolence, asthenia, diarrhea, urinary tract infection (UTI), and postoperative ileus.

Table 7. Adverse Events >2% from Chemotherapy-Induced Nausea and Vomiting Studies

<table>
<thead>
<tr>
<th>Event</th>
<th>ANZEMET Injection</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>16 (5.5%)</td>
<td>10 (3.3%)</td>
</tr>
<tr>
<td>Nausea</td>
<td>23 (7.8%)</td>
<td>20 (6.4%)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>22 (7.3%)</td>
<td>16 (4.9%)</td>
</tr>
<tr>
<td>Somnolence</td>
<td>8 (2.7%)</td>
<td>2 (0.6%)</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>6 (1.9%)</td>
<td>3 (0.9%)</td>
</tr>
</tbody>
</table>

In controlled clinical trials, 2255 adult patients received ANZEMET Injection. The overall adverse event rates were similar with 1.8 mg/kg ANZEMET Injection and etomidate or propofol. Patients were receiving concurrent chemotherapy, postoperatively high-dose (500 mg/m²) captopril, following a combined lidocaine of all adverse events reported in >2% of patients in these controlled clinical trials (Table 7).

Table 8. Adverse Events >2% from Placebo-Controlled Postoperative Nausea and Vomiting Studies

<table>
<thead>
<tr>
<th>Event</th>
<th>ANZEMET Tablets</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>12 (5.1%)</td>
<td>11 (4.3%)</td>
</tr>
<tr>
<td>Nausea</td>
<td>10 (4.3%)</td>
<td>13 (5.1%)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>10 (4.3%)</td>
<td>9 (3.5%)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>12 (4.8%)</td>
<td>17 (6.3%)</td>
</tr>
<tr>
<td>Drowsiness</td>
<td>15 (5.8%)</td>
<td>22 (7.6%)</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>2 (0.8%)</td>
<td>1 (0.3%)</td>
</tr>
</tbody>
</table>

In clinical trials, the following infrequently reported adverse events, assessed to be possibly related to drug therapy, occurred in <2% of patients receiving ANZEMET 25 mg or ANZEMET 100 mg: somnolence, headache, dizziness, nausea, and vomiting.

PRECAUTIONS

ANZEMET® is contraindicated in patients with known hypersensitivity to dolasetron mesylate, to the glucose polymer (dextrose injection), or to the sodium chloride injection.

ADVERSE REACTIONS

ANZEMET® Tablets are contraindicated in patients with known hypersensitivity to dolasetron mesylate, to the glucose polymer (dextrose injection), or to the sodium chloride injection.

Table 9. Adverse Events >2% from Chemotherapy-Induced Nausea and Vomiting Studies

<table>
<thead>
<tr>
<th>Event</th>
<th>ANZEMET Tablets</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>13 (5.5%)</td>
<td>14 (4.9%)</td>
</tr>
<tr>
<td>Nausea</td>
<td>12 (4.7%)</td>
<td>18 (6.1%)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>10 (3.9%)</td>
<td>16 (5.3%)</td>
</tr>
<tr>
<td>Somnolence</td>
<td>8 (3.1%)</td>
<td>7 (2.3%)</td>
</tr>
</tbody>
</table>

In controlled clinical trials, 936 adult female patients have received oral ANZEMET Tablets for the prevention or treatment of chemotherapeutic-induced nausea and vomiting, following a dosing of all adverse events reported in >2% of patients receiving either ANZEMET Tablets or placebo in prevention of postoperative nausea and vomiting in controlled clinical trials (Table 9).

Table 10. Adverse Events >2% from Placebo-Controlled Postoperative Nausea and Vomiting Studies

<table>
<thead>
<tr>
<th>Event</th>
<th>ANZEMET Tablets</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>15 (5.9%)</td>
<td>17 (5.7%)</td>
</tr>
<tr>
<td>Nausea</td>
<td>14 (5.4%)</td>
<td>19 (6.3%)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>13 (4.9%)</td>
<td>18 (6.1%)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>16 (6.1%)</td>
<td>23 (7.6%)</td>
</tr>
<tr>
<td>Drowsiness</td>
<td>18 (6.8%)</td>
<td>25 (8.1%)</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>2 (0.7%)</td>
<td>1 (0.3%)</td>
</tr>
</tbody>
</table>

In clinical trials, the following infrequently reported adverse events, assessed to be possibly related to drug therapy, occurred in <2% of patients receiving ANZEMET Tablets: headache, dizziness, vomiting, increased urination, somnolence, and diarrhea.

PRECAUTIONS

ANZEMET® Tablets are contraindicated in patients with known hypersensitivity to dolasetron mesylate, to the glucose polymer (dextrose injection), or to the sodium chloride injection.

ADVERSE REACTIONS

ANZEMET Tablets are contraindicated in patients with known hypersensitivity to dolasetron mesylate, to the glucose polymer (dextrose injection), or to the sodium chloride injection.

Table 11. Adverse Events >2% from Placebo-Controlled Postoperative Nausea and Vomiting Studies

<table>
<thead>
<tr>
<th>Event</th>
<th>ANZEMET Tablets</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>14 (5.4%)</td>
<td>16 (5.7%)</td>
</tr>
<tr>
<td>Nausea</td>
<td>13 (4.9%)</td>
<td>18 (6.1%)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>12 (4.4%)</td>
<td>17 (5.7%)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>15 (5.6%)</td>
<td>21 (6.9%)</td>
</tr>
<tr>
<td>Drowsiness</td>
<td>17 (6.1%)</td>
<td>24 (7.6%)</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>2 (0.7%)</td>
<td>1 (0.3%)</td>
</tr>
</tbody>
</table>

In clinical trials, the following infrequently reported adverse events, assessed to be possibly related to drug therapy, occurred in <2% of patients receiving ANZEMET Tablets: headache, dizziness, vomiting, increased urination, somnolence, and diarrhea.

PRECAUTIONS

ANZEMET Tablets are contraindicated in patients with known hypersensitivity to dolasetron mesylate, to the glucose polymer (dextrose injection), or to the sodium chloride injection.

ADVERSE REACTIONS

ANZEMET Tablets are contraindicated in patients with known hypersensitivity to dolasetron mesylate, to the glucose polymer (dextrose injection), or to the sodium chloride injection.

Table 12. Adverse Events >2% from Placebo-Controlled Postoperative Nausea and Vomiting Studies

<table>
<thead>
<tr>
<th>Event</th>
<th>ANZEMET Tablets</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>15 (5.6%)</td>
<td>17 (5.7%)</td>
</tr>
<tr>
<td>Nausea</td>
<td>14 (5.1%)</td>
<td>18 (6.1%)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>13 (4.8%)</td>
<td>17 (5.7%)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>16 (5.9%)</td>
<td>22 (7.3%)</td>
</tr>
<tr>
<td>Drowsiness</td>
<td>18 (6.5%)</td>
<td>25 (7.6%)</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>3 (1.1%)</td>
<td>2 (0.6%)</td>
</tr>
</tbody>
</table>

In clinical trials, the following infrequently reported adverse events, assessed to be possibly related to drug therapy, occurred in <2% of patients receiving ANZEMET Tablets: headache, dizziness, vomiting, increased urination, somnolence, and diarrhea.

PRECAUTIONS

ANZEMET Tablets are contraindicated in patients with known hypersensitivity to dolasetron mesylate, to the glucose polymer (dextrose injection), or to the sodium chloride injection.