Do not share your HUMALOG Mix50/50 KwikPen, needles or syringes with other people, even if the needle has been changed. You may give other people a serious infection or get a serious infection from them.

**What is HUMALOG Mix50/50?**
- HUMALOG Mix50/50 is a man-made insulin that is used to control high blood sugar in people with diabetes mellitus.
- It is not known if HUMALOG Mix50/50 is safe and effective in children under 18 years of age.

**Who should not take HUMALOG Mix50/50?**
Do not take HUMALOG Mix50/50 if you:
- are having an episode of low blood sugar (hypoglycemia).
- have an allergy to HUMALOG Mix50/50 or any of the ingredients in HUMALOG Mix50/50. See the end of this Patient Information leaflet for a complete list of ingredients in Humalog Mix50/50.

**What should I tell my healthcare provider before taking Humalog Mix50/50?**
Before taking HUMALOG Mix50/50, tell your healthcare provider about all of your medical conditions, including if you:
- have liver or kidney problems.
- take any other medicines, especially ones called TZDs (thiazolidinediones).
- have heart failure or other heart problems. If you have heart failure, it may get worse while you take TZDs with HUMALOG Mix50/50.
- are pregnant or plan to become pregnant. Talk with your healthcare provider about the best way to control your blood sugar if you plan to become pregnant or while you are pregnant.
- are breastfeeding or plan to breastfeed. Talk with your healthcare provider about the best way to feed your baby while taking HUMALOG Mix50/50.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

Before you start taking HUMALOG Mix50/50, talk to your healthcare provider about low blood sugar and how to manage it.

**How should I take HUMALOG Mix50/50?**
- Read the Instructions for Use that comes with your HUMALOG Mix50/50.
- Take HUMALOG Mix50/50 exactly as your healthcare provider tells you to. Your healthcare provider should tell you how much HUMALOG Mix50/50 to take and when to take it.
- **HUMALOG Mix50/50 starts acting fast.** Inject HUMALOG Mix50/50 within 15 minutes before you eat a meal.
- Know the type, strength, and amount of insulin you take. Do not change the type or amount of insulin you take unless your healthcare provider tells you to. The amount of insulin and the best time for you to take your insulin may need to change if you take different types of insulin.
- Check your insulin label each time you give your injection to make sure you are taking the correct insulin.
- Inject Humalog Mix50/50 under the skin (subcutaneously) of your stomach area (abdomen), buttocks, upper legs or upper arms. Do not inject HUMALOG Mix50/50 into your vein (intravenously) or muscle (intramuscularly) or use in an insulin infusion pump.
- Change (rotate) your injection sites within the area you choose with each dose to reduce your risk of getting lipodystrophy (pits in skin or thickened skin) and localized cutaneous amyloidosis (skin with lumps) at the injection sites.
  - Do not use the exact same spot for each injection.
  - Do not inject where the skin has pits, is thickened, or has lumps.
  - Do not inject where the skin is tender, bruised, scaly or hard, or into scars or damaged skin.
- Do not mix Humalog Mix50/50 with other insulins or liquids.
- Check your blood sugar levels. Ask your healthcare provider what your blood sugars should be and when you should check your blood sugar levels.

Keep HUMALOG Mix50/50 and all medicines out of reach of children.

**Your dose of HUMALOG Mix50/50 may need to change because of a:**
- change in physical activity or exercise, weight gain or loss, increased stress, illness, change in diet, or because of other medicines you take.

**What should I avoid while taking HUMALOG Mix50/50?**
While taking HUMALOG Mix50/50 do not:
- drive or operate heavy machinery until you know how HUMALOG Mix50/50 affects you.
- drink alcohol or take prescription or over-the-counter medicines that contain alcohol.
What are the possible side effects of HUMALOG Mix50/50?

HUMALOG Mix50/50 may cause serious side effects that can lead to death, including:

- **low blood sugar (hypoglycemia).** Signs and symptoms of low blood sugar may include:
  - dizziness or light-headedness
  - sweating
  - confusion
  - headache
  - blurred vision
  - slurred speech
  - shakiness
  - fast heartbeat
  - anxiety, irritability or mood changes
  - hunger

Your healthcare provider may prescribe a glucagon emergency kit so that someone else can give you glucagon if your blood sugar becomes too low (severe hypoglycemia) and you are unable to take sugar by mouth.

- **severe allergic reaction (whole body reaction).** Get medical help right away, if you have any of these signs or symptoms of a severe allergic reaction:
  - a rash over your whole body
  - trouble breathing
  - fast heartbeat
  - sweating

- **low potassium in your blood (hypokalemia).**

- **heart failure.** Taking certain diabetes pills called thiazolidinediones or “TZDs” with HUMALOG Mix50/50 may cause heart failure in some people. This can happen even if you have never had heart failure or heart problems before. If you already have heart failure it may get worse while you take TZDs with HUMALOG Mix50/50. Your healthcare provider should monitor you closely while you are taking TZDs with HUMALOG Mix50/50. Tell your healthcare provider if you have any new or worse symptoms of heart failure including:
  - shortness of breath
  - swelling of your ankles or feet
  - sudden weight gain

Treatment with TZDs and HUMALOG Mix50/50 may need to be adjusted or stopped by your healthcare provider if you have new or worse heart failure.

**Get emergency medical help if you have:**

- fast heartbeat
- sweating
- extreme drowsiness
- dizziness

**The most common side effects of HUMALOG Mix50/50 include:**

- low blood sugar (hypoglycemia)
- reactions at your injection site
- skin thickening or pits at the injection site (lipodystrophy)

- weight gain
- swelling in your hands or feet
- itching
- rash

These are not all the possible side effects of HUMALOG Mix50/50. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**General information about the safe and effective use of HUMALOG Mix50/50.**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not take HUMALOG Mix50/50 for a condition for which it was not prescribed. Do not give HUMALOG Mix50/50 to other people, even if they have the same symptoms that you have. It may harm them.

This Patient Information leaflet summarizes the most important information about HUMALOG Mix50/50. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about HUMALOG Mix50/50 that is written for health professionals.

**What are the ingredients in HUMALOG Mix50/50?**

**Active ingredients:** insulin lispro

**Inactive ingredients:** protamine sulfate, glycerin, dibasic sodium phosphate, metacresol, zinc oxide (zinc ion), phenol and water for injection.

Humalog®, Humalog® Mix50/50™ and Humalog® Mix50/50™ KwikPen® are trademarks of Eli Lilly and Company. Marketed by: Lilly USA, LLC, Indianapolis, IN 46285, USA

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For more information, go to www.humalog.com or call 1-800-545-5979.

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