Lampit® (nifurtimox) Fact Sheet

Lampit Indication

- Lampit® (nifurtimox) is an antiprotozoal medication indicated for use in pediatric patients (from birth to less than 18 years of age and weighing at least 2.5 kg) for the treatment of Chagas disease (American Trypanosomiasis) caused by *Trypanosoma cruzi* (*T.cruzi*).[1]

Lampit dosing and administration select information

- Lampit is available in a new, dividable tablet that can be split on the scored lines by hand.[1-3]
- The tablet is specially formulated to disperse in one-half teaspoon (2.5 mL) of water and taken immediately with food, which can aid in the dosing and administration to pediatric patients who may have difficulty swallowing whole or half tablets according to prescribing instructions.[1-3]
- Lampit tablets (30 mg and 120 mg) are for oral use and are to be administered three times a day with food.[1]
- The recommended duration of treatment with Lampit is 60 days.[1]
- Dosing of Lampit is determined by the patient's body weight. The dosage must be adjusted accordingly if body weight decreases during treatment. See the Lampit Prescribing Information for recommended dosage and important administration instructions.[1]

How Lampit works

- The mechanism of action of Lampit is not fully understood. Studies suggest that Lampit is metabolized/activated by type I (oxygen insensitive) and type II (oxygen sensitive) nitroreductases (NTR) leading to production of toxic intermediate metabolites and/or reactive oxygen species that induce DNA damage and cell death of both intracellular and extracellular forms of *T. cruzi*.[1]

- ❖ See the Lampit (nifurtimox) tablets Full Prescribing Information for additional information and guidance.[1]

Results from the Phase III Chagas' disease In Children treated with nifurtimox Pediatric Study

- ❖ The safety and efficacy of Lampit in pediatric patients aged 0 days to <18 years were demonstrated in the *Chagas' disease In Children treated with nifurtimox* study, the first part of the largest Phase III program ever conducted in pediatric patients for the treatment of Chagas disease.
    - In the study, 330 pediatric patients with serologic evidence of *T. cruzi* infection (ie, without Chagas disease-related cardiovascular and/or gastrointestinal symptoms) were randomly assigned in a 2:1 fashion to receive either a 60-day (n=219) or a 30-day (n=111) Lampit treatment regimen and were followed up for one year after end of treatment.[1]

    - The results showed superiority in favor of the nifurtimox 60-day arm compared to the nifurtimox 30-day arm (not an approved dosing regimen). For additional clinical trial information go to clinicaltrials.gov NCT02625974 and see full prescribing information.[1,4]

    - The most frequently reported AEs (≥5%) in patients treated with Lampit were vomiting (14.6%), abdominal pain (13.2%), headache (12.8%), decreased appetite (10.5%), nausea (8.2%), and pyrexia (raised body temperature or fever) (7.3%), and rash (5.5%).[1]

For more information

- ❖ Contact Bayer Medical Communications at 1-888-842-2937.

IMPORTANT SAFETY INFORMATION

Contraindications

LAMPIT tablets are contraindicated in:

- Patients with known hypersensitivity to nifurtimox or any of the excipients in LAMPIT
- Patients who consume alcohol during treatment

Warnings and Precautions

Potential for Genotoxicity and Carcinogenicity

Genotoxicity

Genotoxicity of LAMPIT has been demonstrated in humans, in vitro in several bacterial species and mammalian cell systems, and in vivo in rodents.

A study evaluating the cytogenetic effect of nifurtimox in pediatric patients ranging from 7 months to 14 years of age with Chagas disease demonstrated a 13-fold increase in chromosomal aberrations.

Carcinogenicity

Carcinogenicity has been observed in mice and rats treated chronically with nitrofuran agents which are structurally similar to nifurtimox. Similar data have not been reported for LAMPIT. It is not known whether LAMPIT is associated with carcinogenicity in humans.

Embryo-Fetal Toxicity

Based on findings from animal studies, LAMPIT can cause fetal harm when administered to a pregnant woman. In animal reproduction studies, nifurtimox administered orally to pregnant mice, rats, and rabbits during organogenesis was associated with reduced fetal body weights in rodents, and abortions, fetal death, and smaller litter sizes in rabbits at doses approximately equivalent to and 2-times, respectively, the maximum recommended human dose (MRHD) of 10 mg/kg/day. Fetal malformations were observed in pregnant rabbits administered nifurtimox doses less than the MRHD.

Advise pregnant women of the potential risk to a fetus. Pregnancy testing is recommended for females of reproductive potential prior to initiating treatment with LAMPIT. Advise females of reproductive potential to use effective contraception during treatment with LAMPIT and for 6 months after the last dose. Advise male patients with female partners of reproductive potential to use condoms during treatment and for 3 months after the last dose of LAMPIT.

Worsening of Neurological and Psychiatric Conditions

Patients with a history of brain injury, seizures, psychiatric disease, or serious behavioral alterations may experience worsening of their conditions when receiving LAMPIT. Administer LAMPIT under close medical supervision in these patients and in patients who develop neurological disturbances or psychiatric drug reactions.

Hypersensitivity

Cases of hypersensitivity have been reported in patients receiving therapy with nifurtimox. The hypersensitivity could be a reaction induced by nifurtimox or an immune response triggered by Chagas disease during treatment. Hypersensitivity reactions could be accompanied by hypotension, angioedema (including laryngeal or facial edema), dyspnea, pruritus, rash or other severe skin reactions. At the first sign of serious hypersensitivity, discontinue treatment with LAMPIT.

Decreased Appetite and Weight Loss

Decreased appetite and weight loss were reported in patients treated with LAMPIT in the clinical trials. During treatment with LAMPIT, patients can lose their appetite or experience nausea/vomiting which can result in weight loss. Check body weight every 14 days, as the dosage may have to be adjusted.

Porphyria

Treatment with nitrofuran derivatives, such as LAMPIT, may precipitate acute attacks of porphyria. Administer LAMPIT tablets under close medical supervision in patients with porphyria.

Adverse Reactions

The most frequently reported adverse reactions (≥1%) in patients treated with nifurtimox were vomiting (14.6%); abdominal pain (13.2%); headache (12.8%); decreased appetite (10.5%); nausea (8.2%); pyrexia (7.3%); rash (5.5%), diarrhea (4.6%), weight decreased (2.7%); anemia (2.7%), dizziness (2.7%), eosinophilia (2.3%) and urticaria (2.3%).

For additional important risk and use information, please see the full Prescribing Information and Instructions for Use. You are encouraged to report side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

References

1. Lampit (nifurtimox) tablets, for oral use prescribing information. Bayer HealthCare Pharmaceuticals Inc., 2023.
2. Patient information: Lampit (nifurtimox) tablets, for oral use. Bayer HealthCare Pharmaceuticals Inc., 2023.
3. Instructions for use: Lampit (nifurtimox) tablets, for oral use. Bayer HealthCare Pharmaceuticals Inc., 2020.
4. Prospective study of a pediatric nifurtimox formulation for Chagas' disease (CHICO). U.S. Department of Health and Human Services, National Institutes of Health, National Library of Medicine; 2020. https://clinicaltrials.gov/ct2/show/results/NCT02625974?term=CHICO&cond=Chagas+Disease&draw=2&rank=1&view=results. Accessed July 27, 2020.

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