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 MJ Meakings
GEN-EYE (Pty) Ltd
PO Box 7408
Halfway House
1685
Midrand

Dear Mr Meakings

Section 21 Extension Authorization for IMMUNOGLOBULIN HUMAN TETANUS 250IU/ML INJ 1ML

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

- **Immunoglobulin Human Tetanus 250IU/mL INJ 1mL (pre-filled syringe)**

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 **30 January 2027**.

Table 1: Provincial estimates

Province	Six Months Estimate	Actual Uptake
Correctional Services	0	0
EC-MT	180	0
EC-PE	300	300
FS	0	0
GP	60	0
KZN	200	200
LP	140	140
MP	125	125
NC	12	12
NW	24	0
SAMHS	0	0
WC	24	0
Total	**1 065**	**777**

Yours sincerely

K Jamaloodien

KHADIJA JAMALOODIEN
CHIEF DIRECTOR: HEALTH PRODUCTS PROCUREMENT
DATE: 9/7/2026

S2100032868

SAHPRA
South African
Health Products
Regulatory Authority

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

Section 21 Outcome Letter

2026-07-08

Ms Khadija Jamaloodien

National Department Of Health

Pretoria

buhle.mbongo@health.gov.za

Dear Ms Khadija Jamaloodien

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 **2026-07-03** refers

A. STATUS: Approved

B. APPLICANT: Ms Khadija Jamaloodien

C. IMPORTING COMPANY: Gen-Eye (Pty) Ltd

D. NUMBER OF PATIENT/(S) INTENDED TO BE TREATED: 100

E. UNREGISTERED MEDICINES: GENERIC NAME: No Data

F. TRADE NAME: Human Tetanus Immunoglobilun 250 IU

G. QUANTITY: 300 Packs (1)

SAHPRA
South African
Health Products
Regulatory Authority

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

H. LETTER NUMBER: S2100032868

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

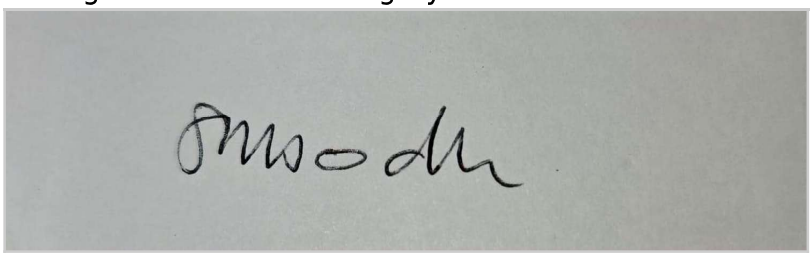
A progress report must be submitted once treatment is completed or on a reauthorization request

Comments:

Yours faithfully,

Dr Shyamli Munbodh

Manager: Section 21 Category A Medicines



Ms Mahlodi Moropa

Final Approver

S2100032868

SAHPRA
South African
Health Products
Regulatory Authority

SAHPRA Head Office
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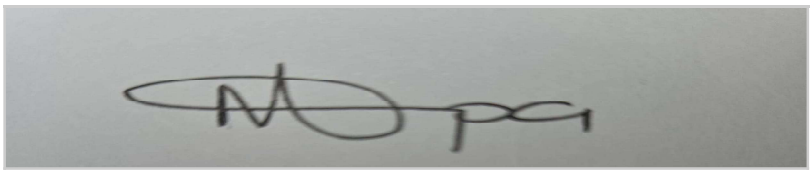

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REQUEST FOR QUOTATION FORM

- 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	S21RFQ165
QUOTE ENQUIRY DATE	07/11/2025	QUOTE CLOSING DATE			18/11/2025
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	HUMAN TETANUS IMMUNOGLOBULIN 125IU/ML INJ		
TRADE DESCRIPTION			
UNIT OF MEASURE	1 vial	PACK or BOX (*SIZE/ QUANTITY*)	1 vial
QUANTITY REQUIRED	1000 vials		

TO BE COMPLETED BY THE SUPPLIER/ SERVICE PROVIDER

SUPPLIER CONTACT DETAILS (as per CSD)

COMPANY NAME	GEN-EYE (PTY) LTD.			
SUPPLIER NUMBER	MAAA1136844			
SECURITY CODE	VPVQ5 (SUPPLIER CODE - NDOH)			
SUPPLIER CODE (NDoH)	VPVQ5			
CONTACT PERSON 1	NAME	CUMI PRETORIUS		
	PHONE	011 312 3812	FAX	N/A
	MOBILE	082 447 5037		
	E-MAIL	cumip@gen-eye.co.za		
CONTACT PERSON 2	NAME	Renard Prinsloo		
	PHONE	011 312 3812		

	MOBILE	076 538 0491
	E-MAIL	renardp@gen-eye.co.za

QUOTE DETAILS

PRICE PER VIAL (INCL. VAT)	R598	TOTAL PRICE (INCL. DELIVERY & VAT)	R598 000
*STOCK'S EXPIRY DATE(SHELF-LIFE)	5 February 2028		
VOLUMES AVAILABLE – 7DAYS			
VOLUMES AVAILABLE – 14DAYS			
VOLUMES AVAILABLE – 21DAYS	1000 units		
VOLUMES AVAILABLE – 28DAYS			
VOLUMES AVAILABLE – 35DAYS			
VOLUMES AVAILABLE - 42DAYS			
VOLUMES AVAILABLE – 49DAYS			
VOLUMES AVAILABLE – 56DAYS			
VOLUMES AVAILABLE – 112DAYS			
QUOTE VALIDITY PERIOD			
NORMAL LEAD/DELIVERY TIME	21 Days		

DEVIATION TO SPECIFICATION

COMMENTS: N/A

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	Cumi Pretorius
CAPACITY	Head of Sales
SIGNATURE *(OF A DULY AUTHORISED REPRESENTATIVE OF THE SUPPLIER)*	
DATE	18/11/2025

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), updated for the current month ✓
- 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 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 supplier submitting the quotation must be the same entity with which the provinces will place their orders.
- 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 form.
- The confirmation letter from manufacturer to supply South Africa with Bivalent Oral Poliomyelitis Vaccine (bOPV) must be provided (only *in cases of a Bivalent Oral Poliomyelitis Vaccine RFQ*).
- Kindly be advised that a picture format of an Artwork shall not be accepted. Artwork must be in a pdf or word format only.
- All prices must please be submitted in two decimals and in ZAR.
- 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 required documentation shall not be considered.
- Any submission with blurry required documents shall not be considered.
- The only electronic GMP Certificate considered is that from EUDRA.
- CSD must be updated for the current month of the RFQ date.
- **Email subject line for responses with quotes must be kept unchanged from the originally sent RFQ email.**

SUBMIT BOTH COMPLETED RFQ FORM AND QUOTATION (ON AN OFFICIAL COMPANY LETTERHEAD)

Royal Palm Business Estate
Unit 7, 646 Washington Street
Halfway house, Midrand 1685
PO Box 7408
Halfway House 1685
South Africa
Telephone: +27 11 312 3812
Fax: +27 11 312 7814
www.gen-eye.co.za

22/01/2026

ATT: NDOH

RE: Section 21 Tetagam P

Human Tetanus Immunoglobulin 125IU/ML INJ. X1000 units

We hereby have the pleasure of submitting the following quotation to you.

Property Name	Description	Pack size	Unit Price Excl VAT	Unit Price Incl VAT	Total Price Excl VAT	Total Price Incl VAT
Tetagam P	Human Tetanus Immunoglobulin	1 vial	R520.00	R598.00	R520 000.00	R598 000.00

Please note: this quotation is valid for 120 days.

Delivery period: 4-6 weeks from date that order is received

I hope you may find this in order.

Yours sincerely

Renard Prinsloo

Head of Marketing – Gen-Eye

renardp@gen-eye.co.za

076 538 0491

CSL Behring

PACKAGE INSERT

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Tetagam® P

Solution for injection for intramuscular use

Active Ingredient:
Human tetanus immunoglobulin

PHARMACOTHERAPEUTIC GROUP

Immune sera and immunoglobulins, human tetanus immunoglobulin, ATC-code: J06B B02

THERAPEUTIC INDICATIONS

Postexposure prophylaxis
Immediate prophylaxis after tetanus prone injuries in patients
- not adequately vaccinated
- whose immunisation status is not known with certainty
- with severe deficiency in antibody production

Therapy of clinically manifest tetanus
Tetanus immunoglobulin should always be administered in conjunction with an active tetanus vaccination unless there are contraindications or confirmation of adequate vaccination.

WHO guidelines and other official guidance regarding the use of human tetanus immunoglobulin for intramuscular use should be observed.

CONTRAINDICATIONS

Known hypersensitivity to any of the components of the product.
Known hypersensitivity to human immunoglobulins.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Do not inject intravascularly! Ensure that Tetagam P is not administered into a blood vessel because of the risk of shock.
True hypersensitivity reactions are rare. Tetagam P contains a small quantity of IgA. Individuals who are deficient in IgA have the potential for developing IgA antibodies and may have anaphylactic reactions after administration of blood components containing IgA. The physician must therefore weigh the benefit of treatment with Tetagam P against the potential risks of hypersensitivity reactions.
Rarely human tetanus immunoglobulin can induce a fall in blood pressure with anaphylactic reactions, even in patients who had tolerated previous treatment with normal human immunoglobulin.
Therapeutic measures depend on the nature and severity of the event.
The current medical standards for shock treatment are to be observed.
Patients should be observed for at least 20 minutes after administration of Tetagam P.
Particularly in cases of inadvertent i.v. injection, patients should be observed for longer term (at least 1 hour) after administration.

Important information about some of the ingredients of Tetagam P
This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially "sodium free".

Virus safety
Standard measures to prevent infections resulting from the use of medicinal products prepared from human blood or plasma include selection of donors, screening of individual donations and plasma pools for specific markers of infection and the inclusion of effective manufacturing steps for the inactivation/ removal of viruses. Despite this, when medicinal products prepared from human blood or plasma are administered, the possibility of transmitting infective agents cannot be totally excluded. This also applies to unknown or emerging viruses and other pathogens.

The measures taken are considered effective for enveloped viruses such as HIV, HBV and HCV, and for the non-enveloped viruses HAV and parvovirus B19.
There is reassuring clinical experience regarding the lack of hepatitis A or parvovirus B19 transmission with immunoglobulins and it is also assumed that the antibody content makes an important contribution to the viral safety.
It is strongly recommended that every time that Tetagam P is administered to a patient, the name and batch number of the product are recorded in order to maintain a link between the patient and the batch of the product.

Pregnancy and lactation
The safety of Tetagam P for use in human pregnancy has not been established in controlled clinical trials. Long lasting clinical experience with immunoglobulins does indicate that no harmful effects on the course of pregnancy, on the foetus or the neonate are to be expected.

Effects on ability to drive and use machines
No effects on ability to drive and use machines have been observed.

INTERACTIONS WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTIONS

Vaccinations with live attenuated virus vaccines
Immunoglobulin administration may impair the efficacy of live attenuated virus vaccines such as measles, rubella, mumps and varicella vaccines for a period of up to three months.
After administration of Tetagam P an interval of at least three months should elapse before vaccination with live attenuated virus vaccines. In the case of measles, this impairment may persist for up to five months. Therefore, patients receiving measles vaccine should have their antibody status checked.

Interference with serological testing
It has to be considered that when serological test results are interpreted, the transitory rise of passively transferred antibodies after immunoglobulin injection may result in misleading positive test results.
Passive transmission of antibodies to erythrocyte antigens, e.g., A, B and D may interfere with some serological tests for red cell allo-antibodies (e.g. Coombs test).

Incompatibilities
In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products, diluents or solvents.

POSOLOGY AND METHOD OF ADMINISTRATION

Children and adults are to receive the same dose.

Posology
Prophylaxis of tetanus prone wounds
250 IU unless the risk is thought to be extremely high.
The dose may be increased to 500 IU in case of:
- infected wounds where surgically appropriate treatment cannot be achieved within 24 hours
- deep or contaminated wounds with tissue damage and reduced oxygen supply, as well as foreign-body injury (e.g., bites, stings or shots)
- burns, congelations
- tissue necrosis
- septicaemic abortion
- adults weighing more than the average.

In case of extensive burns it is advisable to administer a second injection of 250 IU Tetagam P after the exsudative phase of the burn has subsided (about 36 hours after onset of the burn).

Therapy of clinically manifest tetanus
Single doses of 3,000 to 6,000 IU (in combination with other appropriate clinical procedures). Regarding frequency, interval of injection and duration of therapy repeated doses depend on the clinical picture.

Method of administration
Tetagam P should be administered via the intramuscular route.
Do not use solutions which are cloudy or contain residues (deposits/particles).
Tetagam P is a ready for use solution and should be administered at body temperature.
If comparatively large total volumes are required, it is advisable to administer them in divided doses at different sites. This applies in the case of doses above 2 ml for children up to 20 kg bw and doses above 5 ml for persons above 20 kg bw.
In case of simultaneous vaccination the immunoglobulin and the vaccine should be administered at contralateral sites of the body.
In the presence of a severe coagulation disorder, in the case of which intramuscular injections are contraindicated, Tetagam P may be given subcutaneously (under the skin) for prophylaxis. Afterwards the injection site should be compressed with a swab. However, it should be noted that there are no clinical efficacy data to support administration by the subcutaneous route.
For acute therapy, if intramuscular administration is not clinically appropriate, an alternative intravenous product may be used.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

UNDESIRABLE EFFECTS

If you experience reactions which are not mentioned in this package insert, please inform your doctor or pharmacist.

In rare cases (≥ 1/10,000 and < 1/1,000) the following adverse reactions may occur:
- ***Immune system disorders***
  Allergic reactions including fall in blood pressure, dyspnoea, cutaneous reactions, in isolated cases reaching as far as anaphylactic shock, even when the patient has shown no hypersensitivity to previous administration of immunoglobulins.
- ***Generalized reactions***
  Chills, fever, headache, malaise, nausea, vomiting, arthralgia and moderate back pain.
- ***Heart and vascular disorders***
  Cardiovascular reactions particularly if the product is inadvertently injected intravascularly.
- ***Local reactions at the injection site***
  Local pain, tenderness or swelling.

For safety with respect to transmissible agents, see section "Special warnings and precautions for use" subsection "Virus safety".

Reporting of side effects
If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

STORAGE AND STABILITY

Tetagam P is to be stored at +2 °C to +8 °C (refrigerator). Do not freeze!
Keep container in the outer carton in order to protect its contents from light.
Tetagam P must not be used after the expiry date given on the pack and container.
Once the container has been opened the contents have to be used immediately.
Keep out of the reach and sight of children!
Any unused product or waste material should be disposed of in accordance with local requirements.

QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

Active ingredients

Human protein		100 – 170 mg
thereof immunoglobulin	at least	95 %
with antibodies to tetanus toxin	at least	250 IU

Other ingredients
Aminoacetic acid (glycine), sodium chloride, HCl or NaOH (in small amounts for pH adjustment), water for injections

PHARMACEUTICAL FORM AND PRESENTATIONS

Pharmaceutical form
Solution for injection for intramuscular use.
Tetagam P is a clear solution. The colour can vary from colourless to pale-yellow up to light brown during shelf life.

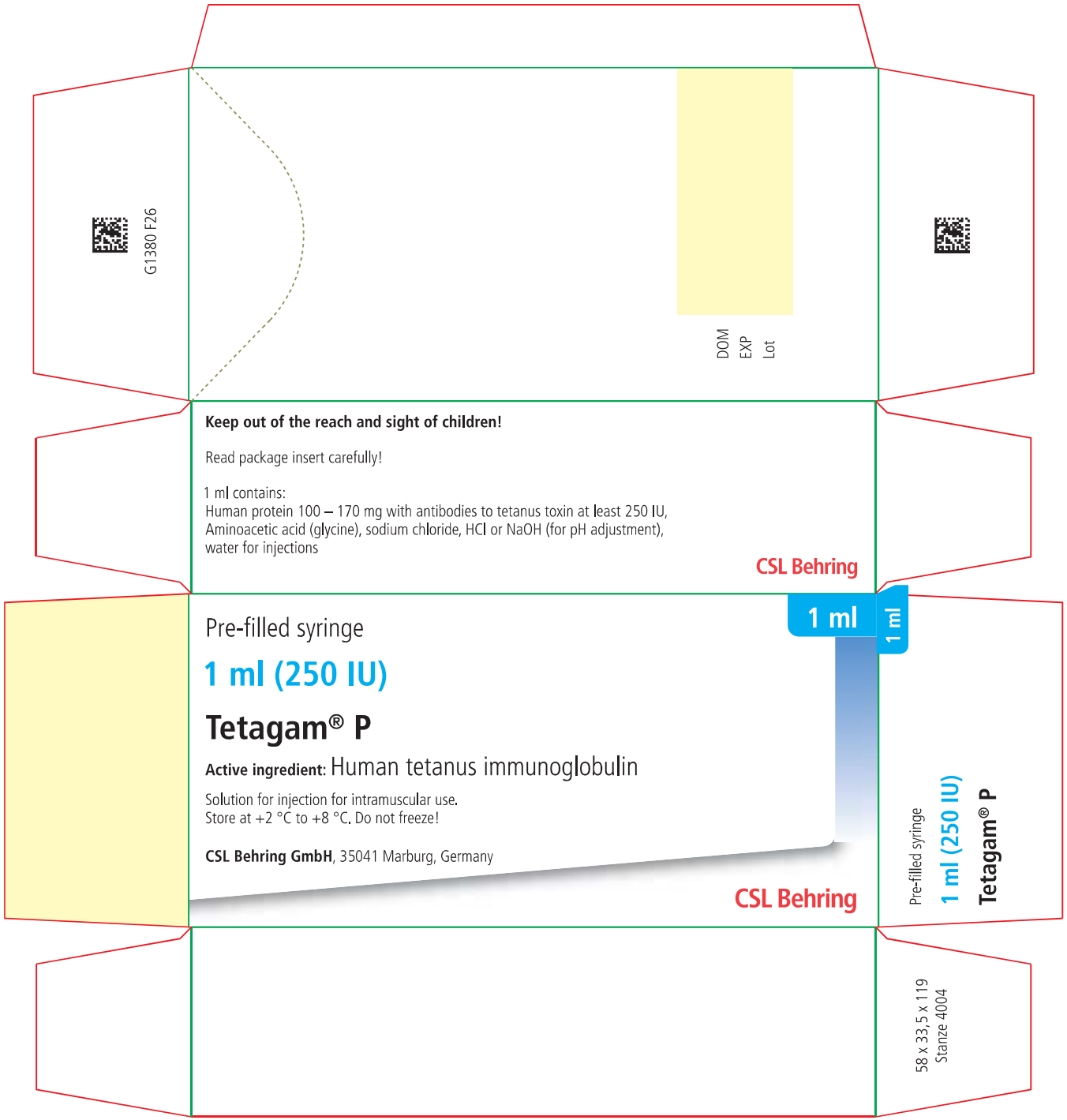
Presentations
Pack with 1 prefilled syringe with 1 ml
Pack with 10 prefilled syringes with 1 ml
Pack with 1 prefilled syringe with 2 ml
Not all pack sizes may be marketed.

NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

CSL Behring GmbH
Emil-von-Behring-Str. 76
35041 Marburg
Germany

DATE OF LAST REVISION

November 2014



58x33,5x119 mm (4004)

- black
- 279
- 185
- cyan
- Varnish free area indication only - not to be printed. (Lackaussparung – wird nicht in Druck übernommen)

etG2554_Tetagam_1ml_FSP_38x32mm_oV_26_Layout 24.11.2016

DOM

EXP

Lot

1 ml (250 IU)

Tetagam® P

Human tetanus Ig for i.m. use

Store at +2 °C to +8 °C.
Do not freeze!

G2554 I26