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In patients with type 2 diabetes, the TITRATE® study demonstrates

# Once-daily Levemir® gets the majority of patients to goal safely<sup>1</sup>

**64% of patients achieved A1C goal <7% with once-daily Levemir®\***

The Levemir® TITRATE trial shows how a majority of patients with type 2 diabetes taking a basal insulin, some with A1C levels as high as 9%, achieved the ADA-recommended target of A1C <7%.<sup>1,2</sup> Patients experienced a mean A1C decrease of -1.2%\* and achieved goal safely with low rates of hypoglycemia, nearly all of which were minor or symptoms only.<sup>11</sup>

\*70 to 90 mg/dL group.

*24/7 glucose control*



Model is for illustrative purposes only.

To see how Levemir® can help your patients achieve their goals, and to learn more about TITRATE, visit [TITRATEstudy.com](http://TITRATEstudy.com).

<sup>1</sup>Minor hypoglycemia rates were 0.42 (70-90 mg/dL) and 0.26 (80-110 mg/dL) per patient-month. A single major hypoglycemic event was reported in the 70 to 90 mg/dL group; no major hypoglycemic events in the 80 to 110 mg/dL group.<sup>1</sup>

Results from a 20-week, randomized, controlled, multicenter, open-label, parallel-group, treat-to-target trial using the PREDICTIVE® 303 self-titration algorithm in insulin-naïve patients with type 2 diabetes, A1C ≥7% and ≤9% on OAD therapy randomized to Levemir® and OAD (1:1) to 2 different FPG titration targets (70-90 mg/dL, [n=121]) or 80-110 mg/dL, [n=122]).<sup>1</sup>

PREDICTIVE = Predictable Results and Experience in Diabetes through Intensification and Control to Target: an International Variability Evaluation.

## Indications and usage

Levemir® is indicated for once- or twice-daily subcutaneous administration for the treatment of adult and pediatric patients with type 1 diabetes mellitus or adult patients with type 2 diabetes mellitus who require basal (long-acting) insulin for the control of hyperglycemia.

## Important safety information

Levemir® is contraindicated in patients hypersensitive to insulin detemir or one of its excipients.

**Levemir® should not be diluted or mixed with any other insulin preparations.**

**Hypoglycemia is the most common adverse effect of all insulin therapies, including Levemir®. As with other insulins, the timing of hypoglycemic events may differ among various insulin preparations. Glucose monitoring is recommended for all patients with diabetes. Levemir® is not to be used in insulin infusion pumps. Any change of insulin dose should be made cautiously and only under medical supervision. Concomitant oral antidiabetes treatment may require adjustment.**

**Needles and Levemir® FlexPen® must not be shared.**

Inadequate dosing or discontinuation of treatment may lead to hyperglycemia and, in patients with type 1 diabetes, diabetic ketoacidosis. Insulin may cause sodium retention and edema, particularly if previously poor metabolic control is improved by intensified insulin therapy. Dose and timing of administration may need to be adjusted to reduce the risk of hypoglycemia in patients being switched to Levemir® from other intermediate or long-acting insulin preparations. The dose of Levemir® may need to be adjusted in patients with renal or hepatic impairment.

Other adverse events commonly associated with insulin therapy may include injection site reactions (on average, 3% to 4% of patients in clinical trials) such as lipodystrophy, redness, pain, itching, hives, swelling, and inflammation. Less common but more serious are severe cases of generalized allergy, including anaphylactic reaction, which may be life threatening.

Please see brief summary of Prescribing Information on adjacent page.

**References:** 1. Blonde L, Meriläinen M, Karve V, Raskin P, for the TITRATE™ Study Group. Patient-directed titration for achieving glycemic goals using a once-daily basal insulin analogue: an assessment of two different fasting plasma glucose targets—the TITRATE™ study. *Diabetes Obes Metab*. 2009;11(6):623-631. 2. American Diabetes Association. Standards of medical care in diabetes—2010. *Diabetes Care*. 2010;33(Suppl 1):S11-S61.



**Levemir®**

insulin detemir (rDNA origin) injection



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## Levemir® (insulin detemir [rDNA origin] injection)

### Rx ONLY

#### BRIEF SUMMARY. Please see package insert for full prescribing information.

**INDICATIONS AND USAGE:** LEVEMIR® is indicated for once- or twice-daily subcutaneous administration for the treatment of adult and pediatric patients with type 1 diabetes mellitus or adult patients with type 2 diabetes mellitus who require basal (long acting) insulin for the control of hyperglycemia.

**CONTRAINDICATIONS:** LEVEMIR® is contraindicated in patients hypersensitive to insulin detemir or one of its excipients.

**WARNINGS: Hypoglycemia is the most common adverse effect of insulin therapy, including LEVEMIR®. As with all insulins, the timing of hypoglycemia may differ among various insulin formulations. Glucose monitoring is recommended for all patients with diabetes. LEVEMIR® is not to be used in insulin infusion pumps. Any change of insulin dose should be made cautiously and only under medical supervision. Changes in insulin strength, timing of dosing, manufacturer, type (e.g., regular, NPH, or insulin analogs), species (animal, human), or method of manufacture (rDNA versus animal-source insulin) may result in the need for a change in dosage. Concomitant oral antidiabetic treatment may need to be adjusted. Needles and LEVEMIR® FlexPen® must not be shared.**

**PRECAUTIONS: General:** Inadequate dosing or discontinuation of treatment may lead to hyperglycemia and, in patients with type 1 diabetes, diabetic ketoacidosis. The first symptoms of hyperglycemia usually occur gradually over a period of hours or days. They include nausea, vomiting, drowsiness, flushed dry skin, dry mouth, increased urination, thirst and loss of appetite as well as acetone breath. Untreated hyperglycemic events are potentially fatal. LEVEMIR® is not intended for intravenous or intramuscular administration. The prolonged duration of activity of insulin detemir is dependent on injection into subcutaneous tissue. Intravenous administration of the usual subcutaneous dose could result in severe hypoglycemia. Absorption after intramuscular administration is both faster and more extensive than absorption after subcutaneous administration. **LEVEMIR® should not be diluted or mixed with any other insulin preparations** (see PRECAUTIONS, Mixing of Insulins). Insulin may cause sodium retention and edema, particularly if previously poor metabolic control is improved by intensified insulin therapy. Lipodystrophy and hypersensitivity are among potential clinical adverse effects associated with the use of all insulins. As with all insulin preparations, the time course of LEVEMIR® action may vary in different individuals or at different times in the same individual and is dependent on site of injection, blood supply, temperature, and physical activity. Adjustment of dosage of any insulin may be necessary if patients change their physical activity or their usual meal plan.

**Hypoglycemia:** As with all insulin preparations, hypoglycemic reactions may be associated with the administration of LEVEMIR®. Hypoglycemia is the most common adverse effect of insulins. Early warning symptoms of hypoglycemia may be different or less pronounced under certain conditions, such as long duration of diabetes, diabetic nerve disease, use of medications such as beta-blockers, or intensified diabetes control (see PRECAUTIONS, Drug Interactions). Such situations may result in severe hypoglycemia (and, possibly, loss of consciousness) prior to patients' awareness of hypoglycemia. The time of occurrence of hypoglycemia depends on the action profile of the insulins used and may, therefore, change when the treatment regimen or timing of dosing is changed. In patients being switched from other intermediate or long-acting insulin preparations to once- or twice-daily LEVEMIR®, dosages can be prescribed on a unit-to-unit basis; however, as with all insulin preparations, dose and timing of administration may need to be adjusted to reduce the risk of hypoglycemia. **Renal Impairment:** As with other insulins, the requirements for LEVEMIR® may need to be adjusted in patients with renal impairment. **Hepatic Impairment:** As with other insulins, the requirements for LEVEMIR® may need to be adjusted in patients with hepatic impairment. **Injection Site and Allergic Reactions:** As with any insulin therapy, lipodystrophy may occur at the injection site and delay insulin absorption. Other injection site reactions with insulin therapy may include redness, pain, itching, hives, swelling, and inflammation. Continuous rotation of the injection site within a given area may help to reduce or prevent these reactions. Reactions usually resolve in a few days to a few weeks. On rare occasions, injection site reactions may require discontinuation of LEVEMIR®. In some instances, these reactions may be related to factors other than insulin, such as irritants in a skin cleansing agent or poor injection technique. **Systemic allergy:** Generalized allergy to insulin, which is less common but potentially more serious, may cause rash (including pruritus) over the whole body, shortness of breath, wheezing, reduction in blood pressure, rapid pulse, or sweating. Severe cases of generalized allergy, including anaphylactic reaction, may be life-threatening.

**Intercurrent Conditions:** Insulin requirements may be altered during intercurrent conditions such as illness, emotional disturbances, or other stresses. **Information for Patients:** LEVEMIR® must only be used if the solution appears clear and colorless with no visible particles. Patients should be informed about potential risks and advantages of LEVEMIR® therapy, including the possible side effects. Patients should be offered continued education and advice on insulin therapies, injection technique, life-style management, regular glucose monitoring, periodic glycosylated hemoglobin testing, recognition and management of hypo- and hyperglycemia, adherence to meal planning, complications of insulin therapy, timing of dosage, instruction for use of injection devices and proper storage of insulin. Patients should be informed that frequent, patient-performed blood glucose measurements are needed to achieve effective glycemic control to avoid both hyperglycemia and hypoglycemia. Patients must be instructed on handling of special situations such as intercurrent conditions (illness, stress, or emotional disturbances), an inadequate or skipped insulin dose, inadvertent administration of an increased insulin dose, inadequate food intake, or skipped meals. Refer patients to the LEVEMIR® "Patient Information" circular for additional information. As with all patients who have diabetes, the ability to concentrate and/or react may be impaired as a result of hypoglycemia or hyperglycemia. Patients with diabetes should be advised to inform their health care professional if they are pregnant or are contemplating pregnancy (see PRECAUTIONS, Pregnancy). **Laboratory Tests:** As with all insulin therapy, the therapeutic response to LEVEMIR® should be monitored by periodic blood glucose tests. Periodic measurement of HbA<sub>1c</sub> is recommended for the monitoring of long-term glycemic control. **Drug Interactions:** A number of substances affect glucose metabolism and may require insulin dose adjustment and particularly close monitoring. The following are examples of substances that may reduce the blood-glucose-lowering effect of insulin: corticosteroids, danazol, diuretics, sympathomimetic agents (e.g., epinephrine, albuterol, terbutaline), isoniazid, phenothiazine derivatives, somatropin, thyroid hormones, estrogens, progestogens (e.g., in oral contraceptives). The following are examples of substances that may increase the blood-glucose-lowering effect of insulin and susceptibility to hypoglycemia: oral antidiabetic drugs, ACE inhibitors, disopyramide, fibrates, fluoxetine, MAO inhibitors, propoxyphene, salicylates, somatostatin analog (e.g., octreotide), and sulfonamide antibiotics. Beta-blockers, clonidine, lithium salts, and alcohol may either potentiate or weaken the blood-glucose-lowering effect of insulin. Pentamidine may cause hypoglycemia, which may sometimes be followed by hyperglycemia. In addition, under the influence of sympatholytic medicinal products such as beta-blockers, clonidine, guanethidine, and reserpine, the signs of hypoglycemia may be reduced or absent. The results of *in-vitro* and *in-vivo* protein binding studies demonstrate that there is no clinically relevant interaction between insulin detemir and fatty acids or other protein bound drugs. **Mixing of Insulins:** If LEVEMIR® is mixed with other insulin preparations, the profile of action of one or both individual components may change. Mixing LEVEMIR® with insulin aspart, a rapid acting insulin analog, resulted in about 40% reduction in AUC<sub>(0-2h)</sub> and C<sub>max</sub> for insulin aspart compared to separate injections when the ratio of insulin aspart to LEVEMIR® was less than 50%. **LEVEMIR® should NOT be mixed or diluted with any other insulin preparations. Carcinogenicity, Mutagenicity,**

**Impairment of Fertility:** Standard 2-year carcinogenicity studies in animals have not been performed. Insulin detemir tested negative for genotoxic potential in the *in-vitro* reverse mutation study in bacteria, human peripheral blood lymphocyte chromosome aberration test, and the *in-vivo* mouse micronucleus test. **Pregnancy: Teratogenic Effects: Pregnancy Category C:** In a fertility and embryonic development study, insulin detemir was administered to female rats before mating, during mating, and throughout pregnancy at doses up to 300 nmol/kg/day (3 times the recommended human dose, based on plasma Area Under the Curve (AUC) ratio). Doses of 150 and 300 nmol/kg/day produced numbers of litters with visceral anomalies. Doses up to 900 nmol/kg/day (approximately 135 times the recommended human dose based on AUC ratio) were given to rabbits during organogenesis. Drug-dose related increases in the incidence of fetuses with gall bladder abnormalities such as small, bilobed, bifurcated and missing gall bladders were observed at a dose of 900 nmol/kg/day. The rat and rabbit embryofetal development studies that included concurrent human insulin control groups indicated that insulin detemir and human insulin had similar effects regarding embryotoxicity and teratogenicity. **Nursing mothers:** It is unknown whether LEVEMIR® is excreted in significant amounts in human milk. For this reason, caution should be exercised when LEVEMIR® is administered to a nursing mother. Patients with diabetes who are lactating may require adjustments in insulin dose, meal plan, or both. **Pediatric use:** In a controlled clinical study, HbA<sub>1c</sub> concentrations and rates of hypoglycemia were similar among patients treated with LEVEMIR® and patients treated with NPH human insulin. **Geriatric use:** Of the total number of subjects in intermediate and long-term clinical studies of LEVEMIR®, 85 (type 1 studies) and 363 (type 2 studies) were 65 years and older. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. In elderly patients with diabetes, the initial dosing, dose increments, and maintenance dosage should be conservative to avoid hypoglycemic reactions. Hypoglycemia may be difficult to recognize in the elderly.

**ADVERSE REACTIONS:** Adverse events commonly associated with human insulin therapy include the following: **Body as Whole:** allergic reactions (see PRECAUTIONS, Allergy). **Skin and Appendages:** lipodystrophy, pruritus, rash. **Mild injection site reactions** occurred more frequently with LEVEMIR® than with NPH human insulin and usually resolved in a few days to a few weeks (see PRECAUTIONS, Allergy). **Other: Hypoglycemia:** (see WARNINGS and PRECAUTIONS). In trials of up to 6 months duration in patients with type 1 and type 2 diabetes, the incidence of severe hypoglycemia with LEVEMIR® was comparable to the incidence with NPH, and, as expected, greater overall in patients with type 1 diabetes (Table 4). **Weight gain:** In trials of up to 6 months duration in patients with type 1 and type 2 diabetes, LEVEMIR® was associated with somewhat less weight gain than NPH (Table 4). Whether these observed differences represent true differences in the effects of LEVEMIR® and NPH insulin is not known, since these trials were not blinded and the protocols (e.g., diet and exercise instructions and monitoring) were not specifically directed at exploring hypotheses related to weight effects of the treatments compared. The clinical significance of the observed differences has not been established.

**Table 4: Safety Information on Clinical Studies\***

Treatment	# of subjects	Weight (kg)		Hypoglycemia (events/subject/month)		
		Baseline	End of treatment	Major**	Minor***	
<b>Type 1</b>						
Study A	LEVEMIR®	N=276	75.0	75.1	0.045	2.184
	NPH	N=133	75.7	76.4	0.035	3.063
Study C	LEVEMIR®	N=492	76.5	76.3	0.029	2.397
	NPH	N=257	76.1	76.5	0.027	2.564
Study D Pediatric	LEVEMIR®	N=232	N/A	N/A	0.076	2.677
	NPH	N=115	N/A	N/A	0.083	3.203
<b>Type 2</b>						
Study E	LEVEMIR®	N=237	82.7	83.7	0.001	0.306
	NPH	N=239	82.4	85.2	0.006	0.595
Study F	LEVEMIR®	N=195	81.8	82.3	0.003	0.193
	NPH	N=200	79.6	80.9	0.006	0.235

\*See CLINICAL STUDIES section for description of individual studies  
\*\* Major = requires assistance of another individual because of neurologic impairment  
\*\*\* Minor = plasma glucose <56 mg/dl, subject able to deal with the episode him/herself

**OVERDOSAGE:** Hypoglycemia may occur as a result of an excess of insulin relative to food intake, energy expenditure, or both. Mild episodes of hypoglycemia usually can be treated with oral glucose. Adjustments in drug dosage, meal patterns, or exercise may be needed. More severe episodes with coma, seizure, or neurologic impairment may be treated with intramuscular/subcutaneous glucagon or concentrated intravenous glucose. After apparent clinical recovery from hypoglycemia, continued observation and additional carbohydrate intake may be necessary to avoid recurrence of hypoglycemia.

**More detailed information is available upon request.**

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# DOCTOR'S DIGEST

The EHR: HITECH and Your Practice

By Elizabeth Gardner

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**E**lizabeth Gardner is a Chicago-based freelance writer specializing in healthcare, science, and technology. She began her journalism career at *Modern Healthcare*, covering information technology and quality measurement. She is a contributing editor for *Health Data Management* and has also contributed to *Inside Healthcare Computing*, *HealthLeaders*, *Health-IT World*, *Bio-IT World*, *Popular Science*, *New Scientist*, and *Internet World*.

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# Dear Doctor:

Are you planning to upgrade your electronic health record (EHR) system or buy a new one? Don't make any decisions until you've read this issue of *Doctor's Digest*. In what may be our most practical and timely issue ever, this resource

will explain the new federal standards and incentives and then give you insights from the experts to help you make smart decisions for your practice.

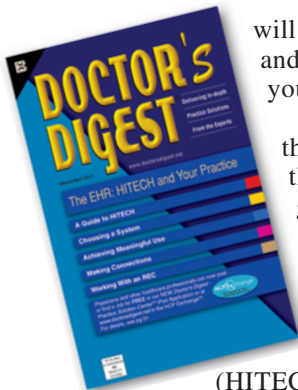
Author Elizabeth Gardner starts by explaining the federal criteria not only for this year but for the near future so you can plan now. Then she gives you tips on how to choose a system, paying particular attention to what "certified" really means. She details how your practice can achieve meaningful use and why systems that came out before the Health Information Technology for Economic and Clinical Health

(HITECH) Act may never meet the new guidelines. She

explains the connections between HITECH and other incentive programs and privacy concerns and what they mean for healthcare in general. Finally, she discusses why your first stop in finding help in your EHR journey should be a Health IT Regional Extension Center (REC).

When it comes to help in finding a job or filling a position, your first stop should be *Doctor's Digest's* new employment service, HCP Exchange™. Whether you're a solo, small- or medium-size practice, you don't want to miss this FREE service for physicians. Just go to [doctorsdigest.net](http://doctorsdigest.net) or look for it in the new, FREE *Doctor's Digest* Practice Solution Center iPad app. This app really delivers! It's available now in iTunes.

I remain dedicated to helping you bridge the gap between the practice of medicine and the business of medicine. As always, I look forward to hearing from you. Contact me at [jbrandofino@doctorsdigest.net](mailto:jbrandofino@doctorsdigest.net) or by fax to 516-364-2575.



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# The EHR: HITECH and Your Practice

It's time to make critical decisions about your electronic health records (EHR) system. But first you need a detailed understanding of the incentives and "meaningful use" requirements as outlined in the federal Health Information Technology for Economic and Clinical Health (HITECH) Act. This issue of *Doctor's Digest* breaks down this complex and confusing topic into easy-to-understand segments and practical tips that you can begin using today.

Author Elizabeth Gardner first guides you through the basics of HITECH, including specifics like registering for payments and seeing how participating in HITECH can work with other incentive programs you may already be involved with. She then explains what HITECH certification really means and how that and other insights will help you choose the right system for your practice. She then dissects the meaning of meaningful use so that you can lose no time in meeting incentive requirements. Next she outlines how core HITECH meaningful use criteria will have an impact on the way you connect with patients, hospitals, and others, and why you should be looking at privacy issues now. Finally she offers a new option: connecting with a Health IT Regional Extension Center (REC) in order to cut costs and get the help you need to earn HITECH money for your practice.

## A Guide to HITECH

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*Learn what HITECH can do for your practice, find out if you're eligible, calculate your HITECH payment, and more.*

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*Find out how to select the right system that will meet meaningful use requirements.*

## Achieving Meaningful Use

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*Get down to the specifics of understanding meaningful use and learning how to make sure you receive HITECH money.*

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*Understand how meaningful use relates to e-prescribing, patient portals, and health information exchanges, and the resulting privacy issues.*

## Working With an REC

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*Find out why a Health IT Regional Extension Center may save you money and ease the hassles of dealing with EHRs and meaningful use.*

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