

DRAFT

Section 6 Antileishmaniasis drugs

Proposed correction of expressed dosage: meglumine antimoniate

- 6.5.2 Antileishmaniasis drugs *WHO current EDL entry (2000)*

meglumine antimoniate

injection, 30%, equivalent to approx. 8.5% antimony, in 5-ml ampoule

Aventis Pharma manufactures and sells meglumine antimoniate (Glucantime®) for the treatment of leishmaniasis. The drug is provided for the Brazilian Government for this disease.

Meglumine antimoniate, solution for injection (1.5g/5ml) has been used for the treatment of leishmaniasis since 1947. The product has been granted an official market authorization in France since 1974. The original licence only mentioned the final concentration of active ingredient, i.e. 30% meglumine antimony or 1.5g/5ml.

In 1997, the market authorization had to go through a regular procedure of validation in France. In the new documents, the content of active ingredient appeared with the equivalent in antimony as follows: meglumine antimoniate: 1.5000g (equivalent to 0.4050g of antimony) for one ampoule of 5ml

This dosage of 0.4050g/5ml has always been the active ingredient concentration of the manufactured formula.

The Brazilian government has asked Aventis Pharma to introduce in the package insert the equivalence in mg of antimony. However the equivalence of 0.4050g antimony, in accordance with the French Licence, is not consistent with the WHO EDL 11 recommendation which lists meglumine antimoniate at the concentration of “*approx. 8.5% antimony, in 5-ml ampoule*”. This means a concentration of 0.425g/ml.

The WHO recommendation may have been based on the French compendium VIDAL which though highly reputable is not an official document. For many years VIDAL indicated a concentration of 0.4250g/5ml antimony for Glucantime® which was not in accordance with the official licence. In 1997 Aventis Pharma asked VIDAL to correct the error and the correction was included in the 1998 edition.

From the company's side, the concentration of 0.4050g antimony is not the result of a change in registration or formulation of the product and requests WHO to reflect this concentration..

Recommended options for the EDL 12

1. meglumine antimoniate injection, 1.5g, equivalent to 0.4050g antimony, in 5-ml ampoule
2. meglumine antimoniate injection, 30%, equivalent to 8.1% antimony, in 5-ml ampoule
3. meglumine antimoniate injection, 81mg/ml of antimony, 5-ml ampoule