



Perspectives on the Challenges of Labeling from Industry

Angie Lindsey

Vice President, Marketing at Fresenius Kabi USA

Disclaimer

Information will be shared about an internal project that is underway — I am not making any product claims on the efficacy or safety of Fresenius Kabi products.

For the full safety information on our Fresenius Kabi products, please visit our catalog:

www.MyFreseniusKabi.com



[View Product Catalog](http://www.MyFreseniusKabi.com)

Industry Positions on Standardization of Color on Labels



[ASTM Work Item: Reinstatement of D4774-11 \(2017\) Standard Specification for User Applied Drug Labels in Anesthesiology](#)

8/03/2023

Developed by ASTM Subcommittee / Staff Manager: W Scott Orthey



[ASA: Statement on Labeling of Pharmaceuticals for Use in Anesthesiology](#)

12/13/2020

Developed by Committee on Equipment and Facilities at American Society of Anesthesiologists (ASA)



[To Color Code, or Not to Color Code? It Is Now Optional](#)

10/18/2023

Jose Nery, PharmD, 2022-2023 ISMP Safe Medication Management Fellow



[Color-coded Syringes for Anesthesia Drugs—Use With Care](#)

4/5/2012

Matthew Grissinger, RPh, FASCP



[APSF Pro/Con Debate on Color-Coded Medication Labels: PRO: Color-Coded Medication Labels Improve Patient Safety](#)

2/15/2019

Luke S. Janik, MD; Jeffery S. Vender, MD, FCCM



[APSF Pro/Con Debate on Color-Coded Medication Labels: CON: Anesthesia Drugs Should NOT Be Color-Coded](#)

2/15/2019

Matthew Grissinger RPh, FISMP, FASCP; Ronald S. Litman, DO, ML

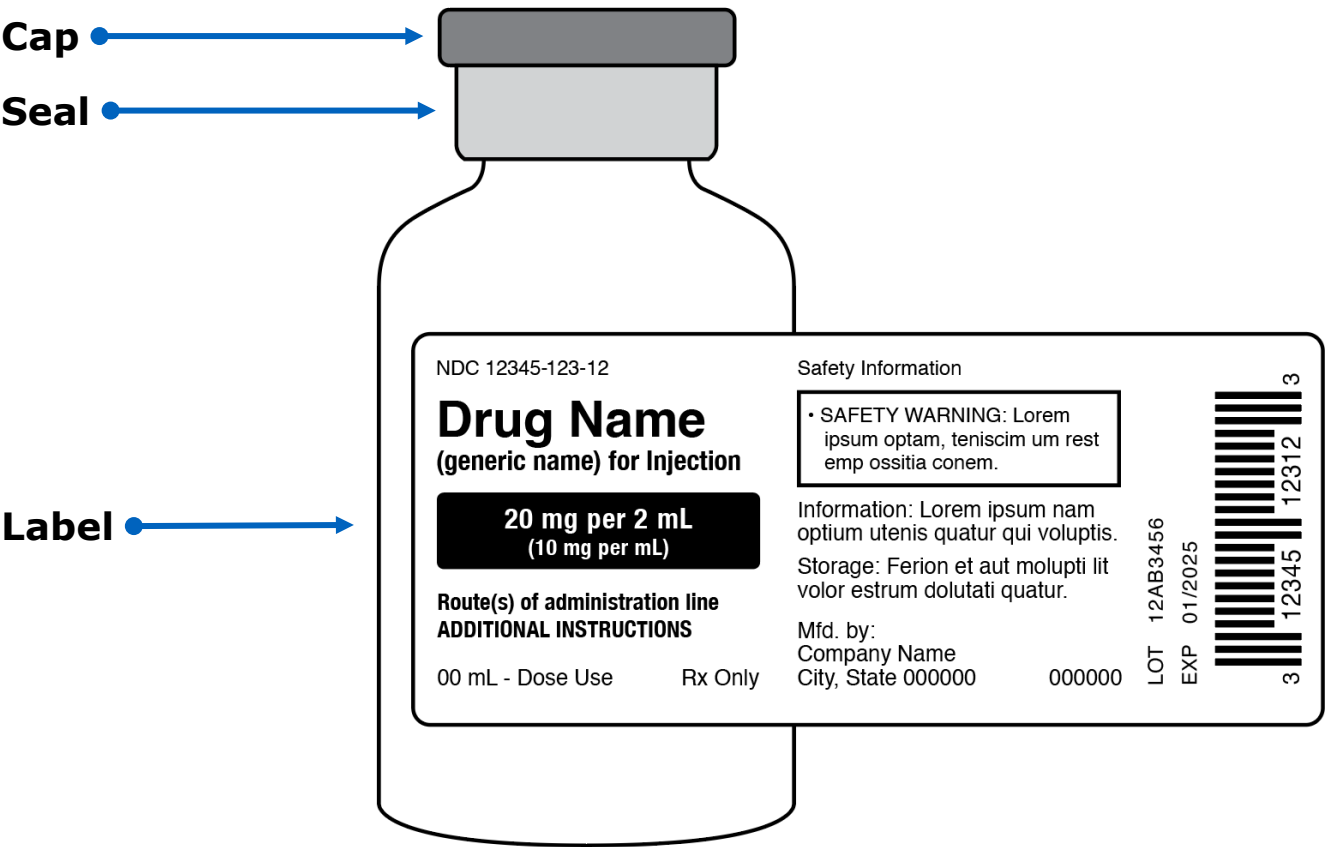


[Color-Coded Medication Labels: Helping or Hurting?](#)

Accessed 7/29/2024

CRNA, SRNA | RRNA, Apex Anesthesia Review

Basics of Color on Medications



“

Color-coded labels add
“one more layer of cheese” to the
defense against medication errors,
which may be the difference
between an uneventful case and
an adverse event.

”

APSF Pro/Con Debate on Color-Coded Medication Labels:
PRO: Color-Coded Medication Labels Improve Patient Safety

Luke S. Janik, MD; Jeffery S. Vender, MD, FCCM

FEB 2019

APSF Look-Alike Drug Vials: Latest Stories & Gallery



Lidocaine, Bupivacaine

Lidocaine, Bupivacaine

January 19, 2024

Lidocaine (used IV at induction) and bupivacaine look very similar from the same manufacturer. Red caps for many manufacturers denote the addition of epinephrine but do not in this case.

<https://www.apsf.org/look-alike-drugs/>



Glycopyrrolate, Ondansetron, Phenylephrine, and others



Dr. Joshua Miller responded to my post with this Pic. All blue tops. Concentrated phenylephrine undiluted can kill. Atropine can kill. Concentrated Precedex can kill. Wrong drug, wrong time in a crisis. Anesthesiologists are fighter pilots. We have 30 seconds to diagnose and treat. And then, in a dark room during a lap chole...this...in the drawer....in small print. People die because of this.

Products shown in the photos above are from various manufacturers, including Fresenius Kabi.

Bupivacaine HCl for Injection, USP

Manufacturer Color Variability



Company 1



Company 2



Company 3



Company 4

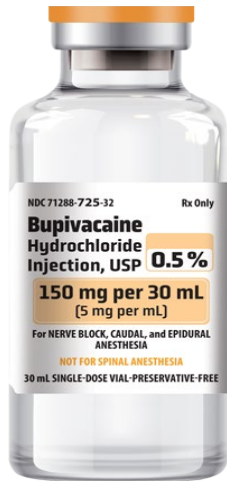
WARNING: RISK OF CARDIAC ARREST WITH USE OF SENSORCAINE IN OBSTETRICAL ANESTHESIA

See full prescribing information for complete boxed warning.

There have been reports of cardiac arrest with difficult resuscitation or death during use of SENSORCAINE for epidural anesthesia in obstetrical patients. In most cases, this has followed use of the 0.75% (7.5 mg/mL) concentration. Resuscitation has been difficult or impossible despite apparently adequate preparation and appropriate management. Cardiac arrest has occurred after convulsions resulting from systemic toxicity, presumably following unintentional intravascular injection. The 0.75% (7.5 mg/mL) concentration of SENSORCAINE is not recommended for obstetrical anesthesia and should be reserved for surgical procedures where a high degree of muscle relaxation and prolonged effect are necessary.

Bupivacaine HCl for Injection, USP 150 mg per 30 mL

Manufacturer Color Variability



Company 1



Company 2



Company 3



Company 4

WARNING: RISK OF CARDIAC ARREST WITH USE OF SENSORCAINE IN OBSTETRICAL ANESTHESIA

See full prescribing information for complete boxed warning.

There have been reports of cardiac arrest with difficult resuscitation or death during use of SENSORCAINE for epidural anesthesia in obstetrical patients. In most cases, this has followed use of the 0.75% (7.5 mg/mL) concentration. Resuscitation has been difficult or impossible despite apparently adequate preparation and appropriate management. Cardiac arrest has occurred after convulsions resulting from systemic toxicity, presumably following unintentional intravascular injection. The 0.75% (7.5 mg/mL) concentration of SENSORCAINE is not recommended for obstetrical anesthesia and should be reserved for surgical procedures where a high degree of muscle relaxation and prolonged effect are necessary.

Situations that prompt change exacerbate risk



Drug Shortages



**Clinician efficiency
pressures**



Locum tenens



Emergent Situations



Patient Degradation



Contract Changes

ISMP Medication Safety Alert: Heparin 100U and 10% Calcium Chloride Syringes

Institute for Safe Medication Practice Acute Care Newsletter

Original Safety Brief:

Scan before you flush.

Sept 2022, Vol 27, Issue 18



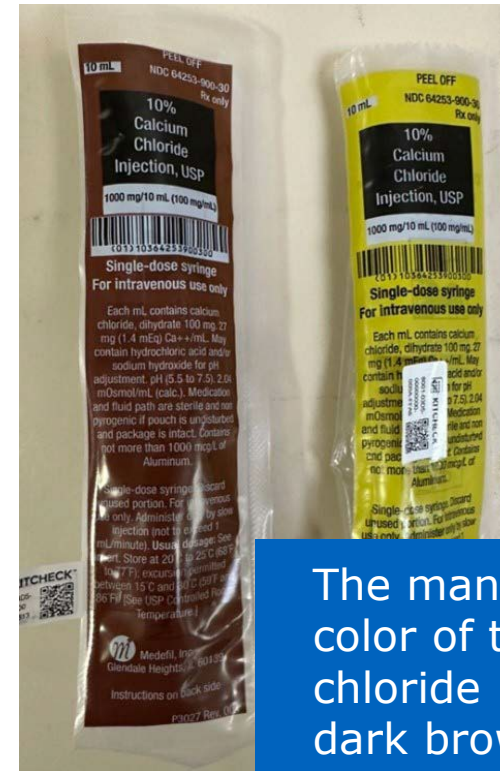
Follow-up Safety Brief:

Delay finding calcium chloride syringe due to yellow color association.

April 2024, Vol 29, Issue 8



Heparin flush syringes were mixed up with 10% calcium chloride syringes, both yellow labels



The manufacturer changed the color of the 10% calcium chloride label from yellow to dark brown, but result was a delay in treatment

Regulatory Guidance on Labels

References:

- Aspden P, Wolcott J, Bootman JL, et al, eds; Institute of Medicine, Committee on Identifying and Preventing Medication Errors. Washington DC: National Academies Press; 2007. ISBN 0309101476.
- [FDA: Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors](#)
- [ISMP Look-Alike Tallman Letters.pdf \(ecri.org\)](#)

- **Labeling and packaging issues cause of 33% of medication errors and 30% of fatalities from medication errors** that were reported to the Institute for Safe Medication Practices (ISMP).
- **FDA generally recommends avoiding color coding in most instances.** Errors can occur when the color code is not meaningful to end users outside the limited environment where the color coding has an established use.
- **Certain applications of color coding may be appropriate.** Examples include the color coding of certain drug product strengths, such as warfarin, levothyroxine, and conjugated estrogen-containing products, where the colors of the strengths are universally color-coded across all manufacturers.
- **Tall man lettering** on approved container labels and carton labeling can sometimes be used to help distinguish similar-looking name pairs that have been confused post-market.
 - Examples: cefo**TE**tan — cef**OX**itin — cef**TAZ**idime — cef**TRIAX**one
- **Moving from a 1D linear barcode to a 2D data matrix** could free up valuable space on a pharmaceutical label, declutter for better readability.

Regulatory Guidance on Caps



Potassium Chloride for Injection Concentrate: BLACK CAP

- The use of a black closure system on a vial (e.g., a black cap overseal and a black ferrule to hold the elastomeric closure)

References:

- [USP General Chapter 7](#)
- [FDA: Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors, Guidance for Industry](#)



Cautionary Statements on Cap

(e.g., Warning—Paralyzing Agent, Dilute Before Using), provided they are intended **to prevent an imminent life-threatening situation**.

- Neuromuscular and Paralyzing agents must have cautionary statements in black or white print:
 “Warning: Paralyzing Agent” or “Paralyzing Agent”
- Alternatively, the overseal may be transparent and without words, allowing for visualization of the warning labeling on the closure ferrule.

“

Manufacturers can incorporate an understanding of how drugs are stored into their packaging and labeling decisions, particularly in cases where products are stored together that are inherently higher risk.

Unraveling a Recurrent Wrong Drug-Wrong Route Error— Tranexamic Acid in Place of Bupivacaine:
A Multistakeholder Approach to Addressing this Important Patient Safety Issue (June 2024)

”


Fresenius Kabi ASTM Color Standard Project Summary

- 1. Fresenius Kabi will assess the use of ASTM color specifications, originally designed for user-applied labels, to commercially available manufactured vials and syringes in these specified drug classes.
- 2. Create a portal where drug label and cap information is easily accessible.
- 3. Collect insights from clinicians, internal subject matter experts, external partners, and publications to make a recommendation on what can be done to improve medication safety on labels and caps.

8/03/2023

[ASTM Work Item: Reinstatement of D4774-11\(2017\) Standard Specification for User Applied Drug Labels in Anesthesiology \(Withdrawn 2022\)](#)

Developed by ASTM Subcommittee / Staff Manager: W Scott Orthey / Technical Contact: Richard Botney

 D4774 – 11 (2017)

DRUG CLASS ^A	EXAMPLES	PANTONE COLOR (unearned)	LABEL EXAMPLES
1 Induction Agents	Etomidate, Ketamine, Methohexital, Propofol, Thiopental, Thiamylal	YELLOW	<div>PROPOFOL mg/mL</div> <div>Date Time Int</div>
2 Benzodiazepines	Diazepam, Midazolam	ORANGE 151	<div>MIDAZOLAM mg/mL</div> <div>Date Time Int</div>
3 Benzodiazepine Receptor Antagonist	Flumazenil	ORANGE 151 AND WHITE DIAGONAL STRIPES	<div>FLUMAZENIL mg/mL</div> <div>Date Time Int</div>
4a Muscle Relaxants (Depolarizer)	Succinylcholine ^B	FLUORESCENT RED 805	<div>SUCCINYLCHOLINE mg/mL</div> <div>Date Time Int</div>
4b (Non-Depolarizer)	Atracurium, Cisatracurium, Mivacurium, Pancuronium, Rocuronium, Vecuronium	FLUORESCENT RED 805	<div>ROCURONIUM mg/mL</div> <div>Date Time Int</div>
5 Relaxant Antagonist (Non-Depolarizer)	Endorphonium, Neostigmine, Pyridostigmine	FLUORESCENT RED 805 AND WHITE DIAGONAL STRIPES	<div>NEOSTIGMINE mg/mL</div> <div>Date Time Int</div>
6 Narcotics	Alfentanil, Fentanyl, Hydromorphone, Meperidine, Morphine, Sufentanil, Remifentanyl	BLUE 297	<div>FENTANYL mcg/mL</div> <div>Date Time Int</div>
7 Narcotic Antagonists	Levallorphan, Naloxone	BLUE 297 AND WHITE DIAGONAL STRIPES	<div>NALOXONE mg/mL</div> <div>Date Time Int</div>
8 Major Tranquilizers	Chlorpromazine, Droperidol	SALMON 156	<div>DROPERIDOL mg/mL</div> <div>Date Time Int</div>
9a Vasopressors	Ephedrine, Norepinephrine, Phenylephrine	VIOLET 256	<div>EPHEDRINE mg/mL</div> <div>Date Time Int</div>
9b Vasopressors	Epinephrine ^B	VIOLET 256	<div>EPINEPHRINE mcg/mL</div> <div>Date Time Int</div>
10 Hypotensive Agents	Hydralazine, Nitroglycerine, Nitroprusside, Phentolamine, Trimethaphan	VIOLET 256 AND WHITE DIAGONAL STRIPES	<div>NITROGLYCERINE mg/mL</div> <div>Date Time Int</div>
11 Local Anesthetics	Bupivacaine, Chloroprocaine, Lidocaine, Mepivacaine, Procaine, Ropivacaine, Tetracaine	GRAY 401	<div>LIDOCAINE mg/mL</div> <div>Date Time Int</div>
12 Anticholinergic Agents	Atropine, Glycopyrrolate, Scopolamine	GREEN 367	<div>GLYCOPYRROLATE mg/mL</div> <div>Date Time Int</div>
13 Beta Blockers	Esmolol ^B , Labetolol ^B , Metoprolol ^B	COPPER 876J	<div>LABEETLOL mg/mL</div> <div>Date Time Int</div>

^A Drugs that do not fit into the above classes should be labeled with black printing on a white background. The examples shown are representative, not restrictive.

^B All printing is to be in black boldtype, with the exception that "succinylcholine" and "epinephrine" shall be printed against the background color as reversed plate letters within a black bar running from edge to edge of the label.

FIG. 1 Standard Background Colors for User Applied Syringe Drug Labels

Date

NEOSTIGMINE mg/mL

Time Int

FIG. 2 Label for an Antagonist Drug

5. Significance and Use
















5.1 The objective of this specification is to facilitate identification of drugs in syringes filled by the user. The use of

colors is intended only as an aid in identification of drug groups and does not absolve the user from the duty to read the label to correctly identify the drug prior to use.

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Test Number: W0400030
See ASTM FILE D4774-11(2017)00001-1
Test for Release 2024 03-22 01:54:21 UTC

Fresenius Kabi ASTM Color Standard Project Summary

Medications per ASTM Drug Class			Families	SKUs	Caps Compliant	Labels Compliant	Cap & Labels Compliant
	1	Induction Agents	3	21	24%	5%	0%
	2	Benzodiazepines	2	12	25%	25%	17%
	3	Benzodiazepine Receptor Antagonist	1	2	0%	0%	0%
	4a	Muscle Relaxants (Depolarizer)	1	1	100%	0%	0%
	4b	Muscle Relaxants (Non-Depolarizer)	3	11	0%	0%	0%
	5	Relaxant Antagonist (Non-Depolarizer)	1	7	29%	29%	29%
	6	Narcotics	5	29	45%	55%	34%
	7	Narcotics Antagonists	1	2	0%	0%	0%
	8	Major Tranquilizers	10	20	0%	0%	0%
	9a	Vasopressors	3	9	0%	0%	0%
	9b	Vasopressors	1	2	100%	50%	50%
	10	Hypotensive Agents	3	7	14%	29%	0%
	11	Local Anesthetics	14	108	2%	0%	0%
	12	Anticholinergic Agents	4	16	25%	63%	25%
	13	Beta Blockers	3	5	0%	20%	0%

252
ASTM eligible SKUs

13%
Caps compliant with
ASTM color assignment

14%
Labels compliant with
ASTM color assignment*

*PFS considered compliant
based on label only

Example Use of Color on Labels and Caps

Integrating ASTM Drug Class Color Indication

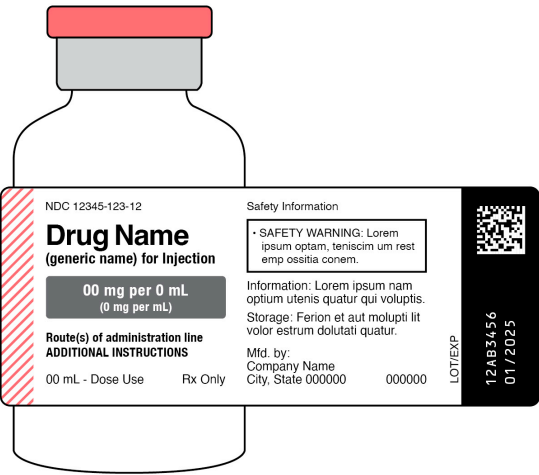


Diagram of a vial with a red cap and a label with a red vertical stripe on the left side. The label contains the following text:

NDC 12345-123-12

Drug Name
(generic name) for Injection

00 mg per 0 mL
(0 mg per mL)

Route(s) of administration line
ADDITIONAL INSTRUCTIONS

00 mL - Dose Use Rx Only

Safety Information

• SAFETY WARNING: Lorem ipsum optam, teniscim um rest emp ossitia conem.

Information: Lorem ipsum nam optium utenis quatur qui voluptis. Storage: Ferion et aut molupti lit volor estrum dolutati quatur.

Mfd. by:
Company Name
City, State 000000 000000

LOT/EXP
12AB3456
01/2025

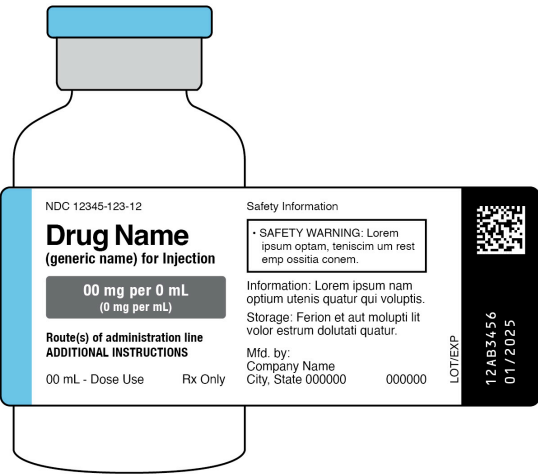


Diagram of a vial with a blue cap and a label with a blue vertical stripe on the left side. The label contains the following text:

NDC 12345-123-12

Drug Name
(generic name) for Injection

00 mg per 0 mL
(0 mg per mL)

Route(s) of administration line
ADDITIONAL INSTRUCTIONS

00 mL - Dose Use Rx Only

Safety Information

• SAFETY WARNING: Lorem ipsum optam, teniscim um rest emp ossitia conem.

Information: Lorem ipsum nam optium utenis quatur qui voluptis. Storage: Ferion et aut molupti lit volor estrum dolutati quatur.

Mfd. by:
Company Name
City, State 000000 000000

LOT/EXP
12AB3456
01/2025

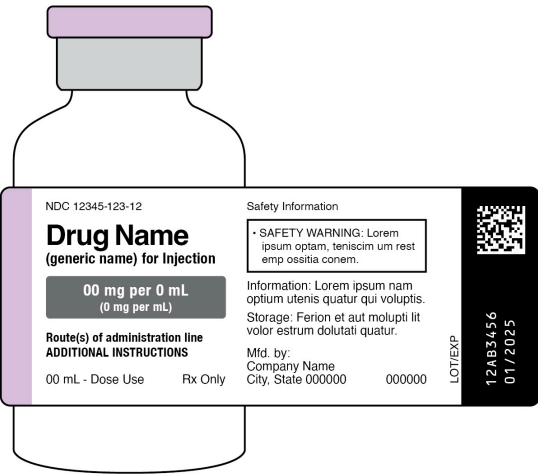


Diagram of a vial with a purple cap and a label with a purple vertical stripe on the left side. The label contains the following text:

NDC 12345-123-12

Drug Name
(generic name) for Injection

00 mg per 0 mL
(0 mg per mL)

Route(s) of administration line
ADDITIONAL INSTRUCTIONS

00 mL - Dose Use Rx Only

Safety Information

• SAFETY WARNING: Lorem ipsum optam, teniscim um rest emp ossitia conem.

Information: Lorem ipsum nam optium utenis quatur qui voluptis. Storage: Ferion et aut molupti lit volor estrum dolutati quatur.

Mfd. by:
Company Name
City, State 000000 000000

LOT/EXP
12AB3456
01/2025




Diagram of a vial with a grey cap and a label with a grey vertical stripe on the left side. The label contains the following text:

NDC 12345-123-12

Drug Name
(generic name) for Injection

00 mg per 0 mL
(0 mg per mL)

Route(s) of administration line
ADDITIONAL INSTRUCTIONS

00 mL - Dose Use Rx Only


Safety Information

• SAFETY WARNING: Lorem ipsum optam, teniscim um rest emp ossitia conem.


Information: Lorem ipsum nam optium utenis quatur qui voluptis. Storage: Ferion et aut molupti lit volor estrum dolutati quatur.

Mfd. by:
Company Name
City, State 000000 000000


LOT/EXP
12AB3456
01/2025




Relaxant Antagonist
(Non-Depolarizer)



Narcotics



Vasopressors



Local Anesthetics

Key Insights and Recommendations

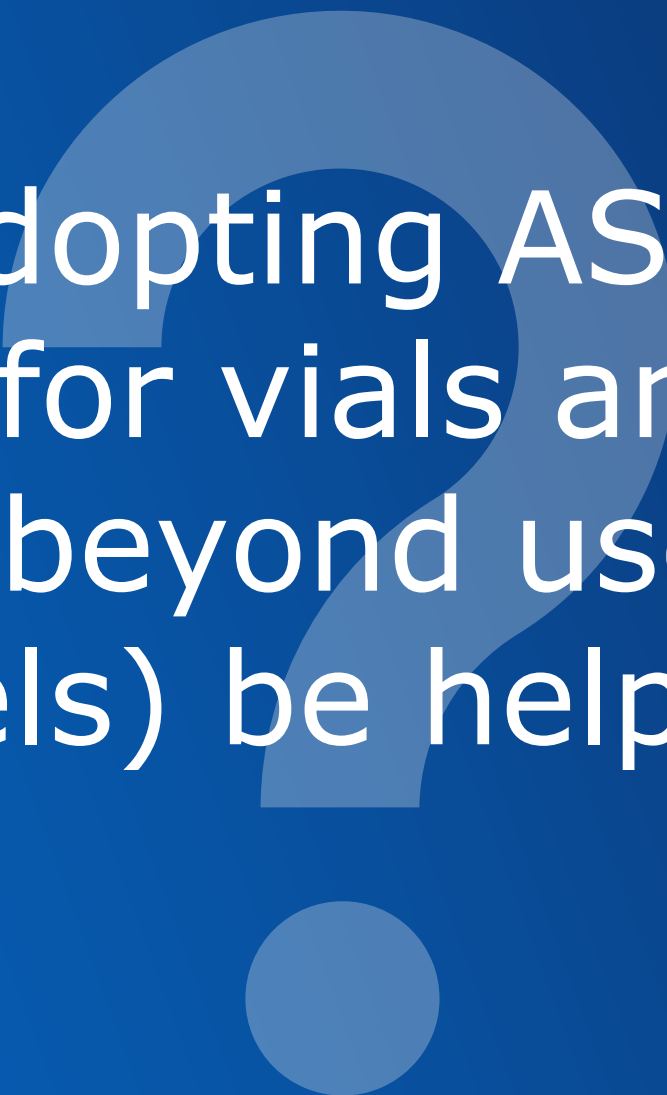
1. Implement auto-identification technologies where possible (i.e., RFID, 2D Data Matrix, Computer Vision)
2. Dispense manufactured Ready-to-Administer products in patient care areas when possible (i.e., prefilled syringes, premix bags)
3. Analyze high-risk situations for medication look-alike bias to address specific issues (i.e., Tranexamic Acid)
4. Prioritize drug classes where errors could be lethal or have the most severe patient outcomes (i.e., neuromuscular blockers)



Simplist® ready-to-administer prefilled syringe



+RFID® pre-tagged medication



Would adopting ASTM color standards for vials and prefilled syringes (beyond user-applied labels) be helpful?

Thank you.

Sensorcaine® and Sensorcaine® - MPF (Bupivacaine HCl Injection, USP)

Important Safety Information (ISI-0155)

INDICATIONS AND USAGE

SENSORCAINE contains bupivacaine, an amide local anesthetic, and SENSORCAINE WITH EPINEPHRINE is a combination of bupivacaine, an amide local anesthetic, and epinephrine, an alpha and beta-adrenergic agonist. SENSORCAINE/ SENSORCAINE WITH EPINEPHRINE is indicated in adults for the production of local or regional anesthesia or analgesia for surgery, dental and oral surgery procedures, diagnostic and therapeutic procedures, and for obstetrical procedures. For each type of block indicated to produce local or regional anesthesia or analgesia, specific concentrations and presentations are recommended.

Limitations of Use

Not all blocks are indicated for use with SENSORCAINE/ SENSORCAINE WITH EPINEPHRINE given clinically significant risks associated with use.

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF CARDIAC ARREST WITH USE OF SENSORCAINE IN OBSTETRICAL ANESTHESIA

See full prescribing information for complete boxed warning.

There have been reports of cardiac arrest with difficult resuscitation or death during use of SENSORCAINE for epidural anesthesia in obstetrical patients. In most cases, this has followed use of the 0.75% (7.5 mg/mL) concentration. Resuscitation has been difficult or impossible despite apparently adequate preparation and appropriate management. Cardiac arrest has occurred after convulsions resulting from systemic toxicity, presumably following unintentional intravascular injection. The 0.75% (7.5 mg/mL) concentration of SENSORCAINE is not recommended for obstetrical anesthesia and should be reserved for surgical procedures where a high degree of muscle relaxation and prolonged effect are necessary.

- SENSORCAINE / SENSORCAINE WITH EPINEPHRINE is not for intrathecal use.
- Avoid use of SENSORCAINE / SENSORCAINE WITH EPINEPHRINE solutions containing antimicrobial preservatives (i.e., multiple dose vials) for epidural or caudal anesthesia.
- See full prescribing information for:
 - Recommended concentrations and dosages of SENSORCAINE / SENSORCAINE WITH EPINEPHRINE according to type of block.
 - Additional dosage and administration information pertaining to use in epidural anesthesia, test dose for caudal and lumbar epidural blocks, use in dentistry, and use in ophthalmic surgery.

Contraindications

- Obstetrical paracervical block anesthesia.
- Intravenous regional anesthesia (Bier Block).
- Known hypersensitivity to bupivacaine or to any local anesthetic agent of the amide-type or to other components of SENSORCAINE/ SENSORCAINE WITH EPINEPHRINE.

Warnings and Precautions

- Dose-Related Toxicity: Monitor cardiovascular and respiratory vital signs and patient's state of consciousness after injection of SENSORCAINE/ SENSORCAINE WITH EPINEPHRINE.
- Methemoglobinemia: Cases of methemoglobinemia have been reported in association with local anesthetic use. See full prescribing information for more detail on managing these risks.
- Chondrolysis with Intra-Articular Infusion: Intra-articular infusions of local anesthetics including SENSORCAINE following arthroscopic and other surgical procedures is an unapproved use, and there have been post-marketing reports of chondrolysis in patients receiving such infusions.

Sensorcaine® and Sensorcaine® - MPF (Bupivacaine HCl Injection, USP)

Important Safety Information (ISI-0155), continued

- Risk of Cardiac Arrest with Intravenous Regional Anesthesia Use (Bier Block): There have been reports of cardiac arrest and death during the use of bupivacaine for intravenous regional anesthesia (Bier Block).
- Allergic-Type Reactions to Sulfites in SENSORCAINE WITH EPINEPHRINE: SENSORCAINE WITH EPINEPHRINE contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people.
- Risk of Systemic Toxicities with Unintended Intravascular or Intrathecal Injection: Unintended intravascular or intrathecal injection may be associated with systemic toxicities, including CNS or cardiorespiratory depression and coma, progressing ultimately to respiratory arrest. Aspirate for blood or cerebrospinal fluid (where applicable) prior to each dose and consider using a test dose of SENSORCAINE-MPF WITH EPINEPHRINE.
- Nonselective Beta-Adrenergic Antagonists: Administration of SENSORCAINE WITH EPINEPHRINE (containing a vasoconstrictor) in patients receiving nonselective beta-adrenergic antagonists may cause severe hypertension and bradycardia. Concurrent use of these agents should generally be avoided.
- Drugs Associated with Methemoglobinemia: Patients are at increased risk of developing methemoglobinemia when concurrently exposed to nitrates, nitrites, local anesthetics, antineoplastic agents, antibiotics, antimalarials, anticonvulsants, and other drugs.
- Potent Inhalation Anesthetics: Serious dose-related cardiac arrhythmias may occur if preparations containing a vasoconstrictor such as epinephrine are used in patients during or following the administration of potent inhalation anesthetics.

Use in Specific Populations

Adverse Reactions

Most common adverse reactions are related to the central nervous system and the cardiovascular system.

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC at 1-800-551-7176 or FDA at 1-800- FDA-1088 or www.fda.gov/medwatch.

Drug Interactions

- Local Anesthetics: The toxic effects of local anesthetics are additive. Monitor for neurologic and cardiovascular effects when additional local anesthetics are administered.
- Monoamine Oxidase Inhibitors and Tricyclic Antidepressants: Administration of SENSORCAINE WITH EPINEPHRINE to patients receiving monoamine oxidase inhibitors or tricyclic antidepressants may produce severe, prolonged hypertension. Concurrent use of these agents should generally be avoided.
- Ergot-Type Oxytocic Drugs: Concurrent administration of SENSORCAINE WITH EPINEPHRINE and ergot-type oxytocic drugs may cause severe, persistent hypertension or cerebrovascular accidents.

- Pediatric Use: Administration of SENSORCAINE/ SENSORCAINE WITH EPINEPHRINE in pediatric patients younger than 12 years is not recommended.
- Geriatric Use: Patients 65 years and over, particularly those with hypertension, may be at increased risk for developing hypotension while undergoing anesthesia with SENSORCAINE/SENSORCAINE WITH EPINEPHRINE
- Moderate to Severe Hepatic Impairment: Consider increased monitoring for bupivacaine systemic toxicity.

This Important Safety Information does not include all the information needed to use Sensorcaine® (bupivacaine HCl Injection, USP) safely and effectively. Please see full prescribing information, including BOXED WARNING, for Sensorcaine® (bupivacaine HCl Injection, USP) at www.fresenius-kabi.com/us.