Company Core Data Sheet

Nifurtimox

prepared on the basis of

Package Insert Leaflets El Salvador, Argentina

PH - PD GRA EU/GS TA AI	
PH - PD TA-AI GPL	
PH - PD GMD GDS	

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GENERAL INFORMATION

Active ingredient: Nifurtimox (3-Methyl-4-(5'nitrofurfuryliden-amino)-tetrahydro-4H-1,4-tianzine-1,1 dixoide)
Tablet for oral administration

Tablets
Nifurtimox 30mg: excipients: dicalcium phosphate, starch, aerosil comp., sodium-laurylsulfate 200mg
Nifurtimox 120mg: excipients: dicalcium phosphate, starch, aerosil comp., sodium-laurylsulfate 400mg

INDICATIONS

TRIPANOCIDE, CHAGAS DISEASE

POSOLOGY AND METHOD OF ADMINISTRATION

Children: from 15.0 to a maximum of 20.0 mg/kg of body weight
Adolescents: from 12.5 to a maximum of 15.0 mg/kg of body weight
Adults: from 08.0 to a maximum of 10.0 mg/kg of body weight

The amount indicated in each case represents the number of tablets that must be given three times a day:

Body weight (kg)	Number of tablets per dosage Lampit 120 mg
Children (<10 years)	
3-4	-
5-6	-
7-9	-
10-12	-
13-15	-
16-18	-
19-21	-
22-26	1
27-32	1 ¼
Adolescents (11 to 16 years)	
33-39	1 ¼
40-46	1 ½
47-54	1 ¾
55-60	2
Adults (>= 17 years)	
45-49	1
50	1

50	1 ¼
51-60	1 ¼
61	1 ¼
61	1 ½
62-72	1 ½
73	1 ½
73	1 ¾
74-84	1 ¾
85-94	2
95-100	2 ¼

It is very important to avoid ingesting a higher dose than that indicated for each case, dosing should be done based on the real body weight and age of the patient. When the patient's body weight exceeds normal limits by 10% or more, dosing will be done considering the theoretical weight corresponding to the height of the patient.

If the body weight decreases under treatment, the dosage must be adjusted accordingly. During treatment, the patient can lose appetite and consequently his weight drops. Therefore, the body weight should be checked every 14 days.

Duration of treatment

Acute infection: 90 days

Chronic infection: 120 days

In order to avoid recidivating infections, especially of the tissue form of Trypanosoma cruzi (leishmania stage), it is absolutely imperative to maintain a regular administration of tablets during the complete period of treatment.

Method of Administration

Tablets should be taken in three times a day, preferably in the morning, at noon and at night, after meals.

Lactating infants may take it pulverized and mixed with a small amount of food. In this case it is convenient to give the medication before the full meal.

CONTRAINDICATIONS

According to the indicated dosage, there seems not to be any absolute contraindication although observation is recommended in patients with a previous history of: cerebral damage, predisposition to seizures or epilepsy, psychosis and serious behavioral alterations.

Allergic affections, especially those involving skin manifestations.

Chronic abuse of medications or alcohol.

Hypersensitivity to hydantoin

Porphyria

Hepatic dysfunction

First trimester pregnancy

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

During therapy, it is recommended to absolutely avoid the ingestion of alcoholic beverages in order to prevent possible side effects.

Gastrointestinal irritation (reduced with simultaneous use of aluminium hydroxide)

History of convulsions requires close medical supervision.

Reduction of daily doses if weight loss, neurological disturbances or other manifestations of intolerance occur

Since the effect of Lampit© in pregnancy and in patients with renal failure, has not been extensively evaluated it is not recommended to give Lampit© under these circumstances.

PREGNANCY AND LACTATION

The action of Lampit in pregnancy is not yet sufficiently understood. It is therefore not advisable to use it during pregnancy.

UNDESIRABLE EFFECTS

During the course of the therapy anorexia may appear with the subsequent weight loss, therefore, therapy should be controlled at intervals no longer than 14 days, readjusting the dose eventually. In case that an overdose occurs unwanted secondary effects may appear.
The main secondary effects observed were: nausea, vomiting, vertigo, abdominal pain. There also may be central nervous system alterations with memory loss, sleep disturbances, tremor, apathy, excitatory states and psychotic behavior.
In long-term therapies, the peripheral nervous system may sometimes be affected and this may manifest as tremors, muscle weakness, mild paresthesia and polyneuritis.
The secondary events that may appear during therapy based on recommended dosage, will disappear rapidly after stopping the medication or through symptomatic treatment.
Up to now, no irreversible damage has been observed.

PHARMACEUTICAL PARTICULARS

Special precautions for use

This medication must be used exclusively under prescription and under medical surveillance and it cannot be sold at the drugstore without a new prescription.