

FEATURES CYTOTOXIC DRUGS FOR INJECTION GROUP ATC L01
((With the exception of preparations in a syringe ready for administration

Lotto	Sub lotto	Descrizione principio attivo	Forma	Dosaggio
728		ERIBULINA	Injectable preparation	0,44mg/ml 2 ml

NOME FARMACO HALAVEN

THINNER BE USED FOR RECOVERY (FOR FORMULA POWDER)	Not applicable
CONCENTRATION OF THE SOLUTION AFTER RECOVERY (FOR FORMULA POWDER)	Not applicable
STABILITY OF THE SOLUTION RECONSTITUTED AND STORAGE TEMPERATURE	Not applicable
SOLUTION TO BE USED FOR DILUTION (IF NECESSARY)	sodium chloride 9 mg/ml (0.9%) solution for injection
LIMITS OF CONCENTRATION IN SOLVENTS COMPATIBLE OR VOLUME OF SOLVENT TO BE USED FOR DILUTION	HALAVEN may be diluted in up to 100 ml of sodium chloride 9 mg/ml (0.9%) solution for injection
STABILITY OF THE SOLUTION READY FOR ADMINISTRATION AND TEMPERATURE OF STORAGE THINNER AND SPECIFYING THE BOX (GLASS / PP / PE / POF)	<p>If not used immediately HALAVEN as the undiluted solution in a syringe should not normally be stored longer than 4 hours at 25°C and ambient lighting, or 24 hours at 2°C - 8°C.</p> <p>Dilued solution of HALAVEN (0.018 mg/ml to 0.18 mg/ml eribulin in sodium chloride 9 mg/ml (0.9%)) solution for injection should not be stored longer than 24 hours at 2°C - 8°C, unless dilution has taken place in controlled and validated aseptic conditions.</p>
INCOMPATIBILITY OF THE SOLUTION READY FOR ADMINISTRATION WITH	Not applicable

CONTAINERS	
DRUG COMPATIBILITY WITH MATERIALS FORMING DEVICES OF ADMINISTRATION AND PREPARATION	<p>Compatibility studies of undiluted solutions of eribulin 0.44 mg/ml (equivalent to eribulin mesilate 0.5 mg/ml) showed that the solution is compatible with polypropylene syringes for up to 6 hours at ambient temperature (20°C - 25°C) and lighting or under refrigeration (2°C - 8°C) up to 24 hours.</p> <p>Studies of diluted solutions of eribulin (0.018 mg/ml to 0.18 mg/ml in normal saline [sodium chloride 0.9% solution for injection]) showed the following:</p> <ul style="list-style-type: none"> • Diluted solutions of eribulin (0.018 – 0.18 mg/ml in normal saline) are compatible with polypropylene syringes for up to 48 hours either refrigerated or at ambient temperature and lighting. • • • Diluted solutions of eribulin (0.018 – 0.18 mg/ml in normal saline) are compatible with intravenous bags constructed from polypropylene and polyethylene or constructed from polyolefin with polyvinylchloride (PVC)/diethylhexyl phthalate (DEHP) ports for up to 48 hours either refrigerated or at ambient temperature and lighting. •

The form must be completed in all its parts; if not applicable to specify "not applicable"