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 GLYCERYL TRINITRATE 1MG/ML INJ 10ML

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

- **Glyceryl Trinitrate 1mg/mL Injection 10mL**

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 **04 December 2025**.

Table 1: Provincial estimates

Province	Six Months Estimate	Actual Uptake
Correctional Services	0	0
EC-MT	120	0
EC-PE	0	
FS	1260	40
GP	6000	5350
KZN	5000	5000
LP	0	0
MP	110	110
NC	600	600
NW	332	400
SAMHS	0	0
WC	7000	1060
Total	**20 422**	**12 560**

Yours sincerely

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

S2100004444

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

Section 21 Outcome Letter

2025-06-04

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 **2025-06-03** 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: 397

E. UNREGISTERED MEDICINES: GENERIC NAME: No Data

F. TRADE NAME: Nitroswiss

G. QUANTITY: 7940 Packs

SAHPRA
South African
Health Products
Regulatory Authority

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

H. LETTER NUMBER: S2100004444

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

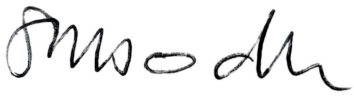
A progress report must be submitted once treatment is completed or on a reauthorization request

Comments:

Yours faithfully,

Dr S Munbodh

Manager: Section 21 Category A Medicines



T Sehloho

Senior Manager: Clinical Evaluations Management

S2100004444

SAHPRA Head Office
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health
Department:
Health
REPUBLIC OF SOUTH AFRICA

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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	**S21RFQ132**
QUOTE ENQUIRY DATE	**07/11/2023**	QUOTE CLOSING DATE			**16/11/2023**
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	**GLYCERYL TRINITRATE 1MG/ML INJECTION 10ML**		
TRADE DESCRIPTION	Nitroswiss (Nitroglycerine) Injection USP 1mg/ml (1 x 10ml)		
UNIT OF MEASURE	**1's**	PACK or BOX (*SIZE/ QUANTITY*)	**1's**
QUANTITY REQUIRED	**20500 Vials**		

TO BE COMPLETED BY THE SUPPLIER/ SERVICE PROVIDER

SUPPLIER CONTACT DETAILS (as per CSD)

COMPANY NAME	Equity Pharmaceuticals (Pty) Ltd			
SUPPLIER NUMBER	MAAA0007480			
SECURITY CODE				
SUPPLIER CODE (NDoH)				
CONTACT PERSON 1	NAME	**Ehrard van Zyl**		
	PHONE	**0123451747**	FAX	**0123451412**
	MOBILE	*0720408511*		
	E-MAIL	**ehrard@equitypharma.co.za**		
CONTACT PERSON 2	NAME	**Jaco Schoeman**		
	PHONE	**0123451747**		

	MOBILE	*0767340080*
	E-MAIL	**jacos@equitypharma.co.za**

QUOTE DETAILS			
PRICE PER UNIT (INCL. VAT)	R 35.47	TOTAL PRICE (INCL. DELIVERY & VAT)	R 727 135.00
VOLUMES AVAILABLE – 14DAYS			
VOLUMES AVAILABLE – 28DAYS			
VOLUMES AVAILABLE – 56DAYS			
VOLUMES AVAILABLE – 112DAYS	20 500		
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	**16/11/2023**

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** must be submitted in two decimals. Failure to do so will result in NDoH determining their own final price.
- 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.
- **Only** quotations should be sent to Section21Quotes@health.gov.za. All other queries to be directed to Buhle.Mbongo@health.gov.za
- Any quotation sent to Buhle.Mbongo@health.gov.za will not be considered.

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

EQUITY
PHARMACEUTICALS

16/11/2023

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 # 20231116

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
	Nitroswiss (Nitroglycerine) Injection USP 1mg/1ml	1 x 10ml	1	R 30.85	R 35.47
			20 500	**R 632 425.00**	**R 727 135.00**
			20 500	**R 632 425.00**	**R 727 135.00**

Valid for 180 days

Employee Signature: _____

Date: 16/11/2023

Approved by: Ehrard van Zyl / Carel Bouwe

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

16/11/2023

National Department of Health

Directorate: Affordable Medicines

E-mail: Section21Quotes@health.gov.za

Attention: Ms Buhle Mbongo

Dear Ms Mbongo

Re: Request for quotation – Glyceroltrinitrate 1mg/ml – Section 21 Supply

Trust you are well. Please find below our quotation for *Glycerol Trinitrate 1mg/ml* supplied under section 21 terms.

- Quantity: **20 500 vials**
- Delivery Time (Weeks): **12 weeks**
- Price (Vat Inclusive): **R 35.47 incl. vat per pack of 10 vials**
- Generic Name: **Nitroglycerin (Glycerol Trinitrate)**
- Trade Name: **Nitroswiss Injection USP 1mg/ml**
- Packaging: **1 x 10ml**
- Specifications: **1mg/ml**
- Shelf Life: **24 months**
- Package Insert: **Attached**
- Manufacturer: **Swiss Parenterals Ltd.**
- 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

NITROSWISS

Prescription Only Medicine

Nitroglycerin Injection USP
1 mg/ml, 10 ml
(Glyceryl Trinitrate)

NITROSWISS

For IV Infusion only

SWISS™

10 x 10 ml Ampoule

NITROSWISS

Composition :
Each ml contains :
Diluted Nitroglycerin USP (10%)
Equivalent to Nitroglycerin.....1 mg
Ethanol BP .....30 % v/v
Propylene Glycol BP .....30 % v/v
Water for Injections BP.....q.s.

Dosage : As directed by the physician.

Not for direct IV Injection, Must be diluted before use.

Discard unused portion.

Storage : Store below 30°C. Protect from light.

KEEP OUT OF REACH OF CHILDREN.

For more information, refer package insert.

Batch No. :

Mfg. Date :

Exp. Date :

Manufactured by:
SWISS PARENTERALS LTD.
808, 809 & 810,
Kerala Industrial Estate,
GIDC, Nr. Bavla,
Dist.: Ahmedabad-382 220,
Gujarat, INDIA.

NITROSWISS

218.20.110

NITROSWISS

PANTONE 1525 C
PANTONE 721 C
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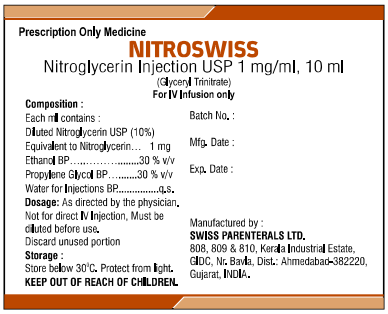

Actual size

Prescription Only Medicine

NITROSWISS

Nitroglycerin Injection USP 1 mg/ml, 10 ml

(Glyceryl Trinitrate)

For IV Infusion only

Composition :
Each ml contains :
Diluted Nitroglycerin USP (10%)
Equivalent to Nitroglycerin… 1 mg
Ethanol BP……30 % v/v
Propylene Glycol BP……30 % v/v
Water for Injections BP……q.s.
Dosage: As directed by the physician.
Not for direct IV Injection, Must be diluted before use.
Discard unused portion
Storage :
Store below 30°C. Protect from light.
KEEP OUT OF REACH OF CHILDREN.

Batch No. :

Mfg. Date :

Exp. Date :

Manufactured by :
SWISS PARENTERALS LTD.
808, 809 & 810, Kerala Industrial Estate,
GIDC, Nr. Bavla, Dist.: Ahmedabad-382220,
Gujarat, INDIA.

Enlarge size

PANTONE 1525 C

PANTONE 721 C

BLACK

Prescription Only Medicine

NITROSWISS

(NITROGLYCERIN INJECTION USP 1 MG/ML, 10 ML)
(Glyceryl Trinitrate)
(For IV Infusion only)

COMPOSITION :
Each ml contains :
Diluted Nitroglycerin USP (10%)
Equivalent to Nitroglycerin…….....1 mg
Ethanol BP……..…30 % v/v
Propylene Glycol BP……..... 30 % v/v
Water for Injections BP.....q.s.

Therapeutic classification : Vasodilators used in cardiac diseases.

PHARMACOLOGY :
Pharmacodynamics Properties :
ATC code : C01DA02
Nitroglycerin exerts a spasmolytic action on smooth muscle, particularly in the vascular system. This action is more marked on the venous capacitance vessels than the arterial vessels; the predominant increase in venous capacitance results in marked diminution of both the left ventricular filling pressure and volume (preload). The moderate dilation of the arteriolar resistance vessels results in a reduction in afterload. These haemodynamic changes (reductions) in preload and afterload lower the myocardial oxygen demand. In addition, by direct action and through the reduction of myocardial wall tension Nitroglycerin also lowers the resistance to flow in the coronary collateral channels and allows re-distribution of blood flow to ischaemic areas of the myocardium. Administration of Nitroglycerin by intravenous infusion to patients with congestive heart failure results in a marked improvement in haemodynamics, reduction of elevated left ventricular filling pressure and systolic wall tension, and an increase in the depressed cardiac output. It reduces the imbalance that exists between myocardial oxygen demand and delivery, thereby diminishing myocardial ischaemia and controlling ischaemia-induced ventricular arrhythmias. Nitroglycerin relaxes smooth muscles cells in other organs to some extent. The cellular molecular mechanism of action is a synthesis of nitric oxide and cyclic guanosyl monophosphate which acts as a mediator for muscle relaxation.

Pharmacokinetic properties : After intravenous administration, Nitroglycerin is widely distributed in the body with an estimated apparent volume of distribution of approximately 200 litres. It is strongly bound to erythrocytes and vessel walls; the plasma protein binding is approx. 60%. The therapeutic plasma concentration range is 0.1 to 3 ng/ml (up to 5 ng/ml). Nitroglycerin is rapidly metabolised to dinitrate and mononitrate and further metabolised by glucuronidation in the liver, showing a marked first-pass effect. Spontaneous hydrolysis occurs in plasma. The estimated plasma half-life of Nitroglycerin is 1 to 4 minutes. The rapid disappearance from plasma is consistent with the high systemic clearance values (up to 3270 litres per hour). The less active metabolites resulting from biotransformation can be recovered from the urine within 24 hours.

INDICATIONS AND USAGE :
The following indications exist for Nitroglycerin :
- Unresponsive congestive heart failure, including that secondary to acute myocardial infarction; acute left-sided heart failure and acute myocardial infarction.
- Refractory unstable angina pectoris and coronary insufficiency, including Prinzmetal's angina.
- Control of hypertensive episodes and/or myocardial ischaemia during and after cardiac surgery.
- Induction of controlled hypotension for surgery.

POSOLOGY AND METHOD OF ADMINISTRATION :
Posology : For intravenous use. Nitroglycerin should be administered by means of a micro-drip set infusion pump or similar device which permits maintenance of constant infusion rate.
Adults : The dose of Nitroglycerin should be adjusted to meet the individual needs of the patient.
The recommended dosage range is 10 - 200 mcg/min but up to 400 mcg/min may be necessary during some surgical procedures.
Paediatric population : The safety and efficacy of Nitroglycerin has not yet been established in children.
Elderly population : There is no evidence that a posology adjustment is required in the elderly.

Use in surgery
A starting dose of 25 mcg/min is recommended for the control of hypertension, or to produce hypotension during surgery. This may be increased by increments of 25 mcg/min at 5 minute intervals until the blood pressure is stabilised. Doses between 10 - 200 mcg/min are usually sufficient during surgery, although doses of up to 400 mcg/min have been required in some cases.
Myocardial ischaemia
The treatment of perioperative myocardial ischaemia may be started with a dose of 15 - 20 mcg/min, with subsequent increments of 10 - 15 mcg/min until the required effect is obtained.

Unresponsive congestive heart failure : The recommended starting dose is 20 - 25 mcg/min. This may be decreased to 10 mcg/min, or increased in steps of 20-25 mcg/min every 15 - 30 minutes until the desired effect is obtained.
Unstable angina : An initial dose of 10 mcg/min is recommended with increments of 10 mcg/min being made at approximately 30 minute intervals according to the needs of the patient.
Method of administration
Nitroglycerin can be administered undiluted by slow intravenous infusion using a syringe pump incorporating a glass or rigid plastic syringe. Alternatively, Nitroglycerin may be administered intravenously as an admixture using a suitable vehicle such as Sodium Chloride Injection B.P. or Dextrose Injection B.P. In case of dilution, Nitroglycerin must be mixed under aseptic conditions immediately after opening. Prepared admixtures should be given by intravenous infusion or with the aid of a syringe pump to ensure a constant rate of infusion. During Nitroglycerin administration there should be close haemodynamic monitoring of the patient. The posology of Nitroglycerin i.v. should be adjusted to achieve the desired clinical response. Additional dose adjustments in patients with severe hepatic insufficiency or severe renal failure may be necessary and require additional monitoring.

CONTRAINDICATIONS : Nitroglycerin should not be used in the following cases :
- Hypersensitivity to the active substance, other nitrates or any of the excipients
- Acute circulatory failure (shock, collapse)
- Cardiogenic shock (unless a sufficient end-diastolic pressure is maintained by appropriate measures)
- Severe anaemia
- Severe cerebral haemorrhage
- Head trauma
- Uncorrected hypovolaemia and hypotensive shock
- Arterial hypoxaemia and angina caused by hypertrophic obstructive cardiomyopathy
- Constrictive pericarditis
- Pericardial tamponade
- Toxic pulmonary oedema
- During nitrate therapy, phosphodiesterase inhibitors type 5 (PDE5) (e. g. sildenafil, vardenafil, tadalafil) must not be used because PDE5 inhibitors may amplify the vasodilatory effects of Nitroglycerin resulting in severe hypotension.
- Conditions associated with an increased intracranial pressure.
- Myocardial insufficiency due to obstruction, aortic or mitral stenosis, hypertrophic obstructive cardiomyopathy or constrictive pericarditis.

WARNINGS : Caution should be exercised in patients with severe liver or renal disease, hypothermia and hypothyroidism.
Nitroglycerin should not be given by bolus injection.
Nitroglycerin must be used only with particular caution and under medical supervision in :
- Low filling pressures e.g. in acute myocardial infarction, impaired left ventricular function (left ventricular failure). Reducing systolic blood-pressure below 90 mmHg must be avoided.
- Orthostatic dysfunction

The development of tolerance and cross tolerance to other nitro compounds has been described. Nitroglycerin must not be used in patients known to be taking phosphodiesterase inhibitor-containing products (e. g. sildenafil, vardenafil, tadalafil). Patients who receive Nitroglycerin solution therapy must be warned not to take phosphodiesterase inhibitor-containing products (e. g. sildenafil, vardenafil, tadalafil).

Hypoxaemia : Caution should be exercised in patients with arterial hypoxaemia due to severe anaemia (including G6PD deficiency induced forms), because in such patients the biotransformation of nitroglycerin is reduced. Similarly, caution is called for in patients with hypoxaemia and ventilation/perfusion imbalance due to lung disease or ischaemic heart failure. Patients with angina pectoris, myocardial infarction, or cerebral ischaemia frequently suffer from abnormalities of the small airways (especially alveolar hypoxia). Under these circumstances vasoconstriction occurs within the lung to shift perfusion from areas of alveolar hypoxia to better ventilated regions of the lung. As a potent vasodilator, nitroglycerin could reverse this protective vasoconstriction and thus result in increased perfusion of poorly ventilated areas, worsening of the ventilation/perfusion imbalance, and a further decrease in the arterial partial pressure of oxygen.

Methaemoglobinaemia : Following treatment with Nitroglycerin, methaemoglobinaemia has been reported. Treatment of methaemoglobinaemia with methylene blue is contraindicated in patients with glucose-6-phosphate deficiency or methaemoglobin-reductase deficiency.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION : Concomitant treatment with other vasodilators, calcium antagonists, ACE inhibitors, beta-blockers, diuretics, antihypertensives, tricyclic antidepressants and neuroleptics, as well as the consumption of alcohol, may potentiate the hypotensive effect of the preparation. The blood pressure lowering effect of Nitroglycerin will be increased if used together with phosphodiesterase inhibitors (e.g. sildenafil, vardenafil, tadalafil) which are used for erectile dysfunction. This might lead to life threatening cardiovascular complications. Patients who are on nitrate therapy must not use phosphodiesterase inhibitors (e.g. sildenafil, vardenafil, tadalafil). Simultaneous intravenous infusions of tissue plasminogen activator (tPA) and Nitroglycerin may accelerate plasma clearance of tPA by increasing hepatic blood flow. Reports suggest that, when administered concomitantly, Nitroglycerin may increase the blood level of dihydroergotamine and its effect. This warrants special attention in patients with coronary artery disease, because dihydroergotamine antagonises the effect of Nitroglycerin and may lead to coronary vasoconstriction. The use of heparin and Nitroglycerin solution can lead to a partial loss of action of heparin when both drugs are given simultaneously by intravenous route. Concurrent administration of Nitroglycerin with acetyl salicylic acid may potentiate the blood pressure lowering effects of Nitroglycerin. The non-steroidal anti-inflammatory drugs except acetyl salicylic acid may diminish the therapeutic response of Nitroglycerin. Sapropterine (Tetrahydrobiopterine, BH4) is a cofactor for nitric oxide synthetase. Caution is recommended during concomitant use of sapropterine-containing medicine with all agents that cause vasodilation by affecting nitric oxide (NO) metabolism or action, including classical NO donors (e.g. Nitroglycerin (GTN), isosorbide dinitrate (ISDN), isosorbide 5-mononitrate (5-ISMN) and others).

FERTILITY, PREGNANCY AND LACTATION :
Fertility
Reproduction toxicity studies performed in rats and rabbits using various routes of administration did not reveal any effect on mating, fertility and general reproductive parameters. There is no data available on the effect of Nitroglycerin on fertility in humans.
Pregnancy
Developmental toxicity studies performed in rats and rabbits using various routes of administration did not reveal any effect on the embryos, fetuses or the young animals even at toxic doses for the dam.
Lactation
Available evidence is inconclusive or inadequate for determining infant risk when used during breastfeeding. There is data that nitrates are excreted in breast milk and may cause methaemoglobinaemia in infants. The extent of excretion of nitroglycerin in human breast milk has not been determined. A risk to the suckling child cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Nitroglycerin therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES : Nitroglycerin may affect the patient's reactivity to an extent that her/his ability to drive or to operate machinery is impaired. This effect is increased in combination with alcohol.

UNDESIRABLE EFFECTS :
Undesirable effects frequencies are defined as: very common (≥1/10), common (≥1/100 <1/10), uncommon (≥1/1,000 <1/100), rare (≥1/10,000 <1/1,000) or very rare (<1/10,000), not known (cannot be estimated from the available data).
During administration of Nitroglycerin the following undesirable effects may be observed :

Nervous system disorders :	Very Common: Common :	Headache Dizziness (including dizziness postural), somnolence
Cardiac disorders :	Common : Uncommon : Not known :	Tachycardia Enhanced angina pectoris symptoms Palpitations
Vascular disorders :	Common : Uncommon : Not known :	Orthostatic Hypotension Circulatory collapse (sometimes accompanied by bradyarrhythmia and syncope) Flushing, Hypotension
Gastrointestinal disorders :	Uncommon : Very rare :	Nausea, Vomiting Heartburn
Skin and subcutaneous tissue disorders :	Uncommon : Not known :	Allergic skin reactions (e.g. rash,) Allergic contact dermatitis. Dermatitis exfoliative, Rash Generalized.
General disorders and administration site conditions :	Common : Uncommon :	asthenia Pruritus, burning, erythema and irritation.
Investigations	Not known :	Heart rate increase

Severe hypotensive responses have been reported for organic nitrates and include nausea, vomiting, restlessness, pallor, and excessive perspiration. During treatment with Nitroglycerin, a temporary hypoxemia may occur due to a relative redistribution of the blood flow in hypoventilated alveolar areas. Particularly in patients with coronary artery disease this may lead to a myocardial hypoxia.

OVERDOSE :
Symptoms of overdose
Symptoms could include the following :
- Fall in blood pressure ≤ 90 mmHg
- Pallor
- Sweating
- Weak pulse
- Reflex tachycardia
- Collapse
- Syncope
- Dizziness postural
- Headache
- Asthenia
- Dizziness
- Nausea
- Vomiting
- Diarrhoea
- Methaemoglobinaemia has been reported in patients receiving other organic nitrates. During Nitroglycerin biotransformation nitrite ions are released, which may induce methaemoglobinaemia and cyanosis with subsequent tachypnoea, anxiety, loss of consciousness and cardiac arrest. It cannot be excluded that an overdose of Nitroglycerin may cause this adverse reaction.
- In very high doses the intracranial pressure may be increased. This might lead to cerebral symptoms.

Treatment of overdose
General procedure :
- Stop delivery of the drug.
- General procedures in the event of nitrate-related hypotension :
- Patient should be kept horizontal with the head lowered and legs raised or, if necessary, compression bandaging of the patient's legs
- Supply oxygen
- Expand plasma volume
- For specific shock treatment admit patient to intensive care unit

Special procedure :
- Raising the blood pressure if the blood pressure is very low.
- Treatment of methaemoglobinaemia:

Treatment with intravenous methylene blue
- Initially 1 to 2 mg/kg, not exceeding 4 mg/kg of a 1% solution over 5 minutes.
- Repeat dose in 60 minutes if there is no response.
- Administer oxygen (if necessary)
- Initiate artificial ventilation

Treatment of methaemoglobinaemia with methylene blue is contraindicated in patients with glucose-6-phosphate dehydrogenase (G-6-PD) deficiency or methaemaglobin reductase deficiency.
Where treatment with methylene blue is contraindicated or is not effective, exchange transfusion and / or transfusion of packed red blood cells is recommended.

Resuscitation measures :
In case of signs of respiratory and circulatory arrest, initiate resuscitation measures immediately.

SHELF-LIFE :
24 months

STORAGE CONDITION :
Store below 30°C. Protect from light.

KEEP OUT OF REACH OF CHILDREN.

DOSAGE FORM AND PACK STYLE AVAILABLE :

Dosage Form :
Solution for Infusion

10 × 10 ml amber glass ampoules packed in a carton along with plastic tray & insert.

Manufactured by :
SWISS PARENTERALS LTD.
Ahmedabad, Gujarat, India.

TSPL-PATR/05/ANS/*-01