PATIENT INFORMATION KYGEVVI (KY-JEH-vee) (doxecitine and doxribtimine) powder, for oral solution

What is KYGEVVI?

KYGEVVI is a prescription medicine used for the treatment of thymidine kinase 2 deficiency (TK2d) in adults and children with a symptom onset on or before 12 years of age.

Before taking or giving KYGEVVI, tell your healthcare provider about all of your medical conditions, including if you:

- have or have had liver problems
- are pregnant or plan to become pregnant. It is not known if KYGEVVI will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if KYGEVVI passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take KYGEVVI.

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

How should I take or give KYGEVVI?

- See the detailed Instructions for Use that comes with KYGEVVI for important information about the correct way to prepare and take or give a dose of KYGEVVI.
- Take or give KYGEVVI exactly as your healthcare provider tells you. Your healthcare provider should tell you how much KYGEVVI to take or give, and when to take or give it.
- Your healthcare provider may change your or your child's dose of KYGEVVI depending on how you or your child respond to treatment and based on your or your child's weight.
- Take or give KYGEVVI 3 times a day about 6 hours apart.
- Take or give KYGEVVI with food.
- KYGEVVI may be given through a feeding tube.
- KYGEVVI comes as a packet containing powder.
 - Prepare a one-day supply of KYGEVVI solution each morning.
 - KYGEVVI should be prepared and given by adults only.
 - Do not open the KYGEVVI packets until you are ready to use them.
 - Mix KYGEVVI powder only with room temperature water. Do not mix with any other liquids or foods.
 - o Only use the dosing cup, mixing bottle, and oral syringes provided with your ZX2000 administration kit. **Do not** use a household measuring cup or measuring spoon.
- If you miss a dose of KYGEVVI, take the missed dose as soon as possible. If it is within 2 hours of your next scheduled dose, do not take the missed dose. Take your next dose at your next scheduled time. **Do not** take 2 doses to make up for the missed dose.
- If you spit out the dose or do not take the full dose of KYGEVVI, **do not** take another dose. Take your next dose at your next scheduled time.

What are the possible side effects of KYGEVVI?

KYGEVVI may cause serious side effects, including:

- Increased liver enzyme levels. Increased liver enzyme levels in your blood are common with KYGEVVI. Your
 healthcare provider will do blood tests to check your liver enzyme levels before starting treatment and during
 treatment with KYGEVVI. Tell your healthcare provider right away if you develop any signs or symptoms of liver
 problems, including:
 - o loss of appetite

- o yellowing of your skin or the white part of your eyes
- o pain on the right side of your stomach area
- nausea and vomiting

o dark or amber-colored urine

- itching
- Stomach and intestinal (gastrointestinal) problems. Diarrhea and vomiting are common with KYGEVVI, but may also be severe and lead to hospitalization. Tell your healthcare provider right away if you have diarrhea or vomiting during treatment with KYGEVVI that lasts longer than a few days.

The most common side effects of KYGEVVI include:

- diarrhea
- stomach area (abdominal) pain including pain in the upper stomach area
- vomiting
- increased liver enzyme levels in your blood

Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with KYGEVVI if you develop certain side effects.

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

How should I store KYGEVVI?

- Store KYGEVVI packets at room temperature between 68°F to 77°F (20°C to 25°C).
- Store prepared KYGEVVI solution at room temperature between 68°F to 77°F (20°C to 25°C) **or** in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Use KYGEVVI solution within 16 hours of preparing. Throw away (discard) any remaining solution 16 hours after preparing **or** after taking or giving the 3 doses, whichever comes first.

Keep KYGEVVI and all medicines out of the reach of children.

General information about the safe and effective use of KYGEVVI.

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

What are the ingredients in KYGEVVI?

Active ingredients: doxecitine and doxribtimine.

Inactive ingredients: colloidal silicon dioxide and magnesium stearate.

Manufactured for: UCB, Inc., Smyrna, GA 30080

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For more information about KYGEVVI, go to www.KYGEVVI.com or call 1-844-599-2273.

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

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