Fexinidazole Phase IIIb study

4th JOINT EANETT/HAT PLATFORM SCIENTIFIC MEETING

Conakry, Sept 20-22, 2016

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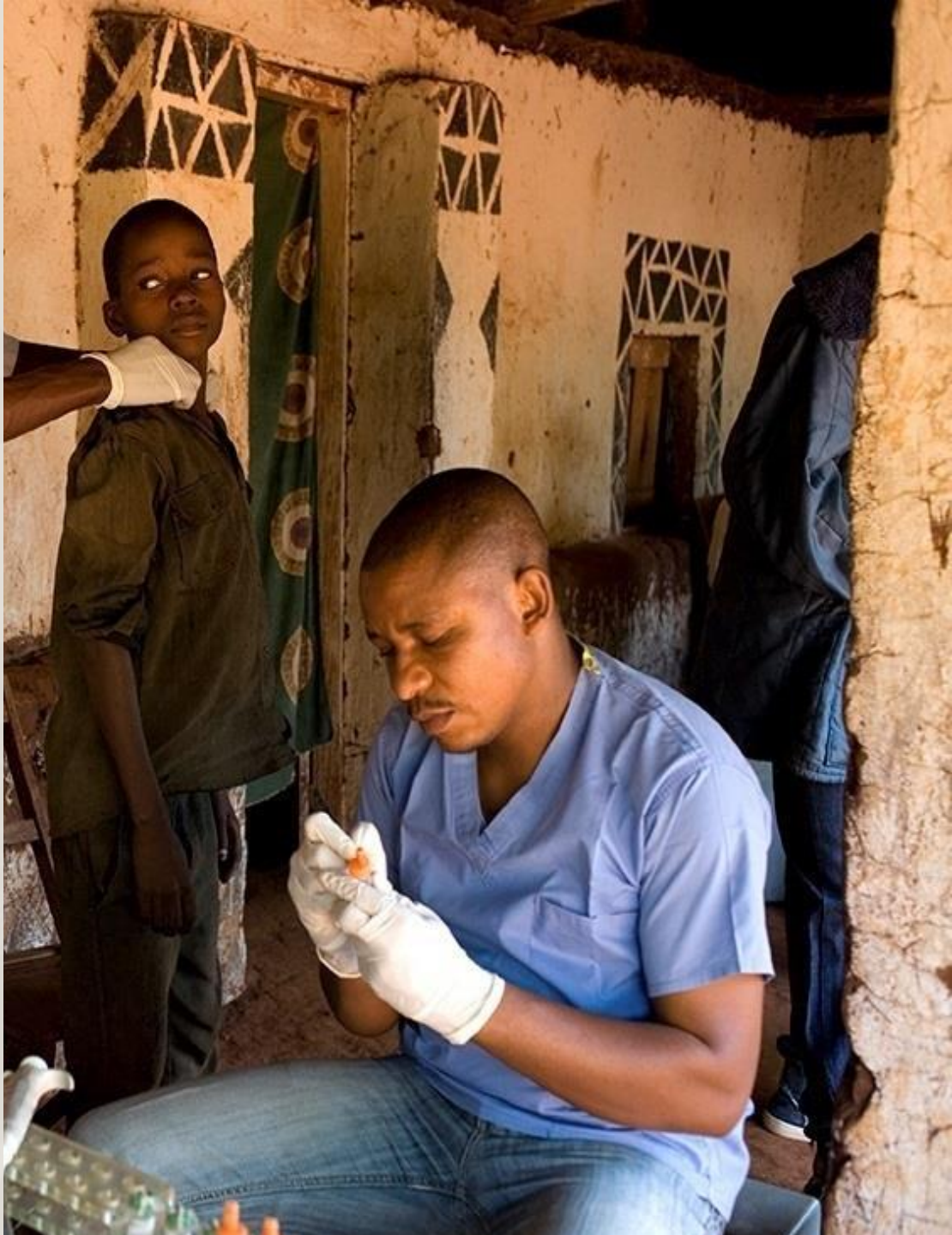
DNDi
Drugs for Neglected Diseases *initiative*



Study design

- Prospective, multicentre, open-label, cohort study, assessing the effectiveness of fexinidazole in adults and children with HAT at any stage
- 174 patients planned (in- and out-patients)
- 3 investigational sites in Democratic Republic of the Congo.


RÉPUBLIQUE CENTRAFRICAINE
CAMEROUN
Yaoundé
Bangui
Oubangui
Uélé
ORIENTALE
Lopori
ÉQUATEUR
Kisangani
Mbandaka
CONGO
GABON
NORD-KIVU
Goma
Bukavu
RWANDA
Mushie
Kasai
KASAÏ-ORIENTAL
SUD-KIVU
RÉPUBLIQUE DÉMOCRATIQUE DU CONGO
Bandundu
BURUNDI
Kinshasa
Bagata
BANDUNDU
MANIEMA
Pointe-Noire
Kikwit
TANZA
Boma
Matadi
KASAÏ-OCCIDENTAL
Kananga
Mbuji-Mayi
Congo
Lualaba
KATANGA
Luanda
ANGOLA

Primary objective

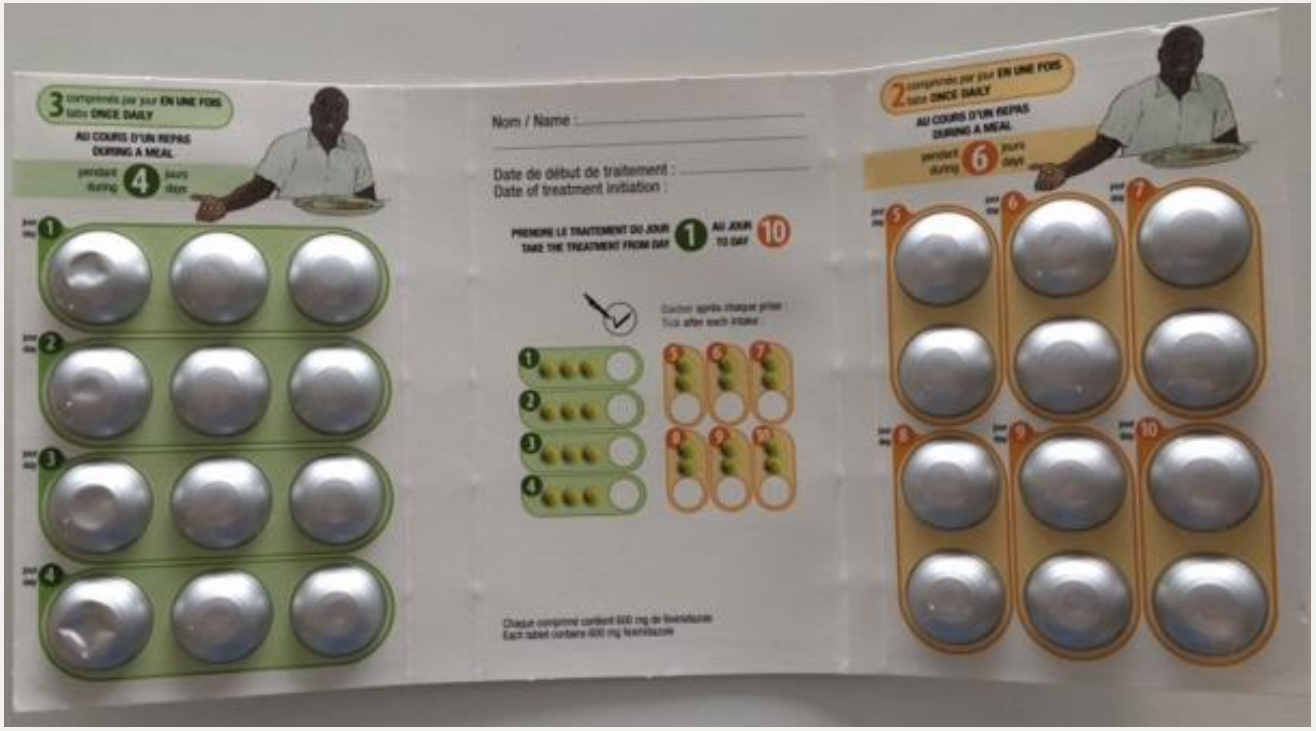
- To assess the effectiveness of fexinidazole administered to in- and out-patients with g-HAT at all stages of the disease
  - Success or failure at 12 and 18 months after the end of the treatment.

Secondary objectives

- To assess the safety of fexinidazole
- To assess treatment compliance and the feasibility of patient self-management of treatment intake
  - Presence of fexinidazole in the blood samples 24hrs after last treatment dose
  - Leftover tablets and compliance interview
- To assess the acceptability of the proposed packaging and understanding of the instructions for use
  - Questionnaire at the beginning and at the end of the treatment period
- To assess the PK of fexinidazole and its main metabolites in the blood (inpatients only)

Treatment / Packaging

- Different dose according to patient weight: ≥ ou < 35 kg



FICHE D'INSTRUCTIONS

Fexinidazole Winthrop®

Fexinidazole

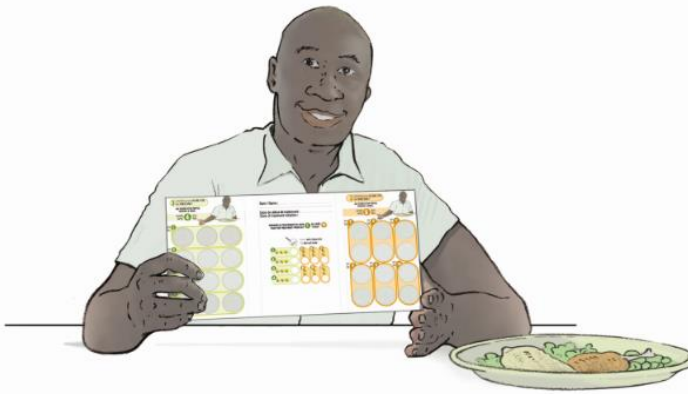
600 mg

Voie orale
Oral use

Adulte et enfant
Adult and child ≥ 35 kg

24 comprimés
tablets

SANOFI



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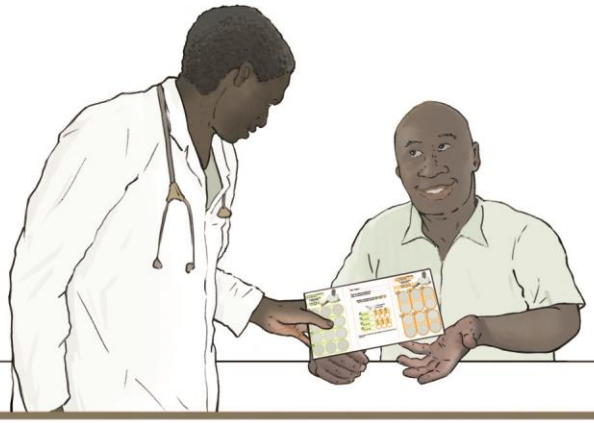
CE MÉDICAMENT N'EST QUE POUR VOUS, NE LE DONNEZ JAMAIS À QUELQU'UN D'AUTRE.

UNE CONSULTATION MÉDICALE EST OBLIGATOIRE.

POUR PRENDRE CE TRAITEMENT, SUIVEZ TOUJOURS LES INSTRUCTIONS DU MÉDECIN.

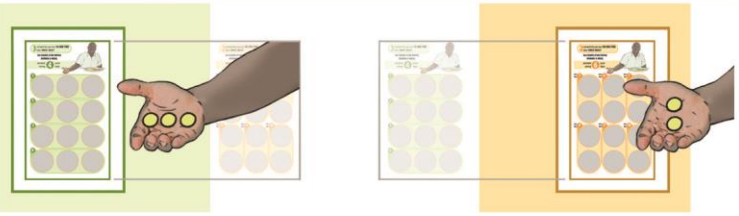


PRENDRE LE TRAITEMENT :

du jour 1 au jour 10

10 JOURS / 2 ETAPES :

ETAPE VERTE
ETAPE ORANGE

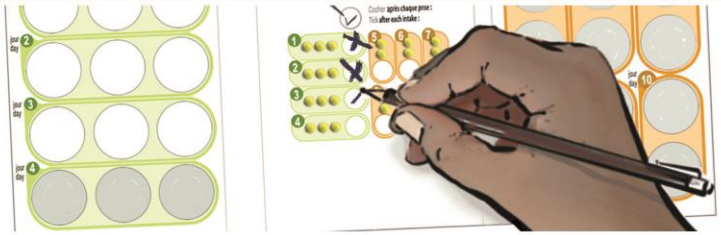


POUR CHAQUE PRISE :

en une fois par jour
au moment du repas

CALENDRIER :

cocher après chaque prise



Eligible patients

- Extended patient population compared to previous trials
- Pregnant women (except 1st trimester)
- Breastfeeding women
- Children from age of 6
- Low body weight
- Any stage of the disease
- Concomitant diseases

Specific criteria for outpatients

- Karnofsky index > 50%
- Understanding of the treatment instructions
- No pregnancy or breastfeeding
- No neurological symptoms and medical and psychiatric contraindications for treatment
- Reachable and residing close to the investigator centre during the treatment period

Specificities for outpatients

- Caregiver :
  - Person designated to accompany the patient during the treatment period (give treatment, provide food, etc.)
  - Responsible to call the investigator in case of AE/SAE and for any question
- Possibility of hospitalization if patient is unable to continue the treatment at home
- PK will be measured at the end of the treatment period as an indicator of compliance
- Interview at the IMP dispensing and after the end of the treatment

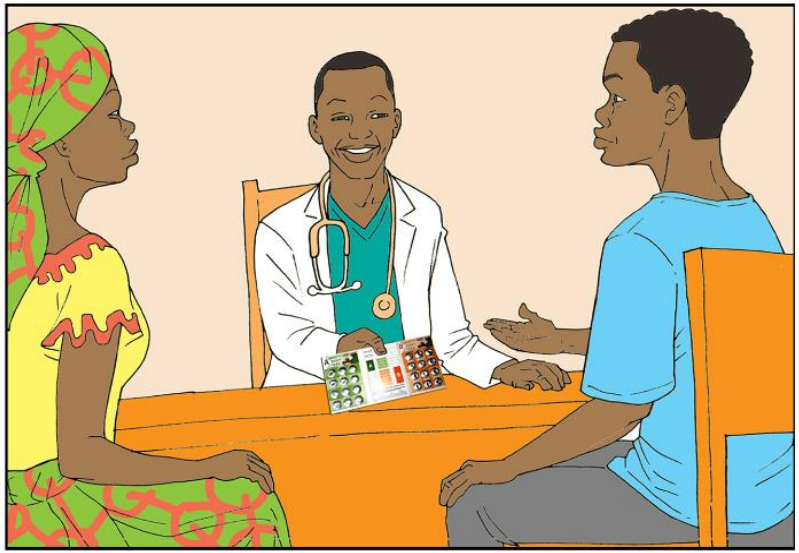
Interview on the dispensing day

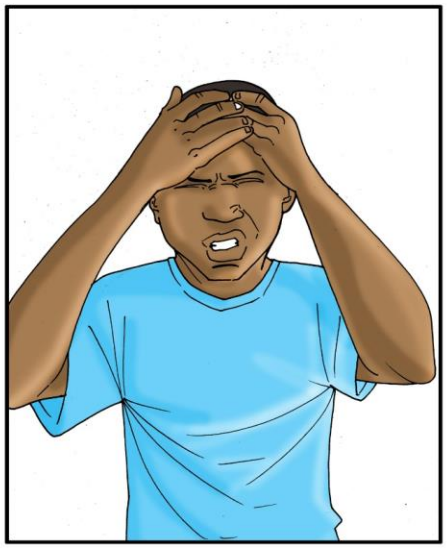
- Specific questionnaire designed with Sanofi
- Check the comprehension of the instructions for use of the treatment by both patient and caregiver:
  - Was the packaging enough?
  - Was investigator help needed?
- Evaluation of patient self-management of treatment intake

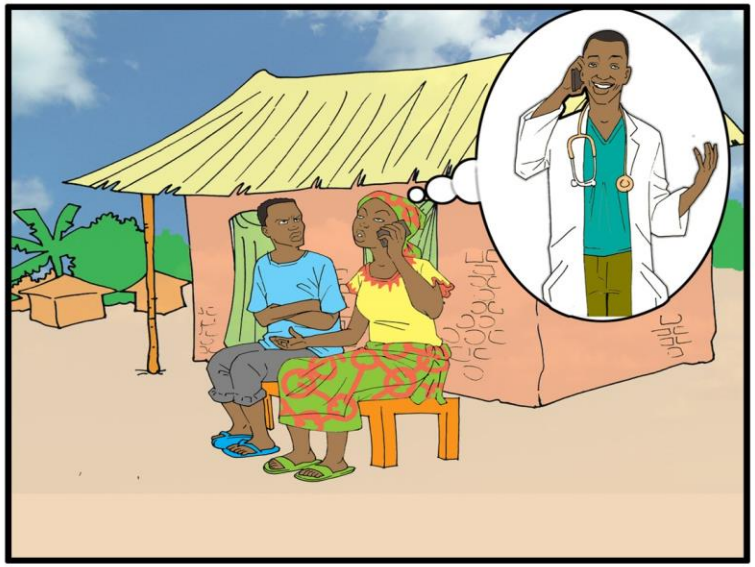
Interview at the end of treatment period

- Verification of treatment compliance
- Understanding and acceptability of packaging and instructions sheet via specific questionnaire designed with Sanofi
- Collection of adverse events and concomitant medication taken by the patient

Specific explicative images developed for the consent process





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Thank you for
your attention
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