



Drug Information Center (DIC)/ KAUH

Stability and Storage of Chemotherapeutic Agents at KAUH

<u>Drug</u>	<u>Trade Name</u>	<u>Storage/ Stability</u>	<u>Class</u> <u>(Irritant/Vesicant)</u>	<u>Photosensitivity</u>
1- 5-fluorouracil	5-Fluorouracil "ebewe"1000 mg/20ml concentrate	It was found to be stable for 24 hours in 0.9% sodium chloride and in 5% glucose at concentration of 0.6mg/ml and 4mg/ml. (leaflet)	Irritant	Protect from light
2- BCG intravesical	No available leaflet in KAUH	Store at 2- 8°C and use within 2 hours of reconstitution.(Lexi)	None	Protect from sunlight (direct or indirect); minimize exposure to artificial light
3- Bendamustine Hydrochloride	Ribomustin 500 mg vial	- To reduce microbiological hazard, use as soon as possible after reconstitution. If storage is necessary, hold at not more than 3.5 hours at 25 °C or at 2°-8°C for not more than 24 hours. (leaflet) - Administration must be completed within 24 hours of dilution when diluted solution is stored under	Irritant with vesicant-like properties	Protect from light

		refrigeration or within 3 hours when stored at room temperature.(lexi)		
4- Bevacizumab	Avastin 100 mg/4 ml concentrate	<ul style="list-style-type: none"> - Solutions diluted in NS are stable for up to 8 hours under refrigeration (lexi). - After dilution with Nacl 0.9% the solution remains chemically and physically stable for 48 hours at (2-30°C).(leaflet) - Do not administer with dextrose solutions. 	None	Protect from light
5- Bleomycin	Bleomedac® 15 IU	<ul style="list-style-type: none"> - Stable for 24 hours in NS at room temperature.(lexi) - No information in leaflet. 	Irritant	Not
6- Bortezomib	Brotex 3.5 mg/vial powder	<ul style="list-style-type: none"> - Use within 8 hours of reconstitution. However, stability studies (using Velcade) have demonstrated that solutions of 1 mg/mL (vial or syringe) may be stored at room temperature for up to 3 days, or under refrigeration for up to 5 days; or refrigerated in the original vial for up to 15 days.(Lexi) -No information in leaflet. 	Irritant	Protect from light

7- Calcium Folate	Calcium Folate injection 10mg/ml	From a microbiological point of view, the product should be used immediately. If not used immediately in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2-8°C.(<u>leaflet</u>)	None	Protect from light.
8- Carboplatin	Carboplan 150mg/15ml 450mg/45ml solution	<p>- May be diluted in Glucose 5% or sodium chloride 0.9% in concentrations not lower than 0.5mg/ml.</p> <p>-When diluted as directed with Glucose chloride 5% carboplan solutions are stable for 8 hours at temperature $\leq 25^{\circ}\text{C}$ or for 24 hours at 2-8°C.(<u>leaflet</u>)</p> <p>-When diluted as directed with sodium chloride 0.9% carboplan solutions are stable for 1 hour at temperature $\leq 25^{\circ}\text{C}$. (<u>leaflet</u>)</p> <p>- Needles or IV administration sets that contain aluminum should not be used in the preparation or administration.</p>	Irritant	Protect from light

9- Cetuximab	Erbix 5 mg/ml solution	<p>- Store intact vials at 2°C to 8°C.</p> <p>- Preparations in infusion containers are stable for up to 48 hours at 25°C when prepared according to manufacturer's recommendations.(<u>lexi</u>)</p> <p>-Erbix 5 mg/ml is chemically and physically stable for up to 48 hours at 25°C.(<u>leaflet</u>)</p>	None	Not
10- Cisplatin	Cisplatin "Ebewe" concentrate 50 mg	<p>After dilution in-use stability has been demonstrated for 24 hours at 25°C for solutions with a final concentration 0.1 mg/ml after dilution of cisplatin 0.5mg/ml concentrate with one of the following solution:</p> <ol style="list-style-type: none"> 1. Nacl solution 0.9% 2.Mixture of Nacl solution 0.9% and glucose solution 5%.(<u>leaflet</u>) <p>- Do not use needles or IV administration sets that contain aluminum.</p>	Vesicant (>0.4 mg/mL); Irritant (≤0.4 mg/mL)	Protect from light
11- Cyclophosphamide	Endoxan 500 , 1000 mg powder	<p>- Store the reconstituted solution in the refrigerator (at 2- 8°C). The reconstituted solution should be used within 24 hours after preparation.(<u>leaflet</u>)</p>	Irritant	Protect from light (<u>Leaflet</u>)

12- Cytarabine	<p>- Alexan liquid 20mg/ml</p> <p>- Cytarine® 1 g/10ml (No information in its leaflet regarding stability and storage after reconstitution)</p>	<p>Reconstituted solutions are stable for 24 hours at temperature below 25 °C and for 4 days at 2-8 °C. If reconstitution does not take place under aseptic conditions the storage life will be 24 hours at temperature 2-8 °C and for max 12 hours at temperature below 25 °C (<u>Alexan leaflet</u>) .</p>	None	Protect from light
13- Dacarbazine	Dacarbazine medac 200 mg powder	<p>- Freshly prepared (reconstituted) solutions of decarbazine medac were demonstrated to be stable for 24 hours at 20°C protected from light. From a microbiological point of view the product should be used immediately of not then in-use storage times would normally be no longer than 24 hours at 2-8°C.(<u>leaflet</u>)</p> <p>- According to the manufacturer, the reconstituted solution (in the vial) should be used within 72 hours if refrigerated and 8 hours if at room temperature; however, additional stability data indicates the reconstituted solution may be stable</p>	Irritant	Protect from light

		for 24 hours at room temperature (20°C) and 96 hours refrigerated (4°C) when protected from light. Following dilution for infusion (in D5W or NS), solutions may be stored for up to 24 hours refrigerated (4°C) or for up to 8 hours at normal room conditions. <u>(lexi)</u>		
14- Dactinomycin	Cosmegen Lyovac 500 mcg powder	<ul style="list-style-type: none"> - Final concentrations (>10 mcg/mL) in D5W or NS should be stored for no more than 4 hours from reconstitution to completion of infusion (due to the lack of preservative).<u>(Lexi)</u> - <u>No information in leaflet.</u> - Solutions in 50 mL D5W are stable for 24 hours at room temperature. <u>(Globalrph)</u> - Only drug product diluted at concentrations greater than 10 mcg/mL and stored for not more than 10 hours at ambient room temperature are recommended for administration. (<u>leaflet from net</u>) 	Vesicant	Protect from light and humidity
15- Denosumab	Xgeva 120 mg solution	- Store in original carton at 2-8°C.	None	Protect from direct

		<p>Do not freeze. Prior to use, bring to room temperature of 25°C in original container (usually takes 15 to 30 minutes); do not use any other methods for warming. Use within 14 days once at room temperature. (<u>lexi</u>)</p> <p>- Once the vial has been left to reach room temperature it must be used within 30 days. (<u>leaflet</u>)</p>		heat and light.
16- Docetaxel	Docetaxel Ebewe 80 mg/8 ml concentrate	<p>-After first opening it must be used within 28 days .Don't store above 25°C .(<u>leaflet</u>)</p> <p>-After dilution the infusion solution should be used within 4 hours including the one hour infusion time at room temperature (below 25°C) or refrigerated. (leaflet)</p> <p>- Storage and stability may vary by manufacturer .(<u>lexi</u>)</p>	Irritant with vesicant-like properties	Protect from light
17- Doxorubicin	Doxorubicin Ebewe 2 mg/ml concentrate	<p>- From microbiological points of view this infusion solution should be used immediately, if not then storage times will usually not exceed 24 hours at 2-8°C. (<u>leaflet</u>)</p> <p>- Storage of vials of solution under refrigeration may result in formation</p>	Vesicant	Protect from light

		of a gelled product; if gelling occurs, place vials at room temperature for 2 to 4 hours to return the product to a slightly viscous, mobile solution.		
18- Etoposide	Etoposide 'Ebewe" 20mg/ml concentrate	- 0.4 mg/mL solutions diluted for infusion in D5W or NS (in glass or plastic containers)are stable for 24 hours at room temperature (precipitation may occur at concentrations above 0.4 mg/mL)(<u>lexi</u>). - Chemical and physical in use stability has been demonstrated for 24 hours at room temperature. From a microbiological point of view, the product should be used immediately. If not used immediately in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2-8°C, unless dilution has taken place in controlled and validated aseptic conditions.(<u>leaflet</u>)	Irritant	Not

19- Fludarabine	Fludarabine "ebewe" 25mg/ml concentrate	- For microbiological point of views the product should be used immediately, if not used immediately then in-use storage times would normally not be longer than 24 hours at 2-8°C.(<u>leaflet</u>)	None	Protect from light(<u>lexi</u>)
20- Gemcitabine	Gemnil 1000 mg powder	Reconstituted vials are stable for 24 hours at room temperature. Do not refrigerate (may form crystals). (<u>lexi,leaflet</u>)	Irritant	Not
21- Idarubicin	Zavedos 10 mg vial powder	- Reconstituted solution is stable for 48 hours at 2°- 8°C or 24 hours at room temperature.(<u>lexi</u>) - The reconstituted solution is chemically stable when stored for at least 48 hours at 2-8°C and 24 hours at room temperature; however it is recommended that in line with good pharmaceutical practice the solution should not normally be stored for longer than 24 hours at 2-8°C.	Vesicant	Protect from light
22- Ifosfamide	Holoxan powder 1g, 2g	Reconstituted solutions are stable for 24 hours refrigerated (don't store above 8°C).(<u>lexi,leaflet</u>)	Irritant	Not
23- Irinotecan	Irinotecan thymoorgan 100mg/5ml	Irinotecan solution should be used (infusion completed) within 12 hours, at room temperature or	Irritant	Protect from light

		within 24 hours if stored at 2-8°C after the first breakage.(<u>leaflet</u>)		
24- L- asparginase	Asparginase 10000 U medac powder	- Once dissolved (4 ml water for injection) the substance can be kept at room temperature for 6 hours. (<u>leaflet</u>) - Reconstituted solution should be used immediately after preparation, although is stable for 3 hours at room temperature or 72 hours refrigerated.(<u>lexi</u>)	None	Not
25- Mesna	Mecen 400mg /4 ml solution	-Don't store above 30°C. - Solutions diluted for infusion in D5W, NS, D5 ¹ / ₄ NS, D5 ¹ / ₃ NS, D5 ¹ / ₂ NS, or lactated Ringer's and stored at room temperature should be used within 24 hours. According to the manufacturer, mesna and ifosfamide may be mixed in the same bag if the final ifosfamide concentration is ≤50 mg/mL. Solutions of mesna and ifosfamide (1:1) in NS at a concentration of up to 20 mg/mL are stable for 14 days in PVC bags. Solutions of mesna (0.5 to 3.2 mg/mL) and cyclophosphamide (1.8 to 10.8 mg/mL) in D5W are stable for 48	None	Protect from light.

		<p>hours refrigerated or 6 hours at room temperature. Mesna injection prepared for oral administration is stable for at least 9 days undiluted in polypropylene syringes and stored at 5°C, 24°C, 35°C; for 7 days when diluted 1:2 or 1:5 with syrups and stored at 24°C in capped tubes; or for 24 hours at 5°C when diluted to 1:2, 1:10, and 1:100 in orange or apple juice, milk, or carbonated beverages. (<u>lexi</u>)</p> <p>- No information in leaflet.</p>		
26- Methotrexate	Trexol 50 mg/2ml	<p>Solution diluted in D5W or NS is stable for 24 hours at room temperature (<u>lexi</u>).</p> <p>- No information in leaflet.</p>	None	Protect from light
27- Methotrexate	Zexate 50mg, 500 mg	<p>- Solution diluted in D5W or NS is stable for 24 hours at room temperature (21°C to 25°C). (<u>lexi</u>).</p> <p>- No information in leaflet.</p>	None	Protect from light
28- Mitoxantrone	No available leaflet in KAUH	<p>- Opened vials may be stored at room temperature for 7 days or under refrigeration for up to 14 days. Solutions diluted in D5W or NS for administration are stable for 7 days at room temperature or under</p>	- Irritant with vesicant like properties	No information in lexi.

		refrigeration, although the manufacturer recommends immediate use.(<u>lexi</u>)		
29- <u>Nivolumab</u>	<u>Opdivo(10 mg/ml)as concentrate</u>	- Store the diluted infusion solution at room temperature for no more than 8 hours (including infusion time) or refrigerated at 2- 8°C for up to 24 hours (including infusion time. Do not freeze solutions prepared for infusion.(<u>lexi,leaflet</u>)	None	Protect from light
30- Oxaliplatin	Oxaliplatin medac 5mg/ml powder for solution for infusion	- After dilution of the reconstituted solution, it will be stable for 24 hours at 2-8°C. (<u>leaflet</u>) - Don't prepare using a chloride-containing solution such as NaCl. - Do not use needles or administration sets containing aluminum during preparation.	Irritant with vesicant-like properties	Protect concentrated solution from light
31- Paclitaxel	Intaxel USP 300mg/50ml	- Solutions diluted for infusion in D ₅ W and NS are stable for up to 27 hours at ambient temperature (~25°C).(lexi, <u>leaflet</u>)	Irritant with vesicant-like properties	Protect from light.
32- <u>Panitumumab</u>	<u>Vectibix 20mg/ml concentrate</u>	-Solutions diluted in NS for infusion should be used within 6 hours of preparation if stored at room temperature or within 24 hours of	None	Protect from direct sunlight

		dilution if stored at 2- 8°C.(Lexi) -No information in leaflet.		
33- Pemetrexed disodium	No available leaflet in KAUH	- Reconstituted solution and solution diluted for infusion are stable for 24 hours when refrigerated at 2-8°C.(lexi)	None	Not
34- Rituximab	Tromax 100mg/10ml, 500mg/50ml concentrate	- Solutions diluted for infusion in NS or D5W may be stored at 2°- 8°C for 24 hours and are stable at room temperature for an additional 24 hours (although because there is no preservative, the manufacturer recommends storing refrigerated).(lexi) -The prepared infusion solution of Tromax is physically and chemically stable for 24 hours at 2-8°C and for 12 hours at 15-25°C. (leaflet)	None	Protect vials from direct sunlight
35- Rituximab	Mabthera 1400 mg solution for SQ injection	- Store in a refrigerator (2-8) °C. - Once transferred from the vial to the syringe is stable for 48 hours at 2-8°C and 8 hours at (30°C) in diffused daylight.(Leaflet)	None	Protect from light.

36- Tocilizumab	Actemra 80 mg/4 ml, 200 mg/20 ml solution	<ul style="list-style-type: none"> - After dilution in NS 0.9% is stable for 24 hours at 2-8°C and at 30°C.(<u>leaflet</u>) - Solutions diluted for IV infusion in NS may be stored at 2- 8°C or room temperature for up to 24 hours; solutions diluted for IV infusion in 1/2 NS may be stored at 2- 8°C for up to 24 hours or at room temperature for up to 4 hours; protect from light.(<u>lexi</u>) 	None	Protect from light.
37- Trastuzumab	Herceptin 440 mg for multiple injection use	<ul style="list-style-type: none"> Herceptin vial reconstituted with bacteriostatic water for injection are stable for 28 days at 2-8°C .(<u>leaflet</u>) - Herceptin solution for infusion in PVC, PE or PP bags containing 0.9% NS is stable for 24 hours in 2-8°C or up to 30°C.(<u>leaflet</u>) 	None	Not
38- Trastuzumab	Herceptin 600/5 ml mg solution for SQ injection	<ul style="list-style-type: none"> - It is ready to use solution which should not be mixed or diluted with other products .(<u>Leaflet</u>) - Store in a refrigerator (2-8) °C. Don't freeze. Once removed from refrigerator must be administered within 6 hours and should not be kept above 30°C.(<u>Leaflet</u>) - Once transferred from the vial to 	None	Protect from light.

		the syringe is stable for 48 hours at 2-8°C and 6 hours at ambient temperature (max 30°C) in diffused daylight.(<u>Leaflet</u>)		
39- Vinblastine	Cytoblastin aqueous injection 10 mg	<p>-Store intact vials at 2°- 8°C.</p> <p>-Solutions diluted for infusion in NS, D5W, or LR (20 mcg/mL concentration) is stable for up to 21 days if protected from light. The formulation of vinblastine may have changed since this stability study was conducted; consult the manufacturer's prescribing information for further information. (<u>lexi</u>)</p> <p>- No information in leaflet except store between 2-8°C.</p>	Vesicant	Protect from light
40- Vincristine	Vincristine hospira 2mg/2ml solution	<p>-Solution diluted in normal saline and store at 25 °C are stable for 24 hours when protected from light or for 8 hours at normal light condition.</p> <p>-Solution diluted for infusion in NS or D5W (20 mcg/ml concentration) are reported to be stable for up to 21 days at 4°C and 25°C if protected</p>	Vesicant	Protect from light.

		from light , although the vincristine formulation may have changed since this stability study was conducted.(lexi). - No information in the leaflet.		
41- Vinorelbine	Vinorelbine "ebewe" 50 mg /5 ml concentrate	- Solutions diluted for infusion in polyvinyl chloride bags (D5W, NS, 1/2NS, D5 1/2NS, LR, or Ringer's) are stable for up to 24 hours at 5°C to 30°C under normal room light.(lexi) -From a microbiological point of view the product should be used immediately. If not used immediately in-use storage times would normally not be longer than 24 hours at 2-8°C.(leaflet)	Vesicant	Protect from light
42- Zoledronic acid	Zoledronic acid Hikma concentrate(4 mg/5ml)	- The total time between dilution, storage in refrigerator at (2-8 °C) and end of administration must not exceed 24 hrs.(Leaflet) - Don't mix with Ca ⁺² containing solutions.	None	Not

References:

- Lexicomp .
- Leaflets.

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