



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

Dear Mr Meakings

Section 21 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 21 authorisation must be accounted for.

Section 21 Authorisation re Immunoglobulin Human Tetanus 250IU/mL INJ 1mL 04022026-2

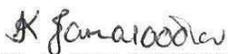
9. Note that this authorization DOES NOT cover supplies to the private sector.
10. Where this authorization is obtained to provide security of supply due to supply challenges from the contracted supplier, PAs are requested to buy out against contracted suppliers and ensure that related orders are cancelled 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 July 2026**.

Table 1: Provincial estimates

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

Yours sincerely


KHADIJA JAMALOODIEN
CHIEF DIRECTOR: SECTOR WIDE PROCUREMENT
DATE: 4/2/2026

Section 21 Outcome Letter

2026-01-30

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 **2026-01-30** refers

- A. STATUS: Approved**
- B. APPLICANT: Ms Buhle Mbongo**
- 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 Immunoglobulin 250 IU**
- G. QUANTITY: 1000 Packs (1)**

H. LETTER NUMBER: S2100021156

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

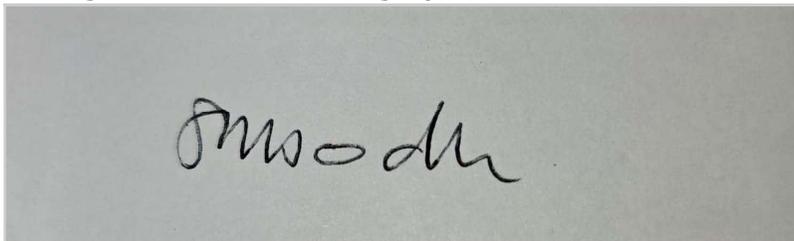
A progress report must be submitted once treatment is completed or on a reauthorization request

Comments:

Yours faithfully,

Dr Shyamli Munbodh

Manager: Section 21 Category A Medicines

A rectangular box containing a handwritten signature in black ink. The signature appears to be 'Ms Moropa' written in a cursive style.

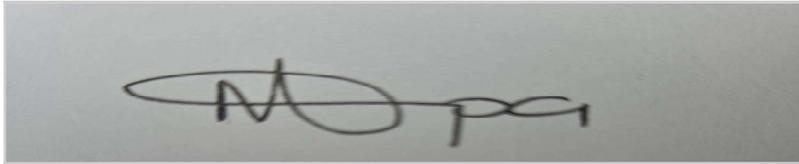
Ms Mahlodi Moropa

Final Approver

S2100021156



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



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.

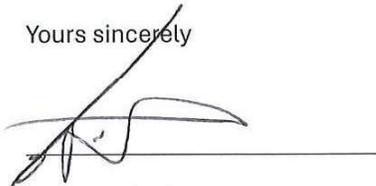
Property Name	Description	Pack size	Unit Price Excl VAT	Unit Price Incl VAT	Total Price Excl VAT	Total Price Incl VAT
Tetagam P	Human Tetanus Immunoglobulin	1 vial	R520.00	R598.00	R520 000.00	R598 000.00

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

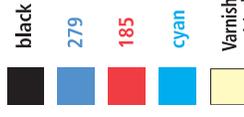
076 538 0491

Gen-Eye (Pty) Ltd
Reg. No.: 2009/009360/07

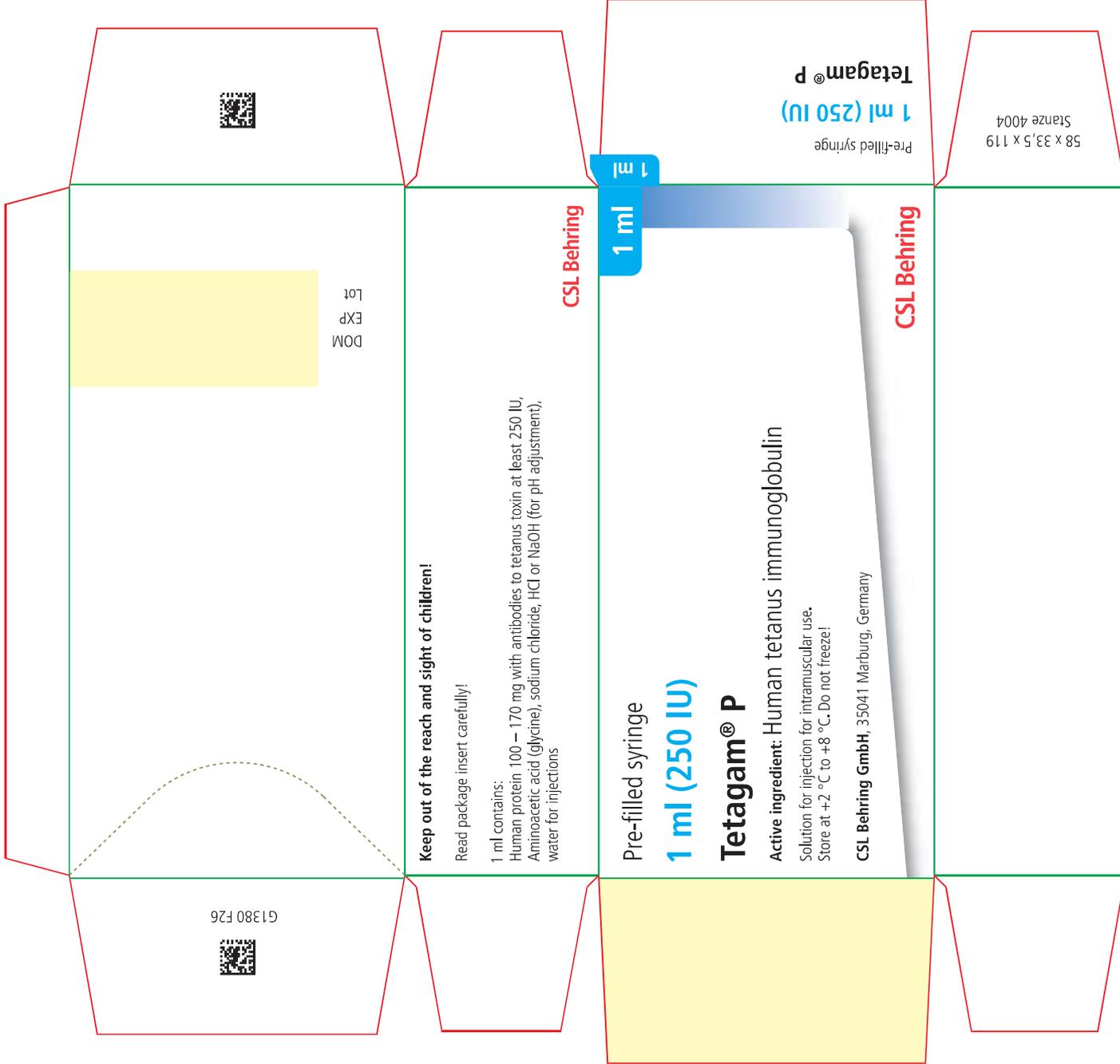
Directors: M. Blane, L. Hilliard-Lomas and ML Hilliard-Lomas



58x33,5x119 mm (4004)



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



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 if used inappropriately.
- 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: B06 B02

THERAPEUTIC INDICATIONS

Postexposure prophylaxis

- Immediate prophylaxis after tetanus prone injuries in patients who are not adequately vaccinated
- whenever 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.
The hypersensitivity reactions are rare. Tetagam P contains a small quantity of egg proteins. In the event of a severe allergic reaction to any of the ingredients, antibodies and may have significant reactions after administration of a product containing eggs. The physician must therefore weigh the benefit of treatment with Tetagam P against the potential risks of hypersensitivity reactions.
Rapid human tetanus immunoglobulin can induce a fall in blood pressure and a rise in body temperature. Tetagam P should therefore be given in treatment with normal human immunoglobulins.
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.
Particular care should be taken in cases of inadequate IV injection, patients should be observed for longer term (at least 1 hour) after administration.

Important information about some of the ingredients of Tetagam P
Tetagam P contains less than 1 mmol sodium (23 mg) per dose, is essentially sodium free.

Virus safety

Standard measures to prevent infections resulting from the use of medicinal products prepared in human blood or plasma are the selection of donors, screening of donors for infectious agents, and the use of appropriate 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 controlled 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 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 immunoglobulin does indicate that no harmful effects on the course of pregnancy, on the fetus 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 MEDICAL 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 3 months after administration.
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 requirement 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 transient rise of passively transferred antibodies after immunoglobulin injection may result in misleadingly positive test results.
Passive transmission of antibodies to serological antigens, e.g., A, B and D antigens, may occur with some serological tests for red cell alloantibodies (e.g., Coombs tests).

Incompatibilities

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

POSLOGY AND METHOD OF ADMINISTRATION

Children and adults are to receive the same dose.

Posology

250 IU makes the risk of tetanus almost 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
- surgical wounds with tissue damage and reduced oxygen supply as well as foreign-body injury (legs, bites, stings or stabs)
- burns, convulsions
- septicæmia, abortion
- tissue necrosis
- In case of severe 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
Symptomatic treatment in conjunction with other appropriate clinical procedures, regarding frequency, interval of injection and duration of therapy repeated doses depend on the clinical picture.

Method of administration

Do not use solutions which are dark 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 above 2 ml for children up to 20 kg and above 5 ml for persons above 20 kg bw.

In case of simultaneous vaccination with 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 administration is not possible, Tetagam P may be given subcutaneous (under the skin) for muscle pain. 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.
In case of therapy of intramuscular administration is not clinically appropriate, an alternative intravenous product may be used.

QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

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

Other ingredients

Polysorbate 20, 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 pre-filled syringe with 1 ml
Pack with 10 pre-filled syringes with 1 ml
Pack with 1 pre-filled syringe with 2 ml
Not all pack sizes may be marketed.

NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

CSL Behring GmbH
Marburg
Königsplatz 76
35041 Marburg
Germany

DATE OF LAST REVISION

November 2014

