Bumetanide Injection 1 mg4 mL (0.25 mgmL) and 2.5 mg/10 mL (0.25 mg/mL) Multiple-Dose Vials

S.No.	Category	Question	Answer
		Clinical Particulars	
1	Use/Indication	What is the product indicated for?	Bumetanide Injection is indicated for the treatment of edema associated with congestive heart failure, hepatic and renal disease, including the nephrotic syndrome.
2	Dosage	What is the recommended dosage?	**DOSAGE AND ADMINISTRATION-ADULTS** Bumetanide Injection may be administered parenterally (IV or IM) to patients in whom gastrointestinal absorption may be impaired or in whom oral administration is not practical. Parenteral treatment should be terminated and oral treatment instituted as soon as possible. The usual initial dose is 0.5 to 1 mg intravenously or intramuscularly. Intravenous administration should be given over a period of 1 to 2 minutes. If the response to an initial dose is deemed insufficient, a second or third dose may be given at intervals of 2 to 3 hours, but should not exceed a daily dosage of 10 mg. **(Dose modifications is required and for the complete details, refer prescribing information**)
3	Administration	Administration precautions	• Caution should be used in calculating the dose to prevent overdose. • When administered subcutaneously, sites for each injection (thigh or abdomen) should be rotated. • New injections should be given at least one inch from an old site and never into areas where the site is tender, bruised, erythematous, or indurated. • If local injection site reactions occur following Bumetanide injection administration subcutaneously, a less concentrated Bumetanide for injection solution may be administered subcutaneously.

	Administration	Reconstitution for intravenous and subcutaneous	• Use proper aseptic technique. • Reconstitute only with the compatibility tests of bumetanide injection with 5% Dextrose Injection in Water, 0.9% Sodium Chloride Injection, and Lactated Ringer's Injection in both glass and plasticized PVC (Viaflex) containers • Bumetanide solutions should be freshly prepared and used within 24 hours. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit **For complete information, please refer to prescribing information**
4	Administration	Use in Pediatric Population	Safety and effectiveness in pediatric patients below the age of 18 have not been established.
5	Administration	Use in Geriatric Population	This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.
6	Mechanism	Mechanism of Action	Bumetanide injection the drug increases urinary excretion of water, sodium, and chloride by inhibiting reabsorption of sodium and chloride through interference with the chloride-binding cotransport system in the ascending loop of Henle.
7	Warning	Warnings and precautions	• Let the health care provider know if you have Volume and Electrolyte Depletion, Hypokalemia, Ototoxicity, Thrombocytopenia before starting the treatment and your doctor could consider giving you Bumetanide subcutaneously and if you experience worsening of symptoms, the doctor can change the dose and/or schedule or stop. • Bumetanide Injection, USP is a potent diuretic which, if given in excessive amounts, can lead to a profound diuresis with water and electrolyte depletion. Therefore, careful medical supervision is required, and dose and dosage schedule have to be adjusted to the individual patient's needs • Successful treatment with bumetanide following instances of allergic reactions to furosemide suggests a lack of cross-sensitivity.
8	Lactation	Use in Lactation	It is not known whether this drug is excreted in human milk. As a general rule, nursing should not be undertaken while the patient is on bumetanide since it may be excreted in human milk.
9	Pregnancy	Use in Pregnancy	There are no adequate and well-controlled studies in pregnant women A small investigational experience in the United States and marketing experience in other countries to date have not indicated any evidence of adverse effects on the fetus.
10	Storage	What are the storage conditions?	When reconstituted as directed, Bumetanide injection may be stored at 20° to 25°C (68° to 77°F).

			The temperature excursions are permitted from excursions permitted to 15° to 30° C (59°to 86°F) and Protect from light.
11	Dispensing	How to Dispense?	As prescribed by physician.
12	Contraindication	What are the contraindications of (medication)?	Bumetanide is contraindicated in anuria. Bumetanide is also contraindicated in patients in hepatic coma or in states of severe electrolyte depletion until the condition is improved or corrected and also contraindicated in patients hypersensitive to this drug.
Pharmaceutical Particulars			
13	Pharmaceutical Form	How Supplied	Bumetanide Injection, USP, 0.25 mg/mL is a sterile, clear, colorless to slightly yellow solution supplied in amber vials as follows: 4 mL Single Dose Vial packaged in 10s (NDC 72205-101-07) 10 mL Multiple Dose Vial packaged in 10s (NDC 72205-102-07)
14	Ingredients	Active and Inactive	**Active ingredient:** Bumetanide **Inactive ingredients:** Sodium chloride, Ammonium acetate, EDETATE di sodium, Benzyl alcohol, Sodium hydroxide and water.
Allergens			
13	Ingredients	Does it contain Gluten?	NO
14	Ingredients	Does it contain alcohol?	Yes (present in API)
15	Ingredients	Does it contain dyes?	NO
16	Ingredients	Does it contain Lactose?	NO
17	Ingredients	Does it contain Nuts?	NO
18	Ingredients	Does it contain Preservatives?	NO
19	Ingredients	Does it contain Soy products?	NO
20	Ingredients	Does it contain peanut?	NO
21	Ingredients	Does it contain any derivatives from tree nuts or any other type of nuts?	NO
Miscellaneous			
22	Miscellaneous	May I know the product availability?	Novadoz Pharmaceuticals products are only available through pharmacies, wholesalers, and other authorized distributors. See our ADR (authorized distributors of record) page at NovadozPharma.com to learn more about where to find our products.
23	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500
24	Miscellaneous	Do you have any patient's assistance program?	Novadoz Pharmaceuticals does not offer patient assistance programs at this time. The company that produces the brand version of your product may or may not offer such a program. Please check for access & eligibility requirements with that company

25	Miscellaneous	Why does my pharmacy, that used to fill your generic formulation of a particular medicine, no longer fills my prescription with Novadoz formulation?	Please check with your pharmacy as to why your prescription is not a Novadoz Pharmaceuticals product. You may refer to NovadozPharma.com ADR (authorized distributor of record) page to learn where to find our products
26	Miscellaneous	May I know where is this product manufactured?	**Manufactured by**: MSN Laboratories Private Limited Telangana – 509 228, INDIA **Distributed by**: Novadoz Pharmaceuticals LLC Piscataway, NJ 08854-3714