health
Department:
Health
REPUBLIC OF SOUTH AFRICA

Private Bag X828, PRETORIA, 0001 Dr AB Xuma Building1112 Voortrekker Road, Pretoria Townlands 351-JR, PRETORIA, 0187 Tel (012) 395 8000, Fax (012) 395 8918

Mr E van Zyl
Equity Pharmaceuticals (Pty) Ltd
100 Sovereign Road
Route 21 Corporate Park
Nellmapius Drive
Irene
**Pretoria**

Dear Mr van Zyl

**Section 21 Extension Authorization for MITOMYCIN 2MG INJECTION 4ML**

Attached, please find the Authorization for exemption under Section 21 of the Medicines and Related Substances Act by SAHPRA granted for:

- **Mitomycin 0.5mg/mL Injection 4mL**

The quantities for which approval was granted are only estimates based on procurement by provinces over the last 6 months. Please note that the National Department of Health (NDOH) cannot guarantee the procurement of these quantities, as NDOH has no control over orders being placed by provincial depots, and current stock holding might influence estimated quantities.

The following process will be followed to ensure the quality of the product being brought in:

1. Manufacturer will submit an assay and identification of every batch imported.
2. An additional assay of every batch will be done by a quality control laboratory.
3. A random sample will be assayed during the authorized period by a quality control laboratory.
4. Aggregate statistics to be submitted to NDOH in the first week of each month of all orders received and quantities supplied per province.
5. The NDOH needs to be advised of the quantities and date of arrival of stocks in terms of this authorization within 7 days after arrival.
6. The supplier will provide monthly reports, by the 7th of each month, using the attached format of orders received and issues done.
7. Participating Authorities (PAs) will provide a consolidated close out report of usage using the attached format on the date when an authorization lapses.

8. The full quantities imported in terms of this Section 21authorisation must be accounted for.
9. Note that this authorization DOES NOT cover supplies to the private sector.
10. Where this authorization is obtained to provide security of supply due to supply challenges from the contracted supplier, PAs are requested to buy out against contracted suppliers and ensure that related orders are cancelled accordingly to prevent overstocking once the contracted supplier gets back into stock.

It should be noted this authorization applies only for use of the product in the public sector with estimated usage quantities for a period of one month. The authorization is expected to expire on **13 December 2025**.

**Table 1: Provincial estimates**

| Province | Six Months Estimate | Actual Uptake |
|---|---|---|
| **Correctional Services** | 0 | 0 |
| **EC-MT** | 60 | 190 |
| **EC-PE** | 180 | |
| **FS** | 600 | 0 |
| **GP** | 0 | 0 |
| **KZN** | 30 | 40 |
| **LP** | 15 | 0 |
| **MP** | 0 | 0 |
| **NC** | 100 | 100 |
| **NW** | 42 | 0 |
| **SAMHS** | 20 | 0 |
| **WC** | 50 | 210 |
| **Total** | **1 097** | **540** |

Yours sincerely

K Jamaloodien

**KHADIJA JAMALOODIEN**
**CHIEF DIRECTOR: SECTOR WIDE PROCUREMENT**
**DATE:** 13/6/2025

S2100005142

SAHPRA Head Office
Building A, Loftus Park
2nd Floor
Kirkness Str
Arcadia
0083

# Section 21 Outcome Letter

2025-06-16

Ms Buhle Mbongo

National Department Of Health

Pretoria

buhle.mbongo@health.gov.za

Dear Ms Buhle Mbongo

**REQUEST TO USE UNREGISTERED MEDICINE IN TERMS OF SECTION 21 OF THE MEDICINES AND CONTROLLED SUBSTANCES ACT, 1965 (ACT 101 of 1965):**

Your application dated **2025-06-11** refers

**A. STATUS: Approved**

**B. APPLICANT: Ms Buhle Mbongo**

**C. IMPORTING COMPANY: EQUITY PHARMACEUTICAL (PTY) LTD**

**D. NUMBER OF PATIENT/(S) INTENDED TO BE TREATED: 20**

**E. UNREGISTERED MEDICINES: GENERIC NAME: No Data**

**F. TRADE NAME: Mitomycin Injection**

**G. QUANTITY: 560 Packs**

SAHPRA
South African
Health Products
Regulatory Authority

SAHPRA Head Office
Building A, Loftus Park
2nd Floor
Kirkness Str
Arcadia
0083

**H. LETTER NUMBER: S2100005142**

Section 21 authorization letters are valid for a period of 6 months from the letter date, unless otherwise specified.

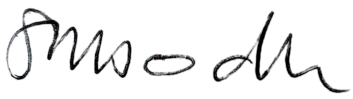
A progress report must be submitted once treatment is completed or on a reauthorization request

**Comments:**

Yours faithfully,

Dr S Munbodh

Manager: Section 21 Category A Medicines



Ms Luleka Dhlamini

Final Approver

S2100005142

SAHPRA
South African
Health Products
Regulatory Authority

SAHPRA Head Office
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# REQUEST FOR QUOTATION FORM

- **Instruction to complete this Request for Quotation (RFQ)**
  **PLEASE PROVIDE A QUOTE FOR THE FOLLOWING PRODUCT(S).**
  **PLEASE QUOTE ON THIS RFQ FORM AND ATTACH YOUR QUOTE WITH THE REQUESTED DETAILS.**
  **THE SECTIONS HIGHLIGHTED IN YELLOW MUST BE COMPLETED BY THE SUPPLIER.**
- **THIS DOES NOT CONSTITUTE ANY OBLIGATION TO PROCURE THE ITEM AS THIS WILL BE SUBMITTED FOR CONSIDERATION TO PROVINCIAL PROCUREMENT UNITS TO SERVE AS A BUY OUT AGAINST CURRENT NON-COMPLIANT SUPPLIERS.**

**ONLY RESPONSES FROM DULY REGISTERED SUPPLIERS WILL BE EVALUATED**

| | | | | | |
|---|---|---|---|---|---|
| REFERENCE NUMBER: | NORMAL | | SECTION 21 | X | **S21RFQ142** |
| QUOTE ENQUIRY DATE | **14/10/2024** | QUOTE CLOSING DATE | | | **22/10/2024** |
| FOR CRITICAL DELIVERY, DELIVERY REQUESTED ON/BEFORE *(SCM Practitioner to Specify if applicable)* | | | | | |

**REQUESTING INSTITUTION CONTACT DETAILS**

| | | | |
|---|---|---|---|
| NAME OF REQUESTOR | Buhle Mbongo | | |
| EMAIL ADDRESS | Buhle.Mbongo@health.gov.za | | |
| PHONE No. | **012 395 9539** | FAX No. | **N/A** |

**PRODUCT INFORMATION**

| | | | |
|---|---|---|---|
| DESCRIPTION PER MPC | **Mitomycin 2mg Injection** | | |
| TRADE DESCRIPTION | Mitomycin 2mg | | |
| UNIT OF MEASURE | **1's** | PACK or BOX (*SIZE/ QUANTITY*) | 1's |
| QUANTITY REQUIRED | **1100 vials** | | |

**TO BE COMPLETED BY THE SUPPLIER/ SERVICE PROVIDER**

**SUPPLIER CONTACT DETAILS (as per CSD)**

| | | | | |
|---|---|---|---|---|
| COMPANY NAME | Equity Pharmaceuticals (Pty) Ltd | | | |
| SUPPLIER NUMBER | MAAA007480 | | | |
| SECURITY CODE | | | | |
| SUPPLIER CODE (NDoH) | | | | |
| CONTACT PERSON 1 | NAME | **Ehrard van Zyl** | | |
| | PHONE | **012 345 1747** | FAX | **012 345 1747** |
| | MOBILE | *072 040 8511* | | |
| | E-MAIL | **ehrard@equitypharma.co.za** | | |
| CONTACT PERSON 2 | NAME | **Jaco Schoeman** | | |
| | PHONE | **012 345 1747** | | |

| | | |
|---|---|---|
| | MOBILE | *076 734 0080* |
| | E-MAIL | **jacos@equitypharma.co.za** |

| **QUOTE DETAILS** | | | |
|---|---|---|---|
| PRICE PER UNIT (INCL. VAT) ZAR | R 78.20 | TOTAL PRICE (INCL. DELIVERY & VAT) | R 86 020.00 |
| VOLUMES AVAILABLE – 14DAYS | | | |
| VOLUMES AVAILABLE – 28DAYS | 1 100 | | |
| VOLUMES AVAILABLE – 56DAYS | | | |
| VOLUMES AVAILABLE – 112DAYS | | | |
| QUOTE VALIDITY PERIOD | 180 days | | |
| NORMAL LEAD/DELIVERY TIME | 3 days | | |

| **DEVIATION TO SPECIFICATION** |
|---|
| *COMMENTS:* |
| |
| |

| **DECLARATION BY SUPPLIER** | |
|---|---|
| **I hereby declare that in submitting this bid, there has been no consultation, communication, agreement or arrangement with any competitor/supplier regarding the price, quality, quantity, specifications and conditions or delivery particulars of the products or services to which this bid invitation relates.** | |
| **NAME** | **Ehrard van Zyl** |
| **CAPACITY** | **Business Unit Manager: Specialist Medicine** |
| **SIGNATURE** *(OF A DULY AUTHORISED REPRESENTATIVE OF THE SUPPLIER)* |  |
| **DATE** | **22/10/2024** |

***Please submit quotations to*** Section21Quotes@health.gov.za

**Please ensure that you include the following as part of the Quotation:**

- Delivery Time (Weeks)
- Price (Vat Inclusive)
- Generic Name
- Trade Name
- Central Supplier Database Summary Report (CSD)
- Medicine Registration Certificate (Only for Locally Registered Products)
- *Artwork/Labelling
- *Package Insert: (Please attach)
- *Manufacturer Certificate: (Please attach)
- *Country of Origin: (Please indicate)

*Additional items required when submitting a quote for a Section 21 Item (Unregistered Medicine)

All of the above is required to expedite the process in considering the quotation.

Please ***SUBMIT COMPLETED RFQ FORM AND QUOTATIONS ON AN OFFICIAL COMPANY LETTERHEAD***

***NB*:**

- The size of each individual attachment must not be more than 2MB (you may attach multiple files in one email but collectively they should not be more than 2MB in size).
- Please ensure that you provide all prescribed documentation that is outlined on page two of this RFQ.
- Kindly be advised that a picture format of an Artwork shall not be accepted. Artwork must be in pdf or word format only.
- All prices (in ZAR) must be submitted in two decimals.
- If submitting more than one quotation, please make sure that your subject line includes e.g., 1 of 2 or 1 of 3 etc.
- Any submission with missing documentation shall not be considered.
- Any submission with blurry relevant documents shall not be considered.
- The only electronic GMP Certificate considered is that from EUDRA.
- ***Email subject line for responses with quotes must be kept unchanged from the originally sent RFQ email.**

Please ***SUBMIT COMPLETED RFQ FORM AND QUOTATIONS ON AN OFFICIAL COMPANY LETTERHEAD***

*22/10/2024*

**Equity Pharmaceuticals (Pty) Ltd.**
1997/009942/07

+27 12 345 1747
+27 12 345 1412
equity@equitypharma.co.za

**www.clinigengroup.com**
**www.equitypharma.co.za**

# QUOTATION # 20241022

**TO: National Department of Health**

**TEL: 012 395 9539**
**FAX:**
**Email: Section21Quotes@health.gov.za**

**CONTACT PERSON / PATIENT: Buhle Mbongo**

NB IMPORTED AND SUPPLIED UNDER SECTION 21 TERMS

| PRODUCT CODE | DESCRIPTION | PACK SIZE | QUANTITY | PRICE EXCL | TOTAL INCL |
|---|---|---|---|---|---|
| | Mitomycin 2mg | 1's | 1 | R 68.00 | R 78.20 |
| | | | **1 100** | **R 74 800.00** | **R 86 020.00** |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | **1 100** | **R 74 800.00** | **R 86 020.00** |

Valid for 180 days

Employee Signature: _____

Date: 22/10/2024

Approved by: Ehrard van Zyl / Carel Bouwer

EQUITY
PHARMACEUTICALS

**Equity Pharmaceuticals (Pty) Ltd.**
1997/009942/07

+27 12 345 1747
+27 12 345 1412
equity@equitypharma.co.za

**www.clinigengroup.com**
**www.equitypharma.co.za**

*22/10/2024*

National Department of Health

Directorate: Affordable Medicines

E-mail: Section21Quotes@health.gov.za

Attention: Ms Buhle Mbongo

Dear Ms Mbongo

**Re: Request for quotation – Mitomycin – Section 21 Supply**

Trust you are well. Please find below our quotation for *Mitomycin 2mg* supplied under section 21 terms.

- Quantity: **1 100 vials**
- Delivery Time (Weeks): **3 weeks**
- Price (Vat Inclusive): **R 78.20 incl. vat per vial**
- Generic Name: **Mitomycin**
- Trade Name: **Mitomycin 2mg**
- Packaging: **1 vial**
- Specifications: **2mg**
- Shelf Life: **24 months**
- Package Insert: **Please find attached**
- Manufacturer: **Naprod**
- Country of Origin: **India**

Please note that the immediate availability of the product is conditioned on the manufacturer receiving notice of our order as soon as possible. Unfortunately, the stock cannot be reserved for our purposes for too long.

We look forward to your response.

Please contact me if you require any additional information.

Kind Regards

Ehrard van Zyl

℞ Mitomycin Injection IP 2mg

**Mitomycin 2**

मिटोमायसिन २

**2 mg**

For I.V. Infusion after dilution

SINGLE USE VIAL

Lyophilized

Zydus Celexa

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.

# Mitomycin Injection IP

## MITOMYCIN

Lyophilized

**WARNING**

Mitomycin injection IP should be administered under the supervision of a qualified physician experienced in the use of cancer chemotherapeutic agents. Appropriate management of therapy and complications is possible only when adequate diagnostic and treatment facilities are readily available.

Bone marrow suppression, notably thrombocytopenia and leukopenia, which may contribute to overwhelming infections in an already compromised patient, is the most common and severe of the toxic effects of Mitomycin injection IP.

Hemolytic Uremic Syndrome (HUS) a serious complication of chemotherapy, consisting primarily of microangiopathic hemolytic anemia, thrombocytopenia, and irreversible renal failure has been reported in patients receiving systemic Mitomycin injection IP. The syndrome may occur at any time during systemic therapy with Mitomycin injection IP as a single agent or in combination with other cytotoxic drugs, however, most cases occur at doses ≥60 mg of Mitomycin injection IP. Blood product transfusion may exacerbate the symptoms associated with this syndrome.

The incidence of the syndrome has not been defined.

**COMPOSITION**

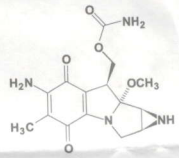
Each vial contains:

| | |
|---|---|
| Mitomycin IP | 2 mg / 10 mg / 40 mg |
| Mannitol IP | q.s. |

**DESCRIPTION**

Mitomycin injection is a sterile bluish violet lyophilised mass. It contains mannitol, sodium hydroxide, water for injection as excipients. Mitomycin is an antibiotic isolated from the broth of Streptomyces caespitosus which has been shown to have antitumor activity.

The molecular formula is $C_{15}H_{18}N_4O_5$ and its molecular weight is 334.33 Its structural formula is.



**CLINICAL PHARMACOLOGY**

**Pharmacodynamics**

Mitomycin injection IP selectively inhibits the synthesis of deoxyribonucleic acid (DNA). The guanine and cytosine content correlates with the degree of Mitomycin injection IP - induced cross-linking. At high concentrations of the drug, cellular RNA and protein synthesis are also suppressed.

**Pharmacokinetics**

In humans, Mitomycin injection IP is rapidly cleared from the serum after intravenous administration. Time required to reduce the serum concentration by 50% after a 30 mg bolus injection is 17 minutes. After injection of 30 mg, 20 mg, or 10 mg I.V., the maximal serum concentrations 2.4 μg/mL, 1.7 μg/mL, and 0.52 μg/mL, respectively. Clearance is effected primarily by metabolism in the liver, but metabolism occurs in other tissues as well. The rate of clearance is inversely proportional to the maximal serum concentration because, it is thought, of saturation of the degradative pathways.

Approximately 10% of a dose of Mitomycin injection IP is excreted unchanged in the urine. Since metabolic pathways are saturated at relatively low doses, the percent of a dose excreted in urine increases with increasing dose. In children, excretion of intravenously administered Mitomycin injection IP is similar.

**INDICATIONS**

Mitomycin is not recommended as single-agent, primary therapy.

It has been shown to be useful in the therapy of disseminated adenocarcinoma of the stomach or pancreas in proven combinations with other approved chemotherapeutic agents and as palliative treatment when other modalities have failed. Mitomycin is not recommended to replace appropriate surgery and/or radiotherapy.

**CONTRAINDICATIONS**

Mitomycin injection IP is contraindicated in patients who have demonstrated a hypersensitive or idiosyncratic reaction to it in the past.

Mitomycin injection IP is contraindicated in patients with thrombocytopenia, coagulation disorder, or an increase in bleeding tendency due to other causes.

**DOSAGE AND ADMINISTRATION**

Mitomycin should be given intravenously only, using care to avoid extravasation of the compound. If extravasation occurs, cellulitis, ulceration, and slough may result.

After full hematological recovery (see guide to dosage adjustment) from any previous chemotherapy, the following dosage schedule may be used at 6 to 8 week intervals:

20 mg/m² intravenously as a single dose via a functioning intravenous catheter.

Because of cumulative myelosuppression, patients should be fully reevaluated after each course of Mitomycin injection, IP and the dose reduced if the patient has experienced any toxicities. Doses greater than 20 mg/m² have not been shown to be more effective, and are more toxic than lower doses.

**Guide to dosage adjustment:**

| Nadir after prior dose | | Percentage of prior dose to be given |
|---|---|---|
| Leucocyte/mm³ | Platelets/mm³ | |
| ≥4000 | ≥100,000 | 100% |
| 3000-3999 | 75,000-99999 | 100% |
| 2000-2999 | 75,000-99999 | 70% |
| <2000 | <25000 | 50% |

No repeat dosage should be given until leukocyte count has returned to 4000/mm³ and a platelet count to 100,000/mm³.

When Mitomycin Injection IP is used in combination with other myelosuppressive agents, the doses should be adjusted accordingly. If the disease continues to progress after two courses of Mitomycin Injection IP, the drug should be stopped since chances of response are minimal.

**Reconstitution:**

Each vial contains Mitomycin 2mg, 10 mg, 40 mg. To administer, add Sterile Water for Injection, 4 ml, 20 ml and 80 ml respectively. Shake to dissolve. If product does not dissolve immediately, allow to stand at room temperature until solution is obtained.

**Stability**

1. Unreconstituted Mitomycin Injection IP stored at room temperature is stable for the lot life indicated on the package. Avoid excessive heat (over 40° C, 104° F).

2. Reconstituted with Sterile Water for Injection to a concentration of 0.5 mg per mL, Mitomycin injection IP is stable for 14 days refrigerated or 7 days at room temperature.

3. Diluted in various I.V. fluids at room temperature, to a concentration of 20 to 40 micrograms per mL:

| I.V. Fluid | Stability |
|---|---|
| 5% Dextrose Injection | 3 hours |
| 0.9% Sodium Chloride Injection | 12 hours |
| Sodium Lactate Injection | 24 hours |

4. The combination of Mitomycin injection IP (5 mg to 15 mg) and heparin (1,000 units to 10,000 units) in 30 mL of 0.9% Sodium Chloride Injection is stable for 48 hours at room temperature.

**OVERDOSAGE**

No data is available.

**ADVERSE REACTIONS**

**Bone Marrow Toxicity**

This was the most common and most serious toxicity. Thrombocytopenia and/or leukopenia may occur anytime within 8 weeks after onset of therapy with an average time of 4 weeks. Recovery after cessation of therapy was within 10 weeks. Mitomycin Injection IP produces cumulative myelosuppression.

**Integument and Mucous Membrane Toxicity**

This has occurred in approximately 4% of patients treated with Mitomycin Injection IP. Cellulitis at the injection site has been reported and is occasionally severe. Stomatitis and alopecia also occur frequently. Rashes are rarely reported. The most important dermatological problem with this drug, however, is the necrosis and consequent sloughing of tissue which results if the drug is extravasated during injection. Extravasation may occur with or without an accompanying

stinging or burning sensation and even if there is adequate blood return when the injection needle is aspirated.

**Renal Toxicity**
Rise in creatinine.

**Pulmonary Toxicity**
This has occurred infrequently but can be severe and may be life threatening. Dyspnea with a nonproductive cough and radiographic evidence of pulmonary infiltrates may be indicative of Mitomycin Injection IP -induced pulmonary toxicity. If other etiologies are eliminated, Mitomycin Injection IP therapy should be discontinued. Steroids have been employed as treatment of this toxicity, but the therapeutic value has not been determined.

**Hemolytic Uremic Syndrome (HUS)**
This serious complication of chemotherapy, consisting primarily of microangiopathic hemolytic anemia (hematocrit $\leq$ 25%), thrombocytopenia ($\leq$100,000/mm$^3$), and irreversible renal failure (serum creatinine $\geq$1.6 mg/dL) has been reported in patients receiving systemic Mitomycin injection IP. Microangiopathic hemolysis with fragmented red blood cells on peripheral blood smears has occurred.

Other less frequent complications of the syndrome may include pulmonary edema, neurologic abnormalities and hypertension. Exacerbation of the symptoms associated with HUS has been reported in some patients receiving blood product transfusions. A high mortality rate has been associated with this syndrome.

The syndrome may occur at any time during systemic therapy with Mitomycin injection IP as a single agent or in combination with other cytotoxic drugs. Less frequently, HUS has also been reported in patients receiving combinations of cytotoxic drugs not including mitomycin injection IP. patients developes the syndrome at total doses exceeding 60 mg of mitomycin injection IP. Consequently, patients receiving $>$ 60 mg of mitomycin injection IP should be monitored closely for unexplained anemia with fragmented cells on peripheral blood smear, thrombocytopenia, and decreased renal function.

The incidence of the syndrome has not been defined. Therapy for the syndrome is investigational.

**Cardiac Toxicity**
Congestive heart failure, often treated effectively with diuretics and cardiac glycosides, has rarely been reported.

Acute side effects due to Mitomycin Injection IP were fever, anorexia, nausea, and vomiting.

**Other**
Headache, blurring of vision, confusion, drowsiness, syncope, fatigue, edema, thrombophlebitis, hematemesis, diarrhea, and pain. These did not appear to be dose related and were not unequivocally drug related. They may have been due to the primary or metastatic disease processes.

## WARNINGS
Patients being treated with Mitomycin Injection IP must be observed carefully and frequently during and after therapy.

The use of Mitomycin Injection IP results in a high incidence of bone marrow suppression, particularly thrombocytopenia and leukopenia. Therefore, the following studies should be obtained repeatedly during therapy and for at least eight weeks following therapy: platelet count, white blood cell count, differential, and hemoglobin. The occurrence of a platelet count below 100,000/mm$^3$ or a WBC below 4,000/mm$^3$ or a progressive decline in either is an indication to withhold further therapy until blood counts have recovered above these levels.

Patients should be advised of the potential toxicity of this drug, particularly bone marrow suppression. Deaths have been reported due to septicemia as a result of leukopenia due to the drug.

Patients receiving Mitomycin Injection IP should be observed for evidence of renal toxicity. Mitomycin Injection IP should not be given to patients with a serum creatinine greater than 1.7 mg percent.

**Usage in Pregnancy**
Pregnancy Category D. Safe use of Mitomycin Injection IP in pregnant women has not been established. Teratological changes have been noted in animal studies. The effect of Mitomycin Injection IP on fertility is unknown.

**Nursing Mothers**
It is not known if mitomycin is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from mitomycin, it is recommended that nursing be discontinued when receiving mitomycin therapy.

## PRECAUTIONS
Acute shortness of breath and severe bronchospasm have been reported following the administration of vinca alkaloids in patients who had previously or simultaneously received Mitomycin Injection IP. The onset of this acute respiratory distress occurred within minutes to hours after the vinca alkaloid injection. The total number of doses for each drug has varied considerably. Bronchodilators, steroids and/or oxygen have produced symptomatic relief.

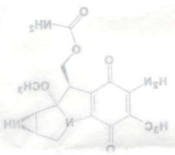
A few cases of adult respiratory distress syndrome have been reported in patients receiving Mitomycin Injection IP in combination with other chemotherapy and maintained at FIO2 concentrations greater than 50% perioperatively. Therefore, caution should be exercised using only enough oxygen to provide adequate arterial saturation since oxygen itself is toxic to the lungs. Careful attention should be paid to fluid balance and overhydration should be avoided.

Bladder fibrosis/contraction has been reported with intravesical administration (not an approved route of administration), which in rare cases has required cystectomy.

**Pediatric Use**
Safety and effectiveness in pediatric patients have not been established.

## STORAGE
Store between 15°C to 30°C.
Protect from light.

## PRESENTATION
**MITOMYCIN** (Mitomycin Injection IP) is available in a vial containing Mitomycin IP 2 mg / 10 mg / 40 mg.




**Zydus Celexa**

Marketed by:
**Zydus Celexa**
(A div. of Cadila Healthcare Limited)
"Zydus Tower", Satellite Cross Road,
Ahmedabad-380 015

Manufactured by:
**Naprod Life Sciences Pvt. Ltd.**
Plot No. G-17/1, M.I.D.C., Tarapur,
Boisar, Dist. Thane 401 506.

M004PSCS

120 x 270mm