



Informe de evaluación completo:

www.osakidetza.euskadi.eus/cevime



INSULINA DEGLUDEC

BIBLIOGRAFÍA

1. Tresiba. Ficha técnica. London (United Kingdom): European Medicines Agency (EMA); 2015. Disponible a: http://www.ema.europa.eu/docs/es_ES/document_library/EPAR_-_Product_Information/human/002498/WC500138940.pdf
2. Committee for Medicinal Products for Human Use, 2012. Tresiba®. EMA/CHMP/557821/2012. London (United Kingdom): European Medicines Agency (EMA); 2012 [citado febrero 2016]. Disponible en: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_Public_assessment_report/human/002498/WC500139010.pdf
3. Heller S, Buse J, Fisher M, Garg S, Marre M, Merker L et al. Insulin degludec, an ultra-longacting basal insulin, versus insulin glargine in basal-bolus treatment with mealtime insulin aspart in type 1 diabetes (BEGIN Basal-Bolus Type 1): a phase 3, randomised, open-label, treat-to-target non-inferiority trial. *Lancet* 2012;379(9825):1489-97.
4. Thalange N, Deeb L, Iotova V, Kawamura T, Klingensmith G, Philotheou A. Insulin degludec in combination with bolus insulin aspart is safe and effective in children and adolescents with type 1 diabetes. *Pediatric Diabetes*. 2015;16:164-176.
5. Mathieu C, Hollander P, Miranda-Palma B, Cooper J, Franek E, Russell-Jones et al. Efficacy and safety of insulin degludec in a flexible dosing regimen vs insulin glargine in patients with type 1 diabetes (BEGIN: Flex T1): a 26-week randomized, treat-to-target trial with a 26-week extension. *J Clin Endocrinol Metab* 2013;98(3):1154-62.
6. Garber AJ, King AB, Del Prato S, Sreenan S, Balci MK, Muñoz-Torres M et al. Insulin degludec, an ultra-longacting basal insulin, versus insulin glargine in basal-bolus treatment with mealtime insulin aspart in type 2 diabetes (BEGIN Basal-Bolus Type 2): a phase 3, randomised, open-label, treat-to-target non-inferiority trial. *Lancet* 2012;379(9825):1498-507.
7. Zinman B, Philis-Tsimikas A, Cariou B, Handelsman Y, Rodbard HW, Johansen T et al. Insulin degludec versus insulin glargine in insulin-naive patients with type 2 diabetes: a 1-year, randomized, treat-to-target trial (BEGIN Once Long). *Diabetes Care* 2012;35(12):2464-71.
8. Gough SC, Bhargava A, Jain R, Mersebach H, Rasmussen S, Bergenstal RM. Low-Volume Insulin Degludec 200 units/mL Once Daily Improves Glycemic Control Similar to Insulin Glargine With a Low Risk of Hypoglycemia in Insulin-Naive Patients With Type 2 Diabetes: A 26-week, randomized, controlled, multinational, treat-to-target trial: The BEGIN LOW VOLUME trial. *Diabetes Care* 2013;36:2536-42.
9. Meneghini L, Atkin SL, Gough SC, Raz I, Blonde L, Shestakova M et al. The efficacy and safety of insulin degludec given in variable once-daily dosing intervals compared with insulin glargine and insulin degludec dosed at the same time daily: a 26-week, randomized, open-label, parallel-group, treat-to-target trial in individuals with type 2 diabetes. *Diabetes Care* 2013;36(4):858-64.
10. Onishi Y, Ono Y, Rabøl R, Endahl L, Nakamura S. Superior glycaemic control with once-daily insulin degludec/insulin aspart versus insulin glargine in Japanese adults with type 2 diabetes inadequately controlled with oral drugs: a randomized, controlled phase 3 trial. *Diabetes Obes Metab* 2013;15(9):826-32.
11. Philis-Tsimikas A, Del Prato S, Satman I, Bhargava A, Dharmalingam M, Skjøth TV, et al. Effect of insulin degludec versus sitagliptin in patients with type 2 diabetes uncontrolled on oral antidiabetic agents. *Diabetes Obes Metab* 2013; 15: 760-66.
12. Bode BW, Buse JB, Fisher M, Garg SK, Marre M, Merker L, et al. Insulin degludec improves glycaemic control with lower nocturnal hypoglycaemia risk than insulin glargine in basal-bolus treatment with mealtime insulin aspart in Type 1 diabetes (BEGIN® Basal-Bolus Type 1): 2-year results of a randomized clinical trial. *Diabet Med* 2013; May 26. doi: 10.1111/dme.12243.
13. Jean-Marc Guettier, MDCMClinical Perspective of Hypoglycemia Analyses and Results Endocrinologic and Metabolic Drugs Advisory Committee Meeting November 8, 2012 slide 24-25. Disponible en: <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/UCM330923.pdf>
14. FDA Briefing Document. NDA 203313 and NDA 203314. Insulin Degludec and Insulin Degludec/Aspart. Endocrinologic and Metabolic Drugs. Advisory Committee Meeting. November 8, 2012. Disponible en: <http://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/drugs/endocrinologicandmetabolicdrugsadvisorycommittee/ucm327015.pdf>
15. Schimdt T. European Medicines Agency must take account of cardiovascular harm associated with degludec insulin. *BMJ* 2013;346:f3731.
16. "Guía de Práctica Clínica sobre Diabetes tipo 2" Osakidetza. 2013. Disponible en: www.osakidetza.euskadi.eus/r85-phgpc00/es