PATIENT INFORMATION HUMULIN® (HU-mu-lin) N

(human insulin [rDNA origin] isophane suspension)

Do not share your HUMULIN N KwikPen 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 HUMULIN N?

• HUMULIN N is a man-made insulin that is used to control high blood sugar in adults and children with diabetes mellitus.

Who should not use HUMULIN N?

Do not use HUMULIN N if you:

- are having an episode of low blood sugar (hypoglycemia).
- have an allergy to HUMULIN N or any of the ingredients in HUMULIN N.

Before using HUMULIN N, tell your healthcare provider about all your medical conditions including, if you:

- have liver or kidney problems.
- take any other medicines, especially ones commonly called TZDs (thiazolidinediones).
- have heart failure or other heart problems. If you have heart failure, it may get worse while you take TZDs with HUMULIN N.
- are pregnant, planning to become pregnant, or are breastfeeding.
- are taking new prescription or over-the-counter medicines, vitamins, or herbal supplements.

Before you start using HUMULIN N, talk to your healthcare provider about low blood sugar and how to manage it.

How should I use HUMULIN N?

- Read the Instructions for Use that come with your HUMULIN N.
- Use HUMULIN N exactly as your healthcare provider tells you to.
- Know the type and strength of insulin you use. Do not change the type of insulin you
 use 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 use different types of
 insulin.
- Check your blood sugar levels. Ask your healthcare provider what your blood sugars should be and when you should check your blood sugar levels.
- Do not share your HUMULIN N KwikPen 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.

Your HUMULIN N dose may need to change because of:

• change in level of physical activity or exercise, weight gain or loss, increased stress, illness, change in diet.

What should I avoid while using HUMULIN N?

While using HUMULIN N do not:

- Drive or operate heavy machinery, until you know how HUMULIN N affects you.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol.

What are the possible side effects of HUMULIN N?

HUMULIN N may cause serious side effects that can lead to death, including:

- low blood sugar (hypoglycemia). Signs and symptoms that may indicate low blood sugar include:
 - dizziness or light-headedness, sweating, confusion, headache, blurred vision, slurred speech, shakiness, fast heartbeat, anxiety, irritability, or mood changes, hunger.
- serious allergic reaction (whole body reaction). Get medical help right away, if you have any of these symptoms of an allergic reaction:
 - a rash over your whole body, trouble breathing, a fast heartbeat, or sweating.
- low potassium in your blood (hypokalemia).
- heart failure. Taking certain diabetes pills called thiazolidinediones or "TZDs" with HUMULIN N 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 HUMULIN N. Your healthcare provider should monitor you closely while you are taking TZDs with HUMULIN N. 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 HUMULIN N 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:

 trouble breathing, shortness of breath, fast heartbeat, swelling of your face, tongue, or throat, sweating, extreme drowsiness, dizziness, confusion.

The most common side effects of HUMULIN N include:

 low blood sugar (hypoglycemia), allergic reactions including reactions at the injection site, skin thickening or pits at the injection site (lipodystrophy), itching, rash, weight gain, and swelling of your hands and feet.

These are not all the possible side effects of HUMULIN N. 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 HUMULIN N:

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your pharmacist or healthcare provider for information about HUMULIN N that is written for health professionals. Do not use HUMULIN N for a condition for which it was not prescribed. Do not give HUMULIN N to other people, even if they have the same symptoms that you have. It may harm them.

What are the ingredients in HUMULIN N?

Active Ingredient: insulin human (rDNA origin)

Inactive Ingredients: protamine sulfate, glycerin, dibasic sodium phosphate, metacresol, phenol, zinc oxide, water for injection, hydrochloric acid or sodium hydroxide

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

This Patient Information has been approved by the U.S. Food and Drug Administration.

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