Company incorporated under section 21 of the Companies Act**, Registration Number:** 2003/009927/08
Address: PO Box 172, Muizenberg, 7950 **Tel**: 021-788 3507 **Fax**: 021-788 3726
Email: tactp@tac.org.za **Web**: http://www.tac.org.za/treatment/

INSTRUCTIONS FOR ORDERING GENERIC ANTIRETROVIRALS THROUGH THE TAC TREATMENT PROJECT

The TAC Treatment Project will, to the extent its capacity allows, assist individuals in procuring generic antiretrovirals. These medicines are not registered with the Medicines Control Council and each patient requires special authorisation to import and hold these medicines under section 21 of the Medicines Act. In order to obtain this authorisation, a set of forms must be filled out by the patient's doctor and submitted to the Medicines Control Council. Authorisation typically takes about two weeks. The TAC Treatment Project does not guarantee that it will be able to help every person who requests help. Priority will be given to uninsured patients, patients whose medical aid schemes do not cover antiretrovirals and unemployed or poor patients who cannot afford branded drugs.

The following drugs can be supplied:

- Cipla Triomune 40 (stavudine 40mg + lamivudine 150mg + nevirapine 200mg)
- Cipla Triomune 30 (stavudine 30mg + lamivudine 150mg + nevirapine 200mg)
- Cipla Lamivudine (lamivudine 150mg)
- Cipla Nevimune (nevirapine 200mg)
- Cipla Stavir (stavudine 30mg)
- Cipla (stavudine 40mg)

Please note *that a patient starting antiretroviral treatment with Triomune needs 14 separate doses of stavudine and of lamivudine. This is necessary because a single dose only of nevirapine is taken during the first 14 days of treatment. In those two weeks one triomune is taken once per day and separate stavudine and lamivudine is taken once per day. After two weeks – if no liver abnormalities appear – the patient switches to triomune twice per day.*

Attached you will find the following: (1) Order form, (2) forms for section 21 application

Steps to obtain authorisation and place an order:

1. Doctor to *prescribe* appropriate regimen to patient
2. Treating doctor to *fill in section 21 forms* and fax to the Medicines Control Council at 012 312 3106 or 012 312 3105
3. Wait for *confirmation of authorisation* from the MCC
4. Phone TAC TP to confirm order form is current; *fill in order form* with doctor's help
5. *Deposit* total amount for order into TAC TP's bank account
6. *Fax (a) order form, (b) deposit slip, (c) prescription, (d) authorisation form* to TAC TP
7. Allow several days for drugs to be *delivered to doctor's postal address* (using counter-to-counter post office courier service). An invoice will be attached.

Make antiretroviral therapy available

TREATMENT PROJECT

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Antiretroviral Medicine Order Form (filled by doctor) [version 1; 15/09/2003]

Product	Unit Price*	Quantity	Amount
Cipla Triomune 40 (stavudine 40mg + lamivudine 150mg + nevirapine 200mg) [60 tabs]	R230.00		
Cipla Triomune 30 (stavudine 30mg + lamivudine 150mg + nevirapine 200mg) [60 tabs]	R230.00		
Cipla Nevimune (nevirapine 200mg) [60 tabs]	R96.90		
Cipla Stavir 30mg [60 tabs]	R32.25		
Cipla Stavir 30mg [14 tabs]	R7.52		
Cipla Stavir 40mg [60 tabs]	R35.90		
Cipla Stavir 40mg [14 tabs]	R8.38		
Cipla Lamivudine [60 tabs]	R102.55		
Postage (*please tick*): _ patient will collect from Lite-Kem pharmacy (*no charge*)† _ counter-to-counter next-day courier to doctor (R34.63)			
Dispensing fee			R55.00
Total			

Please order a three-month supply to save on dispensing and postage costs
** All prices include 14% VAT; Medicines charged at cost price (including shipping on imported items);* ***Prices subject to change without notice.*** *If order form older than 30 days, call for prices.*
† Please wait for telephonic confirmation that your package is ready before collecting
Note: separate stavudine & lamivudine dispensed in 14-day doses for use with Triomune in first 14 days of treatment when only one dose of nevirapine per day is taken

Patient's name:_____ Patient's tel:_____

Doctor's name:_____ Doctor's tel:_____

Doctor's postal address (*package will be delivered to post office counter*):

_____

_____

_____ Postal code: _____

PLEASE ATTACH (1) PRESCRIPTION, (2) PROOF OF SECTION 21 AUTHORISATION AS WELL AS (3) PROOF OF PAYMENT (DEPOSIT SLIP) TO THIS ORDER FORM AND FAX TO 021 788 3726/ 021 7881297

Payments must be made by direct deposit to (pls. write "Antiretrovirals" in reference field):
Account name: TAC Treatment Project
Account number: 1009788914
Bank: Nedbank, *Branch code*: 100909

A. PARTICULARS OF THE APPLICANT (i.e. treating medical doctor/prescriber)

1. Title: First Names: Surname:
2. Health Professions Council (South Africa) Registration Number:
3. Registered qualifications:
4. Registered speciality under which you are currently practicing and treating the patient mentioned in section C below (e.g. General pracitioner, paediatrician, physician, nephrologist, etc.) and designation:
5. Practice number:
6. Registered physical address (where the patient records and/or the medicine may be inspected):
7. Postal address:
8. Telephone number (office hours): Cellular phone number:
9. Fax number (office hours):
10. E-mail address:
11. Signature: Date:
12. Official Stamp:

B. PARTICULARS OF INSTITUTION IMPORTING THE UNREGISTERED MEDICINE

1. Category:	**Pharmacist**	Pharmaceutical Manufacturer	Pharmaceutical Distributor	Pharmaceutical Wholesaler	Other: Specify

2. Registered name of company: **TAC Treatment Project**
3. Registration number of company: **2003/009927/08**
4. Physical address (where the medicine and/or patient data may be inspected): **Lite-Kem Pharmacy, 24 Darling Street, Cape Town. (patient records at doctor's surgery)**
5. Postal address: **PB Box 172, Muizenberg, 7950**
6. Contact person: Title: **Mr** First names: **Gavin Robert** Surname: **Brown**
7. Registered qualifications: **B.Pharm., M.Sc.**
8. Health Professions Council/Pharmacy Council (South Africa) registration number: **11526**
9. Official designation: **Managing Director / Dispensing Pharmacist**
10. Telephone number (office hours): **021 448 8425 / 021 788 3507**
11. Fax number (office hours): **021 788 1297/ 021 7883726**
12. Cellular phone number: **082 880 0776**
13. E-mail address: **tactp@tac.org.za / gavin@tatt2.com**

C. PARTICULARS OF THE PATIENT

1. Title: First names: Surname:

2. Age: Gender: Weight: **kg** Height: **cm**

3. Occupation:

4. Residential address:

5. Work or postal address:

6. Telephone number (office hours):

7. Cellular phone number:

8. Diagnosis (reason for the application to use the unregistered medication; full description including severity, staging and prognosis where applicable):

9. Details of current treatment regimen for the diagnosis in point 8 above. Included medical, surgical and other treatment:

10. Concomitant disease(s) (full description including severity, staging and prognosis where applicable):

11. Current treatment regimen(s) for the concomitant disease(s) in point 10 above

12. Please specify which of, and the doses of the treatment regimens listed in points 9 and 11 above will be continued together with the unregistered medicine:

13. Has Informed Consent been obtained from the patient for the use of the unregistered medicine/device? Please attach a completed valid informed consent form for the patient

YES or NO

D. PARTICULARS OF THE UNREGISTERED MEDICINE FOR WHICH A SECTION 21 APPLICATION IS BEING MADE

1. Manufacturer: **Cipla Ltd.**

2. Country of origin: **India** Name of South African subsidiary: **Cipla Medpro**

3. Generic name:

4. Trade name:

5. Formulation and quantity required (e.g. ampicillin 250mg capsules, 1000 capsules per month for 6 months = 6000 capsules):

6. Is the medicine/device approved and registered for the intended use in other countries, including the country of origin? **YES** or NO

7. Please provide documentary proof of the above point 6 (e.g. medication leaflet, copy of publication in a peer reviewed scientific publication etc.):

8. Prescription and planned treatment regimen of the unregistered medicine/device for the patient described in section C (dose, frequency, route and duration of administration):

9. Specify known adverse drug reactions (ADR's) to this medication, including interactions with concomitant disease(s) and medication(s) listed in section C points 10 and 12:

10. Clearly outline how you intend preventing, monitoring for and managing the above ADR's:

11. Clearly state reasons for not using a similar registered medication/device already available in South Africa or treatment regimen for the disease mentioned in Section C point 8 above:

12. Motivation for the use of the unregistered medication/device (do not repeat the indication and reasons listed in sections C points 8 and11):

13. Have you or any other person or institution applied to the MCC for the use of the same or other unregistered medicine/device for the same patient in the past? YES or **NO**
    If yes, please specify and supply the MCC approval number.

14. I hereby certify that:
    - The use of this unregistered medication/device is purely for the management of the patient's disease and not research,
    - Data collected during the treatment of the patient with the unregistered medication/device may only be used for research after obtaining specific approval from the patient and the MCC, and that the MCC will be supplied with the results (published and unpublished) of such research,
    - A copy of this application form and consent form will be made available on request to the patient and any registered health care professional who may be involved in the treatment of the above patient.

Signed by applicant: Date:

INFORMED CONSENT

I _____ (full names of the patient) hereby voluntarily agree to be treated by _____ (name of doctor, practise, hospital) with the following medication, namely _____ _____ that is not registered in South Africa, for _____ (name of the disease).

I confirm that I have been fully informed and that all my questions have been answered by _____ (name of the applicant i.e. prescribing doctor) about (1) my disease (for which a section 21 application is being made), its cause, severity, prognosis; (2) other registered treatment options available in South Africa; (3) the reasons for the current state of my illness; (4) the unregistered medication and (5) the application to use a medication that is not registered in South Africa; and that:

- as the medication is not registered in South Africa that this implies that the quality, safety and efficacy of this medication has not been verified by the Medicines Control Council (MCC) of South Africa (S.A.).
- the medication will only be supplied to and used by and on me once specific approval has been obtained from the MCC of S.A.
- the medication _____ (generic and trade name) is approved for treatment of _____ (my disease) in _____ (name of the country from which the medication is imported), or that the medication is an advanced stage of development (at least phase III trial) in South Africa and/or _____ _____ (country of origin) and that its quality, safety and efficacy are well documented and within legally and scientifically acceptable levels.
- appropriate measures will be taken to prevent, monitor and manage any unwanted effect I may experience as a result of taking the unregistered medication
- _____ (name of the doctor) will comply with all the regulations of the MCC, laws (South African and foreign) and conditions of approval for use of this unregistered medication/device and accordingly ensure continued availability and supply of the medication
- the use of the unregistered medicine on and by me is for managing my disease and is not for medical research
- any information collected by _____ (name of the applicant), his/her employer, successor or any other person other than the MCC or its legal representative, may be used for research purposes only upon receipt of specific written separate informed consent from me, my guardian or person responsible for my affairs after my death
- I will be free to stop using the medication at any time and that I will inform my (treating) doctor accordingly.

Full names of the patient/guardian:

Signature of the patient/guardian: Date:

Name of the doctor (applicant):

Signature of the doctor: Date:

Name of the witness:

Signature of the witness: Date:

PROGRESS REPORT FORM Initial Follow-up Final

1. Particulars of the treating doctor/pharmacist

Title: Initials: Surname:

Postal address:

Telephone no.: Fax no.: E-mail address:

2. Patient particulars

Title: Initials: Surname:

Age: Gender: Weight: Height:

Telephone no.: Cellular number:

3. Particulars of the unregistered medication

MCC Section 21 approval number:

Disease for which the unregistered medicine was used for:

Generic name of the medicine: Trade name:

Dosage that has been given to the patient (amount, route, frequency and duration of administration):

Date of commencement of treatment with the unregistered medicine:

Date last used: or **A.** Treatment ongoing

4. Outcome of treatment.

4.1 Therapeutic effect

Excellent Satisfactory No effect Not assessed

Brief description/comments:

4.2 Adverse drug reaction (ADR) to the unregistered medication

B. None or C. Present

If present: Local or Severity: Mild Moderate Severe

Description of the ADR including results of laboratory and/or other investigations and management:

Outcome of ADR: Resolved Ongoing Resulted in disability Resulted in death