Medication Information Sheet

decitabine / cedazuridine

(deh-SIH-tuh-been / SED az URE i deen)

This document provides general information about your medication. It does not replace the advice of your health care professional. Always discuss your therapy with your health care professional and refer to the package insert for more details.

Other Name: Inqovi®

Appearance: Oval-shaped red tablets

What is this medication for?

• For treating a group of blood cancers called myelodysplastic syndromes (MDS) including chronic myelomonocytic leukemia (CMML).

What should I do before I have this medication?

Tell your health care team if you have or had significant medical condition(s), especially if you have / had:

- kidney or liver problems
- lung disease
- a low blood cell count (platelets, red or white blood cells)
- an infection or flu-like symptoms or
- any allergies

Decitabine / cedazuridine tablets contains a small amount of lactose. If you cannot have lactose, talk to your health care team.

Remember to:

- Tell your health care team about all of the other medications you are taking.
- Keep taking other medications that have been prescribed for you, unless you have been told not to by your health care team.

The most updated information sheet version can be found on <u>https://www.cancercareontario.ca/drugs</u> Additional symptom management information is available from <u>https://www.cancercareontario.ca/symptoms</u>

Created by the CCO Drug Formulary team, with input from the CCO Patient Education team and Patient & Family Advisors. February 2024

How will this medication affect sex, pregnancy and breastfeeding?

Talk to your health care team about:

- How this medication may affect your sexual health.
- How this medication may affect your ability to have a baby, if this applies to you.

This medication may harm an unborn baby. Tell your health care team if you or your partner are pregnant, become pregnant during treatment, or are breastfeeding.

- If there is **any** chance of pregnancy happening, you and your partner together must use **2 effective forms of birth control** at the same time until **6 months** after your last dose if you are female and **3 months** after your last dose if you are male. Talk to your health care team about which birth control options are best for you.
- Do not breastfeed while on this medication and for at least 2 weeks after your last dose.

How is this medication given?

- This medication is usually taken once a day by mouth for 5 days in a row. This is followed by 23 days with no treatment. Talk to your health care team about how and when to take your medication.
- Swallow whole with a glass of water on an empty stomach, at least 2 hours before or after food.
- Do not cut, crush or chew the tablets.
- If you miss a dose, take it if it is within 12 hours from the missed dose, otherwise skip and take your next dose as scheduled. Extend your dosing period by one day for every missed dose to complete all 5 doses. Do not double the dose to make up for the forgotten dose.
- If you vomit (throw up) after taking a dose of decitabine / cedazuridine, do not take an additional dose on that day. Take your next scheduled dose at your usual time.
- If you take too much of your medication by accident, or if you think a child or a pet may have swallowed your medication, you must call the Ontario Poison Control Center right away at: 1-800-268-9017.

To Prevent or Treat Nausea and Vomiting

Anti-nausea medications are used to prevent or stop nausea (feeling like throwing up) and vomiting (throwing up) before they start. You may be given these medications.

• Anti-nausea medications to prevent nausea and vomiting before they start include ondansetron (Zofran®), granisetron (Kytril®), or others.

Additional symptom management information is available from https://www.cancercareontario.ca/symptoms

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If you already have nausea and/or vomiting, some anti-nausea medication can stop them from getting worse. You may be given anti-nausea medications to have at home in case you start to feel nausea or if you vomit.

• Anti-nausea medications to stop nausea and vomiting include prochlorperazine (Stemetil®), metoclopramide (Maxeran®), or others.

What else do I need to know while on this medication?

Will this medication interact with other medications or natural health products?

- This medication can interact with other medications, vitamins, foods and natural health products. Interactions can make the treatment not work as well or cause severe side effects.
- Tell your health care team about all of your:
 - prescription and over-the-counter (non-prescription) medications and all other drugs, such as marijuana (medical or recreational)
 - natural health products such as vitamins, herbal teas, homeopathic medicines, and other supplements
- Check with your health care team before starting or stopping any of them.
- If you need to take medications to help with heartburn, acid reflux or a stomach ulcer (such as calcium carbonate, ranitidine or omeprazole), take it **4 hours** before or after you take your decitabine / cedazuridine tablet.

What should I do if I feel unwell, have pain, a headache or a fever?

- Always check your temperature to see if you have a fever **before** taking any medications for fever or pain (such as acetaminophen (Tylenol®) or ibuprofen (Advil®)).
 - Fever can be a sign of infection that may need treatment right away.
 - If you take these medications before you check for fever, they may lower your temperature and you may not know you have an infection.

How to check for fever:

Keep a digital (electronic) thermometer at home and take your temperature if you feel hot or unwell (for example, chills, headache, mild pain).

• You have a fever if your temperature taken in your mouth (oral temperature) is:

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• 38.3°C (100.9°F) or higher at any time

OR

• 38.0°C (100.4°F) or higher for at least one hour.

If you do have a fever:

- Try to contact your health care team. If you are not able to talk to them for advice, you MUST get emergency medical help right away.
- Ask your health care team for the <u>Fever</u> pamphlet for more information.

If you do not have a fever but have mild symptoms such as headache or mild pain:

- Ask your health care team about the right medication for you. **Acetaminophen (Tylenol®)** is a safe choice for most people.
- Talk to your health care team before you start taking lbuprofen (Advil®, Motrin®), naproxen (Aleve®) or ASA (Aspirin®), as they may increase your chance of bleeding or interact with your cancer treatment.
- Talk to your health care team if you already take **low dose aspirin** for a medical condition (such as a heart problem). It may still be safe to take.

What to DO while on this medication:

- DO check with your health care team before getting any vaccinations, surgery, dental work or other medical procedures.
- DO tell your health care team about any serious infections that you have now or have had in the past.
- DO wear shoes that have nonslip soles and some ankle support. Also try to stand up slowly after sitting or lying down to lower your chance of falling down.

What NOT to DO while on this medication:

- DO NOT smoke or drink alcohol while on treatment without talking to your health care team first. Smoking and drinking can make side effects worse and make your treatment not work as well.
- DO NOT drive, operate machinery or do any tasks that need you to be alert if you feel drowsy or dizzy.

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How should I safely store this medication?

- Do not throw out any unused medications at home. Bring them to your pharmacy to be thrown away safely.
- Keep this medication in the original packaging at room temperature in a dry place, away from heat and light. Keep out of sight and reach of children and pets.
- How to safely touch oral anti-cancer medications

If you are a patient:

- Wash your hands before and after touching your oral anti-cancer medication.
- Swallow each pill whole. Do not crush or chew your pills.

If you are a caregiver:

- Wear nitrile or latex gloves when touching tablets, capsules or liquids.
- Wash your hands before putting on your gloves and after taking them off, even if your skin did not touch the oral anti-cancer medication.
- Throw out your gloves after each use. Do not re-use gloves.
- Do not touch oral anti-cancer medications if you are pregnant or breastfeeding.
- What to do if oral anti-cancer medication gets on your skin or in your eyes

If medication gets on your skin:

- Wash your skin with a lot of soap and water.
- If your skin gets red or irritated, talk to your health care team.

If medication gets in your eyes:

 Rinse your eyes with running water right away. Keep water flowing over your open eyes for at least 15 minutes.

What are the side effects of this medication?

The following table lists side effects that you may have when getting decitabine / cedazuridine. The table is set up to list the most common side effects first and the least common last. It is unlikely that you will have all of the side effects listed and you may have some that are not listed.

Additional symptom management information is available from https://www.cancercareontario.ca/symptoms

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Read over the side effect table so that you know what to look for and when to get help. Refer to this table if you experience any side effects while on decitabine / cedazuridine.

Very Common Side Effects (50 or more out of 100 people)	
Side effects and what to do	When to contact health care team
Low neutrophils (white blood cells) in the blood (neutropenia) (May be severe)	If you have a fever, try to contact your health care team.
When neutrophils are low, you are at risk of getting an infection more easily. Ask your health care team for the <u>Neutropenia (Low white blood cell count</u>) pamphlet for more information.	If you are unable to talk to the team for advice, you MUST get emergency medical help right away.
What to look for?	away.
 If you feel hot or unwell (for example if you have chills or a new cough), you must check your temperature to see if you have a fever. Do not take medications that treat a fever before you take your temperature (for example, Tylenol®, acetaminophen, Advil® or ibuprofen). Do not eat or drink anything hot or cold right before taking your temperature. 	
You have a fever if your temperature taken in your mouth (oral temperature) is:	
 38.3°C (100.9°F) or higher at any time OR 	
 38.0°C (100.4°F) or higher for at least one hour. 	
What to do?	
If your health care team has told you that you have low neutrophils:	
 Wash your hands often to prevent infection. Check with your health care team before getting any vaccines, surgeries, medical procedures or visiting your dentist. Keep a digital thermometer at home so you can easily check for a fever. 	
If you have a fever:	
If you have a fever, try to contact your health care team. If you are unable to talk to the team for advice, you must get emergency medical help right away.	

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Very Common Side Effects (50 or more out of 100 people)	
Side effects and what to do	When to contact health care team
Low platelets in the blood	Talk to your health
(May be severe)	care team if you have any signs of bleeding. If you
When your platelets are low, you are at risk for bleeding and bruising. Ask your health care team for the Low Platelet Count pamphlet for more information.	have bleeding that doesn't stop or is severe (very
What to look for?	heavy), you MUST get emergency help right away.
Watch for signs of bleeding:	noip right array.
 bleeding from your gums unusual or heavy nosebleeds bruising easily or more than normal black coloured stools (poo) or blood in your stools (poo) coughing up red or brown coloured mucus dizziness, constant headache or changes in your vision heavy vaginal bleeding red or pink coloured urine (pee) 	
What to do? If your health care team has told you that you have low platelets:	
 Tell your pharmacist that your platelet count may be low before taking any prescriptions or over-the-counter medication. Check with your healthcare team before you go to the dentist. Take care of your mouth and use a soft toothbrush. Try to prevent cuts and bruises. Ask your health care team what activities are safe for you. Your treatment may have to be delayed if you have low platelets. Your health care team may recommend a blood transfusion. 	
If you have signs of bleeding:	
 If you have a small bleed, clean the area with soap and water or a saline (saltwater) rinse. Apply pressure for at least 10 minutes. 	
If you have bleeding that does not stop or is severe (very heavy), you must get emergency medical help right away.	

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Very Common Side Effects (50 or more out of 100 people)	
Side effects and what to do	When to contact health care team
 Fatigue What to look for? Feeling of tiredness or low energy that lasts a long time and does not go away with rest or sleep. 	Talk to your health care team if it does not improve or if it is severe.
 What to do? Be active. Aim to get 30 minutes of moderate exercise (you are able to talk comfortably while exercising) on most days. Check with your health care team before starting any new exercise. Pace yourself, do not rush. Put off less important activities. Rest when you need to. Ask family or friends to help you with things like housework, shopping, and child or pet care. Eat well and drink at least 6 to 8 glasses of water or other liquids every day (unless your health care team has told you to drink more or less). Avoid driving or using machinery if you are feeling tired. 	

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
 Constipation What to look for? Having bowel movements (going poo) less often than normal. Small hard stools (poo) that look like pellets. The need to push hard and strain to have any stool (poo) come out. Stomach ache or cramps. A bloated belly, feeling of fullness, or discomfort. Leaking of watery stools (poo). Lots of gas or burping. Nausea or vomiting. 	Talk to your health care team if it does not improve or if it is severe.

What to do? To help prevent constipation: • Try to eat more fiber rich foods like fruits with skin, leafy greens and whole grains. • Drink at least 6 to 8 cups of liquids each day unless your health care team has told you to drink more or less. • Be Active. Exercise can help to keep you regular. • If you take opioid pain medication, ask your health care team if eating more fibre is right for you. To help treat constipation: • If you have not had a bowel movement in 2 to 3 days you may need to take a laxative (medication to help you poo) to help you have regular bowel movements. Ask your health care team what to do. Ask your health care team for the Constipation Pamphlet for more information. Talk to your health care team if it	Common Side Effects (25 to 49 out of 100 people)	
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Headache; mild joint, muscle pain or cramps Talk to your health care team if it does not improve or if it is severe. • Mild headache New pain in your muscles or joints, muscle cramps, or feeling achy. What to do? • Take pain medication (acetaminophen or opioids such as codeine, morphine, hydromorphone, oxycodone) as prescribed. • Read the above section: "What should I do if I feel unwell, have pain, a headache or a fever?" before taking acetaminophen (Tylenol®), ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or Aspirin. These medications may hide an infection that needs treatment or they may increase your risk of bleeding. • Rest often and try light exercise (such as walking) as it may help.	a laxative (medication to help you poo) to help you have regular bowel	
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Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
Mouth sores What to look for?	Talk to your health care team as soon as you notice
 Round, painful, white or gray sores inside your mouth that can occur on the tongue, lips, gums, or inside your cheeks. In more severe cases they may make it hard to swallow, eat or brush your teeth. They may last for 3 days or longer. 	mouth or lip sores or if it hurts to eat, drink or swallow.
What to do?	
To help prevent mouth sores:	
 Take care of your mouth by gently brushing and flossing regularly. Rinse your mouth often with a homemade mouthwash. To make a homemade mouthwash, mix 1 teaspoonful of baking soda and 1 teaspoonful of salt in 4 cups (1L) of water. Do not use store-bought mouthwashes, especially those with alcohol, because they may irritate your mouth. 	
If you have mouth sores:	
 Avoid hot, spicy, acidic, hard or crunchy foods. Your doctor may prescribe a special mouthwash to relieve mouth sores and prevent infection. Talk to your health care team as soon as you notice mouth or lip sores or if it hurts to eat, drink or swallow. 	
Ask your health care team for the Oral Care (Mouth Care) pamphlet for more information.	
Nausea and vomiting	Talk to your healthcare team if
(Generally mild)	nausea lasts more
What to look for?	than 48 hours or vomiting lasts
 Nausea is feeling like you need to throw up. You may also feel light-headed. You may feel nausea within hours to days after your treatment. 	more than 24 hours or if it is severe.
What to do?	

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
To help prevent nausea:	
 It is easier to prevent nausea than to treat it once it happens. If you were given anti-nausea medication(s), take them as prescribed, even if you do not feel like throwing up. Drink clear liquids and have small meals. Get fresh air and rest. Do not eat spicy, fried foods or foods with a strong smell. Limit caffeine (like coffee, tea) and avoid alcohol. 	
If you have nausea or vomiting:	
 Take your rescue (as-needed) anti-nausea medication(s) as prescribed. Ask your health care team for the <u>Nausea & Vomiting</u> pamphlet for more information. Talk to your health care team if: 	
 nausea lasts more than 48 hours vomiting lasts more than 24 hours or if it is severe 	
Cough and feeling short of breath	Talk to your health
What to look for?	care team. If you are not able to talk
You may have a cough and feel short of breath.Symptoms that commonly occur with a cough are:	to your health care team for advice, and you have a
 Wheezing or a whistling breathing Runny nose Sore throat Heartburn Weight loss Fever and chills Rarely this may be severe with chest pain, trouble breathing or coughing up blood. 	fever or severe symptoms, you MUST get emergency medical help right away.
What to do?	
 Check your temperature to see if you have a fever. Read the above section "What should I do if I feel unwell, have pain, a headache or a fever?" If you have a fever, try to talk to your health care team. If you are not able 	

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Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
 to talk to them for advice, you MUST get emergency medical help right away. If you have a severe cough with chest pain, trouble breathing or you are coughing up blood, get medical help right away. 	
Diarrhea What to look for?	Talk to your health care team if no improvement after
 Loose, watery, unformed stool (poo) that may happen days to weeks after you get your treatment. 	24 hours of taking diarrhea medication or if
What to do?	severe (more than 7 times in one day).
If you have diarrhea:	
 Take anti-diarrhea medication if your health care team prescribed it or told you to take it. Do not eat foods or drinks with artificial sweetener (like chewing gum or 'diet' drinks), coffee and alcohol. Eat many small meals and snacks instead of 2 or 3 large meals. Drink at least 6 to 8 cups of liquids each day, unless your health care team has told you to drink more or less. Talk to your health care team if you can't drink 6 to 8 cups of liquids each day when you have diarrhea. You may need to drink special liquids with salt and sugar, called Oral Rehydration Therapy. Talk to your health care team if your diarrhea does not improve after 24 hours of taking diarrhea medication or if you have diarrhea more than 7 times in one day. 	
DizzinessWhat to look for?You may feel light-headed and like you might faint (pass out).	Talk to your health care team if it does not improve or if it is severe.
What to do?	
 Lay down right away so you do not fall. Slowly get up and start moving once you feel better. Do not drive a motor vehicle or use machinery if you feel dizzy. 	

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Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
 Rash; dry, itchy skin What to look for? You may have cracked, rough, flaking or peeling areas of the skin. 	Talk to your health care team if it does not improve or if it is severe.
 Your skin may look red and feel warm, like a sunburn. Your skin may itch, burn, sting or feel very tender when touched. 	
What to do?	
To prevent and treat dry skin:	
 Use fragrance-free skin moisturizer. Protect your skin from the sun and the cold. Use sunscreen with UVA and UVB protection and a SPF of at least 30. Avoid perfumed products and lotions that contain alcohol. Drink 6 to 8 cups of non-alcoholic, non-caffeinated liquids each day, unless your health care team has told you to drink more or less. 	
Rash may be severe in some rare cases and cause your skin to blister or peel. If this happens, get emergency medical help right away.	
Mild swelling	Talk to your health
What to look for?	care team if it does not improve
 You may have mild swelling or puffiness in your arms and/or legs. Rarely, this may be severe. 	or if it is severe.
What to do?	
To help prevent swelling:	
• Eat a low-salt diet.	
If you have swelling:	
 Wear loose-fitting clothing. For swollen legs or feet, keep your feet up when sitting. 	

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Side effects and what to do	When to contac health care tean
Low appetite, Weight loss	Talk to your health care team if it
What to look for?	does not improve or if it is severe.
 Loss of interest in food or not feeling hungry. 	
What to do?	
Try to eat your favourite foods.	
Eat small meals throughout the day.You may need to take meal supplements to help keep your weight up.	
 Talk to your health care team if you have no appetite. 	
Ask your health care team for the <u>Loss of Appetite</u> pamphlet for more information.	
Liver problems	Get emergency help right away.
Your health care team may check your liver function with a blood test. The liver changes do not usually cause any symptoms.	neip ngni away.
What to look for?	
 Rarely, you may develop yellowish skin or eyes, unusually dark pee or pain on the right side of your belly. This may be severe. 	
What to do?	
If you have any symptoms of liver problems, get emergency medical help right away.	
Pains or cramps in the belly	Talk to your health care team if it
What to look for?	does not improve or if it is severe.
Pain or cramps in your belly.Constipation and diarrhea can cause pain in your belly.	
What to do?	
 If the pain is severe, gets worse or doesn't go away, talk to your health care team about other possible causes. 	

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Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
Kidney problems Your health care team may check for proteins in your urine (pee) and your kidney function regularly with a blood test. You may have blood in your urine.	Get emergency medical help right away.
What to look for?	
 Swelling in your hands, ankles, feet or other areas of your body. Weight gain that is not normal for you. Pain in your lower back. Muscle twitches and cramps or itchiness that won't go away. Nausea (feeling like you need to throw up) and vomiting. Changes in urination (peeing) such as less urine than usual. 	
What to do?	
 If you have any of these signs, talk to your health care team or go to your closest emergency department. 	
To prevent kidney infections:	
 Drink at least 6 to 8 cups (2 litres) of water or other liquids per day unless your health care team has told you to drink more or less. When you feel the need to pee, go as soon as possible. Do not wait or hold in the pee. 	
Neuropathy (Tingling, numb toes or fingers) What to look for?	Talk to your health care team, especially if you
 Numbness or tingling of your fingers and toes may happen after starting your treatment. Sometimes it can be painful and feel like burning sensation, which may be severe. 	have trouble doing tasks like doing up buttons, writing, moving, or if you have severe pain or numbness.

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
What to do?	
 Talk to your health care team if you have symptoms of neuropathy. Numbness and tingling may slowly get better after your treatment ends. 	
In rare cases, it may continue long after treatment ends. If you continue to have bothersome symptoms, talk to your health care team for advice.	
Trouble Sleeping	Talk to your health
Your medications may cause trouble sleeping. It may get better once your body gets used to the medication or when your treatment ends.	care team if it does not improve or if it is severe.
What to look for?	
 You may find it hard to fall asleep or stay asleep. How well you sleep may change over your treatment. For example, you may have several nights of poor sleep followed by a night of better sleep. You may wake up too early or not feel well-rested after a night's sleep. You may feel tired or sleepy during the day. 	
What to do?	
Talk to your health care team if it does not improve or if it is severe,	
Heart problems	Get emergency
What to look for?	medical help right away.
 You may have an irregular heartbeat, shortness of breath, chest pain or fainting spells. Swelling in your legs, ankles and belly. Sharp pain in the centre or left side of the chest (often worsens when taking a deep breath). Extreme tiredness that prevents you from exercising or doing normal activities. 	
What to do?	
Get emergency medical help right away.	

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
 Low blood pressure What to look for? You may feel tired, dizzy or light-headed. You may have nausea (feeling like you need to throw up), vomiting or blurred vision. You may faint (pass out). What to do? Check your blood pressure often. Talk to your health care team to find out what a safe blood pressure is for you. If you feel dizzy or unwell lay down right away so that you do not fall. Try to get up and move slowly only once you feel better. Do not drive a motor vehicle or operate machinery if you feel dizzy. 	Talk to your health care team if it does not improve or if it is severe.

Other rare, but serious side effects are possible.

If you experience ANY of the following, speak to your cancer health care provider or get emergency medical help right away:

- Signs of an allergic reaction: itchiness, rash, swollen lips, face or tongue, chest and throat tightness, especially during or shortly after the medication is given
- New swelling of arms, legs, neck, groin, or underarm area
- Unusual fast weight gain, bone pain
- Sudden fever, sore red spots or blisters mostly on the arms, face, neck, back or legs; unusual joint pain, sore eyes

Who do I contact if I have questions or need help?

My cancer health care provider is: _____

During the day I should contact:_____

Evenings, weekends and holidays:

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Other Notes:



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For more links on how to manage your symptoms go to www.cancercareontario.ca/symptoms.

The information set out in the medication information sheets, regimen information sheets, and symptom management information (for patients) contained in the Drug Formulary (the "Formulary") is intended to be used by health professionals and patients for informational purposes only. The information is not intended to cover all possible uses, directions, precautions, drug interactions or side effects of a certain drug, nor should it be used to indicate that use of a particular drug is safe, appropriate or effective for a given condition.

A patient should always consult a healthcare provider if he/she has any questions regarding the information set out in the Formulary. The information in the Formulary is not intended to act as or replace medical advice and should not be relied upon in any such regard. All uses of the Formulary are subject to clinical judgment and actual prescribing patterns may not follow the information provided in the Formulary.

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