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FORMULA NUMBER: 1418

FORMULA NAME: Emetine Hydrochloride 30−mg/mL Sterile Injection

DOSAGE FORM: Injection, Solution

FORMULA (Rx):

Ingredients	For: 100 mL		Lot#	RPh Initials
Emetine Hydrochloride		3 g	_____	_____
Sodium Hydroxide 10% Aqueous Solution		qs	_____	_____
Hydrochloric Acid, Diluted [10%]		qs	_____	_____
Water, Sterile for Injection [Preservative−free]	qs	100 mL	_____	_____

SYNONYMS:

USE/TYPE:
Human Use
Sterile Preparation

CATEGORY:
Amebicide
AntiProtozoal

NOTES:
This preparation should be prepared in a laminar flow hood in a cleanroom or via isolation barrier technology by a validated aseptic compounding pharmacist using strict aseptic technique. This is a high−risk preparation.

SPECIALIZED EQUIPMENT:

pH Meter
Sterilizing Filter

METHOD OF PREPARATION:

1. Calculate the required quantity of each ingredient for the total amount to be prepared.
2. Weigh and/or measure each ingredient accurately.
3. Dissolve the emetine hydrochloride in about 90−mL of sterile water for injection.
4. Add a 10% solution of sodium hydroxide or hydrochloric acid to adjust the pH to the range of 2.7 to 3.3.
5. Add sufficient sterile water for injection to volume and mix well.
6. Filter through an appropriate sterile 0.22−µm filter into sterile vials.
7. Package and label.

LABELING:

For Injection Only
Keep Out of Reach of Children
For Office Use
Pregnant Women Must Not Handle this Medicine

PRESERVATION, PACKAGING AND STORAGE:

Sterile Container
Keep Refrigerated − Refrigerate Upon Receipt
Protect from Light and Moisture
Do Not Use After _____

STABILITY:
The stated stability advised for each formula should be followed; otherwise, if a program of sterility testing is NOT in place, then the following beyond use dates can be used:

Risk Level	Room Temperature 20 to 25° C	Refrigeration 2 to 8° C	Freezer −25 to −10° C
Low	48 hours	14 days	45 days
Medium	30 hours	9 days	45 days
High	24 hours	3 days	45 days

If a program of sterility IS in place, a beyond use date of 14 days when stored in a refrigerator can be used.

ENDOTOXIN ASSESSMENT:

USE:
Emetine hydrochloride injection has been used in the treatment of amebic infections.

STANDARD OPERATING PROCEDURE FOR QUALITY CONTROL:
Quality−control assessments include weight/volume, physical observation, pH, specific gravity, osmolality, assay, color, clarity, particulate matter, sterility and pyrogenicity.

REGULATORY CONTROL:

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More information about this formula and its components available at the formula section of www.CompoundingToday.com

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