



health

Department:  
Health  
REPUBLIC OF SOUTH AFRICA



Private Bag X828, PRETORIA, 0001 Dr AB Xuma Building 1112 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 Authorization for THIOPENTONE 500MG INJECTION**

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

- **Thiopentone 500mg Injection**

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 7<sup>th</sup> 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 21 authorisation must be accounted for.
9. Note that this authorization DOES NOT cover supplies to the private sector.

**Section 21 Authorisation re Thiopentone 500mg INJ 04092023**

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 over stocking 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 **02 March 2024**.

**Table 1: Provincial estimates**

| <b>Provinces</b>      | <b>Six Month's Estimated Quantity</b> |
|-----------------------|---------------------------------------|
| Correctional Services | 0                                     |
| EC-MT                 | 0                                     |
| EC-PE                 | 80                                    |
| FS                    | 85                                    |
| GP                    | 0                                     |
| KZN                   | 0                                     |
| LP                    | 1 310                                 |
| MP                    | 0                                     |
| NC                    | 0                                     |
| NW                    | 0                                     |
| SAMHS                 | 0                                     |
| WC                    | 0                                     |
| <b>Total</b>          | <b>1 475</b>                          |

Yours sincerely

  
**KHADIJA JAMALOODIEN**  
**CHIEF DIRECTOR: SECTOR WIDE PROCUREMENT**  
**DATE: 08/09/2023**



## Section 21 Response Letter

9/2/2023 9:12 AM

Khadija Jamaloodien

National Department of Health  
Dr AB Xuma Building  
1112 Voortrekker Rd  
Pretoria Townlands 351-JR  
Pretoria  
0187

Buhle.Mbongo@health.gov.za

Dear Khadija Jamaloodien,

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

Your application dated **9/1/2023 12:33 PM** refers

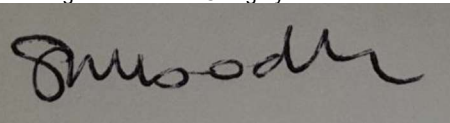
- A. STATUS: Approved**
- B. APPLICANT: Khadija Jamaloodien**
- C. IMPORTING COMPANY: Equity Pharmaceuticals (Pty) Ltd**
- D. PATIENT/(S):**
- E. UNREGISTERED MEDICINES:**
  - GENERIC NAME: Thiopental Sodium  
for Injection USP 500mg**
  - TRADE NAME: Thiopental Sodium**
- F. QUANTITY: Thiopental Sodium for  
Injection USP 500mg x 1500 vials**
- G. LETTER NUMBER: B-20341**

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

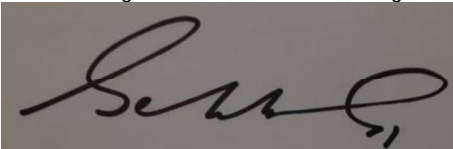
Comments:

Yours faithfully,

Dr S Munbodh  
Manager: Section 21 Category A Medicines

A handwritten signature in black ink on a grey background, appearing to read 'S. Munbodh'.


T Sehloho  
Senior Manager: Clinical Evaluations Management

A handwritten signature in black ink on a grey background, appearing to read 'T. Sehloho'.



Private Bag X828, PRETORIA, 0001 Dr AB Xuma Building 1112 Voortrekker Road, Pretoria Townlands 351-JR, PRETORIA, 0187 Tel (012) 395 8000, Fax (012) 395 8918

| <b>REQUEST FOR QUOTATION FORM</b>   |  |                              |            |            |
|---|--|------------------------------|------------|------------|
| <ul style="list-style-type: none"> <li><b>Instruction to complete this Request for Quotation (RFQ)</b><br/>PLEASE PROVIDE A QUOTE FOR THE FOLLOWING PRODUCT(S).<br/>PLEASE QUOTE ON THIS RFQ FORM AND ATTACH YOUR QUOTE WITH THE REQUESTED DETAILS.<br/>THE SECTIONS HIGHLIGHTED IN YELLOW MUST BE COMPLETED BY THE SUPPLIER.</li> <li><b>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.</b></li> </ul> |  |                              |            |            |
| <b>ONLY RESPONSES FROM DULY REGISTERED SUPPLIERS WILL BE EVALUATED</b>  |  |                              |            |            |
| REFERENCE NUMBER:   | NORMAL   | SECTION 21                   | X          | S21RFQ128  |
| QUOTE ENQUIRY DATE  | 26/07/2023   | QUOTE CLOSING DATE           | 04/08/2023 |            |
| FOR CRITICAL DELIVERY, DELIVERY REQUESTED ON/BEFORE<br><i>(SCM Practitioner to Specify if applicable)</i>   |  |                              |            |            |
| <b>REQUESTING INSTITUTION CONTACT DETAILS</b>   |  |                              |            |            |
| NAME OF REQUESTOR   | Buhle Mbongo   |                              |            |            |
| EMAIL ADDRESS   | <a href="mailto:Buhle.Mbongo@health.gov.za">Buhle.Mbongo@health.gov.za</a> |                              |            |            |
| PHONE No.   | 012 395 9539   | FAX No.                      | N/A        |            |
| <b>PRODUCT INFORMATION</b>  |  |                              |            |            |
| DESCRIPTION PER MPC   | THIOPENTONE 500MG INJECTION 20ML   |                              |            |            |
| TRADE DESCRIPTION   | Thiopental Sodium for Injection USP 500mg                                  |                              |            |            |
| UNIT OF MEASURE   | 1's  | PACK or BOX (SIZE/ QUANTITY) | 1's        |            |
| QUANTITY REQUIRED   | 1 500 VIALS/AMPOULES   |                              |            |            |
| <b>TO BE COMPLETED BY THE SUPPLIER/ SERVICE PROVIDER</b>  |  |                              |            |            |
| <b>SUPPLIER CONTACT DETAILS (as per CSD)</b>  |  |                              |            |            |
| COMPANY NAME  | Equity Pharmaceuticals (Pty) Ltd   |                              |            |            |
| SUPPLIER NUMBER   | MAAA007480   |                              |            |            |
| SECURITY CODE   |  |                              |            |            |
| SUPPLIER CODE (NDoH)  |  |                              |            |            |
| CONTACT PERSON 1  | NAME   | Ehrard van Zyl               |            |            |
|   | PHONE  | 0123451747                   | FAX        | 0123451412 |
|   | MOBILE   | 0720408511                   |            |            |
|   | E-MAIL   | ehrdard@equitypharma.co.za   |            |            |
| CONTACT PERSON 2  | NAME   | Jaco Schoeman                |            |            |
|   | PHONE  | 0123451747                   |            |            |

|  |  |                                    |             |
|--|--|------------------------------------|-------------|
|  | MOBILE   | 0767340080                         |             |
|  | E-MAIL   | jacos@equitypharma.co.za           |             |
| <b><u>QUOTE DETAILS</u></b>  |  |                                    |             |
| PRICE PER UNIT (INCL. VAT)   | R 36.57  | TOTAL PRICE (INCL. DELIVERY & VAT) | R 54 855.00 |
| VOLUMES AVAILABLE – 14DAYS   |  |                                    |             |
| VOLUMES AVAILABLE – 28DAYS   |  |                                    |             |
| VOLUMES AVAILABLE – 56DAYS   | 1 500  |                                    |             |
| VOLUMES AVAILABLE – 112DAYS  |  |                                    |             |
| QUOTE VALIDITY PERIOD  | 180 days   |                                    |             |
| NORMAL LEAD/DELIVERY TIME  | 3 days   |                                    |             |
| <b><u>DEVIATION TO SPECIFICATION</u></b>   |  |                                    |             |
| <b>COMMENTS:</b>   |  |                                    |             |
|  |  |                                    |             |
|  |  |                                    |             |
| <b><u>DECLARATION BY SUPPLIER</u></b>  |  |                                    |             |
| 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<br>(OF A DULY AUTHORISED REPRESENTATIVE OF THE SUPPLIER)   |  |                                    |             |
| DATE   | 04/08/2023   |                                    |             |
| <b>Please submit quotations to <a href="mailto:Section21Quotes@health.gov.za">Section21Quotes@health.gov.za</a></b>  |  |                                    |             |

**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 must please 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.
- 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**

04/08/2023



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 # 20230804

TO: National Department of Health

TEL: 012 395 9539

FAX:

Email: Buhle.Mbongo@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  |
|--------------|--|-----------|----------|-------------|-------------|
|              | Thiopental Sodium for Injection<br>500mg | 1's       | 1        | R 31.80     | R 36.57     |
|              |  |           | 1 500    | R 47 700.00 | R 54 855.00 |
|              |  |           |          |             |             |
|              |  |           |          |             |             |
|              |  |           |          |             |             |
|              |  |           |          |             |             |
|              |  |           |          |             |             |
|              |  |           |          |             |             |
|              |  |           | 1 500    | R 47 700.00 | R 54 855.00 |

Valid for 180 days

Employee Signature: 

Date: 04/08/2023

Approved by: Ehrard van Zyl / Carel Bouwer



04/08/2023

National Department of Health

Directorate: Affordable Medicines

E-mail: [Buhle.Mbongo@health.gov.za](mailto:Buhle.Mbongo@health.gov.za)

Attention: Ms Buhle Mbongo

**EQUITY**  
PHARMACEUTICALS

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

+27 12 345 1747

+27 12 345 1412

[equity@equitypharma.co.za](mailto:equity@equitypharma.co.za)

[www.clinigengroup.com](http://www.clinigengroup.com)  
[www.equitypharma.co.za](http://www.equitypharma.co.za)

Dear Ms Mbongo

**Re: Request for quotation – Thiopentone 0.5g – Section 21 Supply**

Trust you are well. Please find below our quotation for *Thiopentone 0.5g* supplied under section 21 terms.

|                          |  |
|--------------------------|--|
| • Quantity:              | <b>1 500 vials</b>                               |
| • Delivery Time (Weeks): | <b>7 Weeks</b>                                   |
| • Price (Vat Inclusive): | <b>R 36.57 per vial</b>                          |
| • Generic Name:          | <b>Thiopentone 500mg</b>                         |
| • Trade Name:            | <b>Thiopental Sodium for Injection USP 500mg</b> |
| • Packaging:             | <b>1's (singles)</b>                             |
| • Specifications:        | <b>0.5g vial</b>                                 |
| • Shelf Life:            | <b>24 months</b>                                 |
| • Package Insert:        | <b>Attached</b>                                  |
| • Manufacturer:          | <b>Kwality Pharmaceuticals Ltd.</b>              |
| • Country of Origin:     | <b>India</b>                                     |

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



Ehrhard van Zyl

# Thiopental

## Sodium For Injection USP

500mg/Vial

**WARNING : MAY BE HABIT FORMING.**

**Composition:**

Each vial contains:

Thiopental Sodium Sterile USP ..... 500mg.

Contains Sodium Carbonate (anhydrous) as a buffer.

**CATEGORY :** Intravenous barbiturate; general anaesthetic.

**GENERAL INFORMATION :** It is a very short acting barbiturate which on I.V. administration quickly induces anaesthesia and hypnosis. It does not cause analgesia. The anaesthesia is induced rapidly, without excitement and pleasantly. It is a weak muscle relaxant, irritation of respiratory passages does not occur. Hypotension occurs after administration but recovery occurs rapidly. Cardiac muscle is not sensitized to adrenaline. Extravasation of thiopentone or inadvertent intra-arterial injection leads to intense pain and necrosis.

**PHARMACOKINETIC :**

After administration it is distributed initially in organs which are highly vascular e.g. Brain. Subsequently the termination of its effect depends upon redistribution of drug from brain to fatty tissues and other tissues.

On Set of Action : I.V. within 1 minute.

Duration of Action : 20-30 minutes.

**INDICATIONS :** Anaesthesia of short duration, status epilepticus. Rapid control of convulsions. Infusion of subanaesthetic doses can be used to facilitate verbal communication with psychiatric patients.

**DOSAGE AND ADMINISTRATION :**

**This drug should be administered only by persons qualified in the use of intravenous anaesthesia.**

**Preferable by** Anaesthesiologist.

Adults : Inject I.V. (3-5mg/kg) as a 2.5% solution. It produce unconsciousness in 15-30 seconds.

initially, 100 to 500 mg, repeated if necessary after 20 to 30 seconds; maximum dose 2 g.

Other Features are: Can be given per rectal, may be used to control convulsions, may cause respiratory depressions, may cause hypotension, shows `slug` effect.

**CONTRAINDICATIONS :** Hypersensitivity, hypotension, status asthmaticus, hepatic dysfunction, Addison's disease, myxoedema, acute intermittent porphyria and severe cardiovascular disease.

**ADVERSE EFFECTS :** Hypotension, hiccups, apnoea for short period, nausea, vomiting. The use of other non-compatible drugs during anaesthesia or in conjunction with anaesthesia can be fatal.

**SPECIAL PRECAUTIONS :** Thiopental should not be mixed with Succinylcholine in the same syringe. Do not use other non-compatible drugs during anaesthesia or in conjunction with anaesthesia.

**Pregnancy :** Caution, use only when clearly indicated.

**Breast feeding :** Use with caution.

**INTERACTIONS :** Narcotics: Those of phenobarbitone required to induce anaesthesia reduced.

Phenothiazines: Increased frequency and severity of neuromuscular excitation and hypotension.

**STORAGE :** Store below 25°C. Protect from moisture.

Keep out of the reach of children.

**PRESENTATION :** One vial packed in a printed carton.




Manufactured by:

**KWALITY PHARMACEUTICALS LTD.**

Nag Kalan, Majitha Road, Amritsar - INDIA



|  |
|--|
| <b>Component : Carton</b>                            |
| <b>Dimension : 35 x 35 x 65 mm</b>                   |
| <b>Colour : CMYK</b>                                 |
| <b>Specification: 320 GSM, ITC Cyber XL</b>          |
| <b>Varnish / coating: Matte Lamination + Spot UV</b> |
| <b>Embossing on brand name</b>                       |

|   |   |  |   |   |
|---|---|--|---|---|
| <p>500mg / Vial</p> <p><b>Thiopental Sodium For Injection USP</b></p> | 1 | <p><b>Thiopental Sodium For Injection USP</b></p> <p>500mg / Vial</p> <p><b>FOR IV USE</b></p> | <p><b>Composition:</b><br/>Each vial contains:<br/>Thiopental Sodium Sterile USP ..... 500mg.<br/>Contains Sodium Carbonate (anhydrous) as a buffer.</p> <p><b>Dosage:</b><br/>As directed by the Physician.</p> <p><b>Storage:</b> Store below 25°C. Protect from moisture.</p> <p><b>Direction for use:</b><br/>Dissolve in 20ml of Sterile Water for Injection for 2.5%(w/v) solution or 10 ml of Sterile Water for Injection for 5%(w/v) solution. Use if the solution is clear.</p> <div style="border: 1px solid black; padding: 2px; width: fit-content;">Warning : May be habit forming.</div> <p>This drug should be administered only by persons qualified in the use of intravenous anesthetics.</p> | <p>Keep out of the reach of children.</p> <div style="border: 1px solid black; padding: 2px; width: fit-content;">Warning: If any foreign Particle is visible after dissolving the contents, Please do not use the solution.</div> <p>The injection should be freshly prepared and used immediately.</p> <p>Mfg. Lic No.: 1804-B</p> <p>Batch : </p> <p>Mfg. : </p> <p>Exp. : </p> <p>Manufactured by:<br/><b>KWALITY PHARMACEUTICALS LTD.</b><br/>Nag Kalan, Majitha Road,<br/>Amritsar - INDIA</p> |
|   | ↓ |  |   |   |

| Check List for Labeling   |             |               |        |                     |                  |                            |        |  |            |          | Formulation No.: |          |  |         |
|---|-------------|---------------|--------|---------------------|------------------|----------------------------|--------|--|------------|----------|------------------|----------|--|---------|
| Expiry Date is 36 months from the Mfg. Date. For eg. Feb/2017 to Jan/2020 |             |               |        |                     |                  |                            |        |  |            |          |                  |          |  |         |
| Work Order No. :  | Version     | Pharmacop.    | Spell. | Compo.              | Batch, Mfg. Exp. | Expiry as per Schedule 'P' | M.R.P. | Mfg. Lic.No./ Neutral Code   | Packing    | Category | Mfg. Name        | Reg. No. | Check Order for strength, Volume & Packing | STORAGE |
| 10722/5   | English     |               |        |                     |                  |                            |        |  |            |          |                  |          |  |         |
| Matching all parameters between Box and Label                             |             |               |        |                     |                  |                            |        |  |            |          |                  |          |  |         |
| Matching the parameter with label of leader brand                         |             |               |        |                     |                  |                            |        |  |            |          |                  |          |  |         |
| Previous specimen artwork : NEW   |             |               |        | Designed by : Chinu |                  |                            |        | Order Quantity   | Party Name |          | Packing          |          |  |         |
| Checked by :  |             | Approved by : |        | Authorized by :     |                  | Party Approval             |        | 7000   | Trust      |          |                  |          |  |         |
| Production Incharge   | QC Incharge | Q.A.          |        | M.D.                |                  |                            |        | Card Board used for carton :   |            |          |                  |          |  |         |
|   |             |               |        |                     |                  |                            |        | <input type="checkbox"/> G/B <input type="checkbox"/> W/B <input type="checkbox"/> I.T.C. <input type="checkbox"/> Pearl |            |          |                  |          |  |         |



|  |
|--|
| <b>Component : Label</b>               |
| <b>Dimension : 67 x 28 mm</b>          |
| <b>Colour : CMYK</b>                   |
| <b>GSM : 60 gsm chromoart</b>          |
| <b>Varnish / coating: U.V. coating</b> |



| Check List for Labeling   |             |               |        |                 |                     |                            |        |  |            |          | Formulation No.: |         |  |         |  |
|---|-------------|---------------|--------|-----------------|---------------------|----------------------------|--------|--|------------|----------|------------------|---------|--|---------|--|
| Expiry Date is 36 months from the Mfg. Date. For eg. Feb/2017 to Jan/2020 |             |               |        |                 |                     |                            |        |  |            |          |                  |         |  |         |  |
| Work Order No. :  | Version     | Pharmacop.    | Spell. | Compo.          | Batch, Mfg. Exp.    | Expiry as per Schedule 'P' | M.R.P. | Mfg. Lic.No./ Neutral Code   | Packing    | Category | Mfg. Name        | Reg.No. | Check Order for strength, Volume & Packing | STORAGE |  |
| 10722/5   | English     |               |        |                 |                     |                            |        |  |            |          |                  |         |  |         |  |
| Matching all parameters between Box and Label                             |             |               |        |                 |                     |                            |        |  |            |          |                  |         |  |         |  |
| Matching the parameter with label of leader brand                         |             |               |        |                 |                     |                            |        |  |            |          |                  |         |  |         |  |
| Previous specimen artwork : NEW   |             |               |        |                 | Designed by : Chinu |                            |        | Order Quantity   | Party Name | Packing  |                  |         |  |         |  |
| Checked by :  |             | Approved by : |        | Authorized by : |                     | Party Approval             |        | 7000   | Trust      |          |                  |         |  |         |  |
| Production Incharge   | QC Incharge | Q.A.          |        | M.D.            |                     |                            |        | Card Board used for carton :   |            |          |                  |         |  |         |  |
|   |             |               |        |                 |                     |                            |        | <input type="checkbox"/> G/B <input type="checkbox"/> W/B <input type="checkbox"/> I.T.C. <input type="checkbox"/> Pearl |            |          |                  |         |  |         |  |

100 x 170 mm

# Thiopental

## Sodium For Injection USP

500mg/Vial

**WARNING : MAY BE HABIT FORMING.**

**Composition:**

Each vial contains:  
Thiopental Sodium Sterile USP ..... 500mg.  
Contains Sodium Carbonate (anhydrous) as a buffer.

**CATEGORY :** Intravenous barbiturate; general anaesthetic.

**GENERAL INFORMATION :** It is a very short acting barbiturate which on I.V. administration quickly induces anaesthesia and hypnosis. It does not cause analgesia. The anaesthesia is induced rapidly, without excitement and pleasantly. It is a weak muscle relaxant, irritation of respiratory passages does not occur. Hypotension occurs after administration but recovery occurs rapidly. Cardiac muscle is not sensitized to adrenaline. Extravasation of thiopentone or inadvertent intra-arterial injection leads to intense pain and necrosis.

**PHARMACOKINETIC :**

After administration it is distributed initially in organs which are highly vascular e.g. Brain. Subsequently the termination of its effect depends upon redistribution of drug from brain to fatty tissues and other tissues.  
Onset of Action : I.V. within 1 minute.  
Duration of Action : 20-30 minutes.

**INDICATIONS :** Anaesthesia of short duration, status epilepticus. Rapid control of convulsions. Infusion of subanaesthetic doses can be used to facilitate verbal communication with psychiatric patients.

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Adults : Inject I.V. (3-5mg/kg) as a 2.5% solution. It produces unconsciousness in 15-30 seconds. Initially, 100 to 500 mg, repeated if necessary after 20 to 30 seconds; maximum dose 2 g.  
Other Features are: Can be given per rectal, may be used to control convulsions, may cause respiratory depressions, may cause hypotension, shows 'slug' effect.

**CONTRAINDICATIONS :** Hypersensitivity, hypotension, status asthmaticus, hepatic dysfunction, Addison's disease, myxoedema, acute intermittent porphyria and severe cardiovascular disease.

**ADVERSE EFFECTS :** Hypotension, hiccups, apnoea for short period, nausea, vomiting. The use of other non-compatible drugs during anaesthesia or in conjunction with anaesthesia can be fatal.

**SPECIAL PRECAUTIONS :** Thiopental should not be mixed with Succinylcholine in the same syringe. Do not use other non-compatible drugs during anaesthesia or in conjunction with anaesthesia.

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**INTERACTIONS :** Narcotics: Those of phenobarbitone required to induce anaesthesia reduced.  
Phenothiazines: Increased frequency and severity of neuromuscular excitation and hypotension.

**STORAGE :** Store below 25°C. Protect from moisture.  
Keep out of the reach of children.

**PRESENTATION :** One vial packed in a printed carton.

Manufactured by:  
**KWALITY PHARMACEUTICALS LTD.**  
Nag Kalan, Majitha Road, Amritsar - INDIA