

## For the Patient: ULKMDSDC

Other Names: Therapy of Myelodysplastic Syndrome using Decitabine-Cedazuridine (INQOVI®)

U = Undesignated
 LK = LeuKemia
 MDS = MyeloDysplastic Syndrome
 D = Decitabine
 C = Cedazuridine

### **ABOUT THIS TREATMENT**

## What are these drugs used for?

 Decitabine-cedazuridine (dee sye' ta been-sed" az ure' i deen) is a drug that is used to treat myelodysplastic syndrome (MDS). It is an oral tablet that you take by mouth.

## How does this drug work?

- There are two active ingredients in the tablet:
  - Decitabine kills cancer cells by interfering with the genetic material of replicating cells and preventing an increase in the number of cancer cells.
  - Cedazuridine stops the body from breaking down decitabine, so decitabine can kill cancer cells.

### **INTENDED BENEFITS**

- Decitabine-cedazuridine is for patients with MDS who are not planned to have stem cell transplantation.
- This therapy is being given to extend life.

#### TREATMENT SUMMARY

#### How is this drug given?

- Decitabine-cedazuridine tablets will be provided to you, to be taken by mouth on an empty stomach, at least 2 hours before or 2 hours after a meal.
- The medication should be taken around the same time each day on treatment days.
- The medication should be swallowed whole. Do not crush or chew the tablet.
- Tablets contain lactose.
- Your treatment plan consists of chemotherapy "cycles". Each cycle lasts 4 weeks (28 days).
- Decitabine-cedazuridine is usually taken once daily for 5 days, followed by a 23 day break.

The calendar on the next page outlines how the medication is given for each 4 week cycle.

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С	DATE	TREATMENT PLAN	
Y		► Week 1 → Decitabine-cedazuridine orally once daily for 5 days	
C L		Week 2 → no treatment	
E		Week 3 → no treatment	
1		Week 4 → no treatment	

This 28-day cycle will repeat until your treatment is completed, as determined by your cancer care team.

## What will happen when I get my medication?

- A blood test is done before treatment starts.
- A blood test is also done weekly for the first cycle, then before each cycle, on or before the first day of each cycle. The dose and timing of your chemotherapy may change based on your blood counts and/or other side effects.
- You will have a discussion about the chemotherapy with a member of your health care team prior to starting the medication. It is a good idea to bring someone with you to this appointment.

#### Note:

- If you miss a dose of decitabine-cedazuridine, take it as soon as you can if it is within 12 hours of the missed dose. If it is more than 12 hours since your missed dose, skip the missed dose and go back to your usual dosing time. Do NOT take a double dose to make up for the missed dose. Ask your doctor if you need to extend your dosing period by one day to make up for the missed dose.
- If you **vomit** the dose of decitabine-cedazuridine, do not take a second dose. Skip the missed dose and go back to your usual dosing time. Let your doctor know as a medication to prevent nausea may be required for future doses.
- Medications interactions:
  - Other drugs may **interact** with decitabine-cedazuridine. Check with your doctor or pharmacist before you start or stop taking any other drugs. Drugs to reduce stomach acid (e.g., omeprazole (LOSEC®), ranitidine (ZANTAC®), calcium carbonate (TUMS®)) should NOT be taken within 4 hours of decitabine-cedazuridine.

### SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Unexpected and unlikely side effects can occur with any medication treatment. The ones listed below are particularly important for you to be aware of as they are directly related to the common actions of the medication in your treatment plan.

A member of your care team will review the risks of treatment and possible side effects, and the management of side effects with you before starting treatment.

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## Changes in blood counts

Decitabine-cedazuridine may cause temporary a drop in your blood counts. Your cancer care team will be following these changes carefully by performing blood tests.

Adjustment of your treatment may be needed in certain circumstances.

BLOOD COUNTS	MANAGEMENT
Normal white blood cells protect your body by fighting bacteria (germs) that cause infection. When they are low, you are at greater risk of having an infection.	<ul> <li>To help prevent infection:</li> <li>Wash your hands often and always after using the bathroom.</li> <li>Avoid crowds and people who are sick.</li> <li>Call your doctor <i>immediately</i> at the first sign of an infection such as fever (over 100°F or 38°C by an oral thermometer), chills, cough, or burning when you pass urine.</li> </ul>
Normal platelets help your blood to clot normally after an injury (e.g., cut). When the platelet count is low, you may be more likely to bruise or bleed.	<ul> <li>To help prevent bleeding problems:</li> <li>Try not to bruise, cut, or burn yourself.</li> <li>Clean your nose by blowing gently. Do not pick your nose.</li> <li>Avoid constipation.</li> <li>Brush your teeth gently with a soft toothbrush as your gums may bleed more easily. Some medications such as ASA (e.g., ASPIRIN®) or ibuprofen (e.g., ADVIL®) may increase your risk of bleeding.</li> <li>Do not stop taking any medication that has been prescribed by your doctor (e.g., ASA for your heart) without discussing with them first.</li> <li>For minor pain, try acetaminophen (e.g., TYLENOL®).</li> </ul>

Side effects are listed in the following table in the order in which they may occur. Tips to help manage the side effects are included.

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SIDE EFFECTS	MANAGEMENT
Nausea and vomiting may sometimes occur. Most people have little or no nausea.	You may be given a prescription for antinausea drug(s) to take at home. It is easier to prevent nausea than treat it once it has occurred, so follow directions closely.  • Drink plenty of fluids.  • Eat and drink often in small amounts.  • Try the ideas in <i>Practical Tips to Manage Nausea.</i> *
<b>Tiredness</b> and lack of energy commonly occur.	<ul> <li>Do not drive a car or operate machinery if you are feeling tired.</li> <li>Try the ideas in Fatigue/Tiredness – Patient Handout.*</li> </ul>
Skin rashes may sometimes occur.	If itching is very irritating, call your doctor. Otherwise, be sure to mention it at your next visit.
Fever may sometimes occur.	Fever (over 38°C or 100°F by an oral thermometer) which occurs more than a few days after treatment may be a sign of an infection. Report this to a doctor <i>immediately</i> .
Diarrhea may sometimes occur.	If diarrhea is a problem:  Drink plenty of fluids.  Eat and drink often in small amounts.  Avoid high fibre foods as outlined in Food Choices to Help Manage Diarrhea.*  Note: If lactose in milk usually gives you diarrhea, the lactose in the tablet may be causing your diarrhea. Take LACTAID® tablets just before your decitabine-cedazuridine dose.
Constipation may sometimes occur.	<ul> <li>Exercise if you can.</li> <li>Drink plenty of fluids.</li> <li>Try ideas in Food Choices to Manage Constipation.*</li> </ul>
<b>Sugar control</b> may sometimes be affected in patients with diabetes.	Check your blood sugar regularly if you are diabetic.

SIDE EFFECTS	MANAGEMENT
Sore mouth may sometimes occur. Mouth sores can occur on the tongue, the sides of the mouth, or in the throat. Mouth sores or bleeding gums can lead to an infection.	Brush your teeth gently after eating and at bedtime with a very soft toothbrush. If your gums bleed, use gauze instead of a brush. Use baking soda instead of toothpaste.
	<ul> <li>Make a mouthwash with ¼ teaspoon baking soda AND ¼ teaspoon salt in 1 cup warm water and rinse several times a day.</li> </ul>
	Try the ideas in <i>Food Ideas to Try with a</i> Sore Mouth.*
Headache may sometimes occur.	Take acetaminophen (e.g., TYLENOL®) every 4-6 hours if needed, to a maximum of 4 g (4000 mg) per day.
Muscle or joint pain may sometimes occur.	You may take acetaminophen (e.g., TYLENOL®) every 4-6 hours to a maximum of 4 g (4000 mg) per day. Tell your doctor if the pain interferes with your activity.
<b>Swelling</b> of hands, feet, or lower legs may sometimes occur if your body retains extra fluid.	If swelling is a problem:  • Elevate your feet when sitting.  Avoid tight clothing.
You may sometimes have <b>trouble</b> sleeping.	Talk to your doctor if you continue to have trouble sleeping.
Loss of appetite and weight loss may sometimes occur and may persist after stopping decitabine-cedazuridine.	Try the ideas in Food Ideas to Help with Decreased Appetite.*
Numbness or tingling of the fingers or toes may sometimes occur.	Be careful when handling items that are sharp, hot, or cold.  Tell your doctor at your next visit, especially if you have trouble with buttons, writing, or picking up small objects.
Hair loss does not occur with decitabine-cedazuridine. *Please ask your purse or pharmacist for a company of the company of th	

<sup>\*</sup>Please ask your nurse or pharmacist for a copy.

# STOP TAKING DECITABINE-CEDAZURIDINE AND SEE YOUR DOCTOR OR GET EMERGENCY HELP IMMEDIATELY IF YOU HAVE:

- Signs of an infection such as fever (over 38°C or 100°F by an oral thermometer), shaking chills; severe sore throat, productive cough (coughing up thick or green sputum); cloudy or foul smelling urine; painful, tender, or swollen red skin wounds or sores.
- Signs of bleeding problems such as black, tarry stools; blood in urine; pinpoint red spots on skin; extensive bruising.
- Signs of an **allergic reaction** (rare) including dizziness, fast heartbeat, face swelling, or breathing problems.
- Signs of **heart problems** such as fast, slow, or uneven heartbeat.
- Signs of lung problems such as new or worsening cough, chest pain, shortness of breath, or difficulty in breathing.
- Rapid weight gain.

# SEE YOUR DOCTOR AS SOON AS POSSIBLE (DURING OFFICE HOURS) IF YOU HAVE:

- Signs of anemia such as unusual tiredness or weakness.
- Signs of liver problems such as yellow eyes or skin, white or clay-coloured stools.
- Signs of kidney problems such as lower back or side pain, swelling of feet or lower legs.

# CHECK WITH YOUR DOCTOR IF ANY OF THE FOLLOWING CONTINUE OR BOTHER YOU:

- Abdominal pain.
- Dizziness.
- For patients with diabetes: uncontrolled blood sugars.

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