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NovoLog (insulin aspart (rDNA origin)) - Drug Summary

Novo Nordisk

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Novolog
(insulin aspart (rDNA origin))

THERAPEUTIC CLASS

Insulin (rapid-acting)

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Diabetes Mellitus

SQ/IV:
Total Daily Insulin Requirement:
Usual: 0.5-1 U/kg/day; generally used w/ an intermediate- or long-acting insulin

Meal-Related SQ Regimen:
 50-70% of total requirement may be provided by insulin aspart; remainder provided by an intermediate- or long-acting insulin

PEDIATRIC DOSAGE & INDICATIONS

Type 1 Diabetes Mellitus

≥2 Years:
SQ:
Total Daily Insulin Requirement:
Usual: 0.5-1 U/kg/day; generally used w/ an intermediate- or long-acting insulin

Meal-Related SQ Regimen:
 50-70% of total requirement may be provided by insulin aspart; remainder provided by an intermediate- or long-acting insulin

ADMINISTRATION

SQ/IV route

SQ
 Administer in the abdominal region, buttocks, thigh, or upper arm; rotate inj sites w/in the same region
 Administer immediately (w/in 5-10 min) ac
 May be diluted w/ insulin diluting medium
 If mixed w/ NPH insulin, draw insulin aspart into syringe first and inject immediately after mixing


Continuous SQ Insulin Infusion by External Pump
 Infuse premeal boluses immediately (w/in 5-10 min) ac
 Rotate infusion sites w/in the same region
 Do not use diluted or mixed insulins w/ external pump

Initial Programming of External Insulin Infusion Pump:
 Base on total daily insulin dose of previous regimen
 Approx 50% of total dose given as meal-related boluses; remainder given as basal infusion
 Change insulin in the reservoir at least every 6 days; change infusion sets and infusion set insertion site at least every 3 days


IV
 Use at concentrations 0.05-1.0 U/mL in infusion systems using polypropylene infusion bags; stable in infusion fluids such as 0.9% NaCl
 Do not administer insulin mixtures IV

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HOW SUPPLIED

Inj: 100 U/mL [3mL, PenFill cartridge, FlexPen, FlexTouch; 10mL, vial]

CONTRAINDICATIONS

During episodes of hypoglycemia.

WARNINGS/PRECAUTIONS

Insulin delivery devices should never be shared between patients, even if needle is changed; may carry a risk for transmission of blood-borne pathogens. Any change of insulin dose should be made cautiously and under medical supervision. Changing from 1 insulin product to another or changing the insulin strength may result in the need for a change in dosage. May require dosage adjustment w/ change in physical activity or meal plan. Illness, emotional disturbances, or other stresses may alter insulin requirements. Hypoglycemia may occur and may impair ability to concentrate and react; caution in patients w/ hypoglycemia unawareness and who may be predisposed to hypoglycemia. Hypokalemia, inj-site redness/swelling/itching, and severe, life-threatening, generalized allergy may occur. Contains metacresol as excipient; localized reactions and generalized myalgias reported. Increases in anti-insulin antibodies observed; may need to adjust insulin dose to correct a tendency towards hyper/hypoglycemia. Malfunction of the insulin pump or infusion set or insulin degradation can lead to a rapid onset of hyperglycemia and ketosis; prompt identification and correction of the cause is necessary. Train patients using continuous SQ infusion pump therapy to administer by inj and have alternate insulin therapy available in case of pump failure. IV administration should be under medical supervision w/ close monitoring of blood glucose and K⁺ levels. Caution w/ renal/hepatic impairment.

ADVERSE REACTIONS

Hypoglycemia, headache, hyporeflexia, onychomycosis, sensory disturbance, UTI, nausea, diarrhea, chest pain, abdominal pain, skin disorder, sinusitis.

DRUG INTERACTIONS

May require dose adjustment and increased frequency of glucose monitoring w/ drugs that may increase the risk of hypoglycemia (eg, ACE inhibitors, MAOIs, salicylates), drugs that may decrease the glucose-lowering effect (eg, atypical antipsychotics [eg, olanzapine, clozapine], corticosteroids, oral contraceptives), or drugs that may increase or decrease the glucose-lowering effect (eg, alcohol, β -blockers, clonidine, lithium salts). Pentamidine may cause hypoglycemia, sometimes followed by hyperglycemia. Signs and symptoms of hypoglycemia may be blunted w/ β -blockers, clonidine, guanethidine, and reserpine. Caution w/ K⁺-lowering drugs or drugs sensitive to serum K⁺ concentrations. Observe for signs/symptoms of heart failure (HF) if treated concomitantly w/ a peroxisome proliferator-activated receptor (PPAR)-gamma agonist (eg, thiazolidinedione); consider discontinuation or dose reduction of the PPAR-gamma agonist if HF develops.

PREGNANCY AND LACTATION

Category B, caution in nursing.

MECHANISM OF ACTION

Insulin aspart (rDNA origin); regulates glucose metabolism. Binds to the insulin receptors on muscle and fat cells and lowers blood glucose by facilitating the cellular uptake of glucose and simultaneously inhibiting the output of glucose from the liver.

PHARMACOKINETICS

Absorption: C_{max}=82 mU/L; T_{max}=40-50 min (median). **Distribution:** Plasma protein binding (<10%).
Elimination: T_{1/2}=81 min.

ASSESSMENT

Assess for predisposition to hypoglycemia, risk of hypokalemia, hypersensitivity, renal/hepatic impairment, pregnancy/nursing status, and possible drug interactions. Obtain baseline blood glucose and HbA1c levels.

MONITORING

Monitor for signs/symptoms of hypoglycemia, hypokalemia, allergic reactions, and other adverse effects. Monitor blood glucose, HbA1c, K⁺ levels, and renal/hepatic function.

PATIENT COUNSELING

Advise to never share insulin delivery device w/ another person, even if needle is changed. Inform about potential risks and benefits of therapy. Counsel on proper inj technique, lifestyle management, regular glucose monitoring, periodic HbA1c testing, recognition and management of hypo/hyperglycemia, adherence to meal planning, complications of insulin therapy, timing of dose, instruction in the use of inj or SQ insulin infusion pump, and proper storage of insulin. Inform that the ability to concentrate and react may be impaired as a result of hypoglycemia; advise to use caution when driving or operating machinery. Instruct to always carefully check that appropriate insulin is administered to avoid medication errors. Advise to inform physician if pregnant or intending to become pregnant.

STORAGE

Unused: 2-8°C (36-46°F) until expiration date. Do not freeze or store directly adjacent to the refrigerator cooling element; do not use if it has been frozen. Should not be drawn into a syringe and stored for later use. Opened: <30°C (86°F) for up to 28 days. (Vials) May refrigerate. (PenFill/FlexPen/FlexTouch) Do not refrigerate. Pump: Discard insulin in reservoir after exposure to >37°C (98.6°F). Diluted Sol: <30°C (86°F) for 28 days. Sol in Infusion Fluids: Stable at room temperature for 24 hrs. Protect from direct heat and light.

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