Cisplatin, Gemcitabine, and Durvalumab

Patient Education Sheets
Understanding Your Cancer Treatment

Care Team Contact Information: _____

Pharmacy Contact Information: _____

Diagnosis: _____

- This treatment is used for biliary tract cancer (BTC), bladder cancer, and non-small cell lung cancer (NSCLC).
- It may also be used for other reasons.

Goal of Treatment: _____

- Treatment may continue for a certain time period, until it no longer works, or until side effects are no longer controlled.

Treatment Regimen

Treatment Name	How the Treatment Works	How the Treatment is Given
Cisplatin (sis-PLA-tin): Platinol (PLA-tih-nol)	Slows down or stops the growth of cancer cells by damaging the genetic material that cancer cells need to multiply.	Infusion into a vein (intravenous (IV) infusion).
Gemcitabine (jem-SY-tuh-been): Gemzar (JEM-zar)	Stops cancer cells from making the instructions they need to grow and multiply, causing the cells to die.	Infusion into a vein (intravenous (IV) infusion).
Durvalumab (dur-VAL-yoo-mab): Imfinzi (im-FIN-zee)	Boosts your immune system to help it attack cancer cells more effectively.	Infusion into a vein (intravenous (IV) infusion).

Treatment Administration and Schedule

Treatment is typically repeated every 3 or 4 weeks. This length of time is called a “cycle.” Your treatment typically has 2 parts: induction and maintenance. During the induction phase, treatment is typically repeated every 21 days. During the maintenance phase, treatment is typically repeated every 28 days. You may receive up to 4 to 8 cycles with cisplatin, gemcitabine, and durvalumab, followed by treatment with durvalumab alone. Your care team will tell you how many treatment cycles you will receive and how long you will continue taking durvalumab.

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Treatment Administration and Schedule (Continued)

☐ **Option 1: Induction (Cycles 1 to 8: 21-day Cycles)**

- Cisplatin is given on Day 1.
- Gemcitabine is given on Days 1 and 8.
- Durvalumab is given on Day 1.

Treatment Name	Cycle 1						Next Cycle
	Day 1	Day 2	…	Day 8	…	Day 21	Day 1
Cisplatin	✓						✓
Gemcitabine	✓			✓			✓
Durvalumab	✓						✓

Maintenance (Cycles 9 and Beyond: 28-day Cycles)

- Durvalumab is given on Day 1.

Treatment Name	Cycle 9							Next Cycle
	Day 1	Day 2	Day 3	Day 4	Day 5	…	Day 28	Day 1
Durvalumab	✓							✓

☐ **Option 2: Induction (Cycles 1 to 8: 21-day Cycles)**

- Cisplatin is given on Days 1 and 8.
- Gemcitabine is given on Days 1 and 8.
- Durvalumab is given on Day 1.

Treatment Name	Cycle 1						Next Cycle
	Day 1	Day 2	…	Day 8	…	Day 21	Day 1
Cisplatin	✓			✓			✓
Gemcitabine	✓			✓			✓
Durvalumab	✓						✓

Maintenance (Cycles 9 and Beyond: 28-day Cycles)

- Durvalumab is given on Day 1.

Treatment Name	Cycle 9							Next Cycle
	Day 1	Day 2	Day 3	Day 4	Day 5	…	Day 28	Day 1
Durvalumab	✓							✓

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Appointments

Appointments may include regular check-ups with your care team, treatment appointments, lab visits, and imaging tests. It's important to keep your appointments whenever you can. If you miss an appointment, call your care team as soon as possible to reschedule it.

Supportive Care to Prevent and Treat Side Effects

Description	Supportive Care Given at the Clinic or Hospital	Supportive Care Taken at Home
To help prevent or treat nausea and vomiting		
To help lower the risk of infusion-related reactions		
Other		

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Common Side Effects

Side Effect	Important Information
Low White Blood Cell (WBC) Count (Neutropenia) and Increased Risk of Infection (Boxed Warning)	Description: WBCs help protect your body from infections. A low WBC count increases your risk of infection. Recommendations: • Wash your hands often and bathe regularly. • Avoid crowded places and close contact with people who are sick. • Follow food safety and wound care advice from your care team. • Your care team may prescribe medicine to help your WBCs recover. Talk to your care team if you have: • Fever of 100.4°F (38°C) or higher • Chills • New or worsening cough or sore throat • Painful urination or signs of a urinary infection • Feeling much more tired than usual • Red, swollen, warm, or painful areas on the skin (possible skin infection)
Low Platelet Count (Thrombocytopenia) (Boxed Warning)	Description: Platelets help your blood clot and wounds heal. A low platelet count increases your risk of bruising and bleeding. Recommendations: • Blow your nose gently and avoid picking it. • Brush your teeth gently with a soft toothbrush and keep good oral hygiene. • Use an electric razor for shaving and a nail file instead of nail clippers. • Avoid over-the-counter medicines that can increase bleeding risk (for example, nonsteroidal anti-inflammatory drugs (NSAIDs) like ibuprofen). • Talk with your care team or dentist before medical or dental procedures — you may need to pause treatment. Talk to your care team if you have: • A nosebleed lasting more than 5 minutes despite pressure • A cut that continues to bleed • Heavy gum bleeding when brushing or flossing • Sudden or severe headache • Blood in your urine or stool • Blood in your spit after coughing
Low Red Blood Cell (RBC) Count and Hemoglobin (Hgb) (Anemia) (Boxed Warning)	Description: Red blood cells carry oxygen throughout your body. Low levels can make you feel tired, weak, dizzy, or short of breath. Recommendations: • Aim for 7 to 8 hours of sleep each night. • Do not drive, operate heavy machinery, or do other dangerous activities if you are very tired. • Balance activity and rest — stay as active as you can, but rest when needed. • Eat a balanced diet and follow any nutrition or supplement advice from your care team. Talk to your care team if you have: • Shortness of breath • Dizziness or fainting • Fast or irregular heartbeats • Sudden or severe headache

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Kidney Problems (Boxed Warning)	Description: Treatment can cause kidney problems, including damage to the kidneys and decreased kidney function. This may lead to acute kidney injury or long-term kidney failure. It can also cause low magnesium levels that last after treatment. These issues usually happen within days of getting the drug. Recommendations: • Drink 8 to 10 glasses of water or other fluids each day, unless your care team tells you otherwise. • Your care team may give you fluids and electrolytes with your treatment. Talk to your care team if you have: • Decrease in your amount of urine • Blood in your urine • Swelling of your ankles • Loss of appetite
Fatigue	Description: Fatigue is a constant and sometimes strong feeling of tiredness. Recommendations: • Routine exercise can help reduce fatigue. Talk with your care team to find the right type and amount of activity for you. • Ask family and friends for help with daily tasks and for emotional support. • Try healthy ways to feel better, such as meditation, journaling, yoga, or guided imagery, to reduce anxiety and improve well-being. • Aim for 7 to 8 hours of sleep each night. Limit daytime naps to help you sleep better at night. • Do not drive, operate heavy machinery, or do other potentially dangerous activities if you are very tired. Talk to your care team if you have: • Tiredness that affects your daily life or prevents you from doing normal activities • Tiredness that does not get better with rest • Dizziness or weakness along with severe tiredness
Nausea and Vomiting	Description: Nausea is an uncomfortable feeling in your stomach or the need to throw up. You may or may not vomit. Recommendations: • Eat smaller, more frequent meals. • Avoid fatty, fried, spicy, or highly sweet foods. • Eat bland foods at room temperature and drink clear liquids. • If you vomit, start with small sips of water, broth, or other clear liquids. If these stay down, try soft foods (such as gelatin, plain cornstarch pudding, yogurt, strained soup, or strained cooked cereal) and gradually return to solid foods. • Your care team may prescribe medicine for these symptoms. Talk to your care team if you have: • Vomiting for more than 24 hours • Nonstop vomiting • Signs of dehydration (very thirsty, dry mouth, dizziness, or dark urine) • Blood in your vomit or vomit that looks like coffee grounds • Severe stomach pain that does not go away after vomiting

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<table>
<tr><td>Constipation</td><td>Description: Constipation means hard, dry stools or fewer bowel movements than normal. It can cause discomfort or pain.
Recommendations:
Track how often you have bowel movements each day.
Drink 8 to 10 glasses of fluids daily, unless your care team says otherwise.
Stay active and exercise regularly.
Eat more high-fiber foods (such as raw fruits, vegetables, and whole grains) unless advised otherwise.
Your care team may recommend laxatives such as polyethylene glycol (MiraLAX) or senna.
Talk to your care team if you have:
Constipation lasting 3 or more days
No bowel movement 48 hours after using a laxative</td></tr>
<tr><td>Skin Problems</td><td>Description: Treatment can cause a rash with itchy, dry, red, or puffy skin.
Recommendations:
Bathe or shower daily with warm (not hot) water and mild, unscented soap or body wash.
Pat your skin dry with a towel instead of rubbing.
Apply unscented lotion or moisturizing cream right after bathing to prevent dryness and cracking.
Use lip balm for dry or chapped lips.
Avoid direct sun when you can. Use a broad-spectrum sunscreen with a sun protection factor (SPF) of 30 or higher and reapply every 2 hours when outdoors.
Use unscented, gentle laundry detergent to reduce skin irritation.
Your care team may recommend medicine for skin problems.
Talk to your care team if you have:
Skin rash
Raised red bumps
Redness of the skin
Very dry skin that may affect the mucous membranes (such as mouth and eyes)</td></tr>
<tr><td>Fever and Flu-like Symptoms</td><td>Description: Fever and flu-like symptoms often occur after gemcitabine infusions. Symptoms such as fever, chills, fatigue, and muscle aches typically begin within a few hours after the infusion and last about 1 to 2 days.
Recommendations:
Take your temperature if you feel like you have a fever.
Your care team may recommend medicines to treat your fever.
Talk to your care team if you have:
Fever of 100.4°F (38°C) or higher
Fever lasting for more than 3 days
Any signs of infection, such as a persistent cough, shortness of breath, or pain</td></tr>
</table>

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Select Rare Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms
Numbness, Tingling, or Burning in Your Hands or Feet (Peripheral Neuropathy) (Boxed Warning)	• New or worsening "pins and needles," burning, or numbness in your hands or feet • Trouble moving your arms or legs or weakness • Problems with balance or frequent falls
Capillary Leak Syndrome (CLS)	CLS happens when fluid and proteins leak from your small blood vessels into surrounding tissues. It requires immediate treatment to prevent a drop in blood pressure and other serious complications. • Swelling or puffiness and are urinating less than usual • Swelling of your stomach area (abdomen) and feeling of fullness • Trouble breathing • Dizziness or feeling faint • A general feeling of tiredness
Thrombotic Microangiopathy (TMA) and Hemolytic Uremic Syndrome (HUS)	TMA is a serious condition in which small blood vessels are damaged, leading to blood clots, low platelet counts, and destruction of red blood cells. HUS is a type of TMA that can damage the kidneys and other organs and may lead to life-threatening kidney failure. • Loss of color in the skin • Extreme tiredness or weakness • Easy bruising or unusual bleeding (nose, mouth, gums) • Decreased urine output or blood in your urine • Swelling of the legs, feet, or ankles (or swelling of face, hands, full body) • Confusion, seizures, or stroke (weakness, numbness, trouble speaking) • New or worsening high blood pressure
Intestinal Problems	• Diarrhea (loose stools) or more frequent bowel movements than usual • Stools that are black, tarry, sticky, or have blood or mucus • Severe stomach-area (abdominal) pain or tenderness
Lung Problems	• Cough • Shortness of breath • Chest pain or chest tightness
Eye Problems	• Dry or red eyes • Eye pain or swelling • Vision changes • Increased tears • Sensitivity to light • Blurred vision

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Hearing Loss	• New or worsening hearing loss • Ringing, buzzing, or other noises in your ears (tinnitus)	• Trouble understanding speech or needing higher volume on devices • Dizziness or balance problems
Hormone Gland Problems	• Headaches that will not go away, or unusual headaches • Eye sensitivity to light • Eye problems • Rapid heartbeat • Increased sweating • Extreme tiredness • Weight gain or weight loss • Feeling more hungry or thirsty than usual	• Urinating more often than usual • Hair loss • Feeling cold • Constipation • Your voice gets deeper • Dizziness or fainting • Changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness
Problems in Other Organs and Tissues	• Chest pain, irregular heartbeat, shortness of breath, swelling of ankles • Confusion, sleepiness, memory problems, changes in mood or behavior, stiff neck, balance problems, tingling or numbness of the arms or legs	• Double vision, blurry vision, sensitivity to light, eye pain, changes in eyesight • Persistent or severe muscle pain or weakness, muscle cramps • Low red blood cells, bruising
Infusion-Related Reactions	• Chills or shaking • Itching, rash, or flushing • Trouble breathing, wheezing, or tongue swelling • Dizziness or feeling faint	• Feeling of impending doom • Fever of 100.4°F (38°C) or higher • New or severe pain in your back or neck
Allergic Reactions, Including Anaphylaxis	Get emergency medical help right away if you develop any of the following signs or symptoms: • Swelling of your lips, mouth, tongue, or throat • Trouble breathing or swallowing • Raised red areas on your skin (hives)	• A very fast heartbeat • You feel dizzy or faint
Risk of New Cancers	There is a risk of developing one or more new cancers during or after treatment. Talk with your care team about this risk, and ask about the signs and symptoms to watch for.	

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Before starting treatment, ask your care team when to call 9-1-1 or seek emergency help.
If you experience any new, worsening, or uncontrolled side effects, contact your care team immediately.

Intimacy, Fertility, Pregnancy, and Breastfeeding

- Treatment may **change how you feel about intimacy and your body.** However, physical closeness—such as holding hands and hugging—remains safe. It is common to have questions about intimacy. If needed, talk to your care team for guidance.
- Treatment can affect your **ability to have children**. It may damage your reproductive organs or stop them from working. If you are worried about fertility, talk to your care team before starting treatment.
- Treatment may **harm an unborn baby**.
    - If you are able to become pregnant:
        - Your care team will verify your pregnancy status before treatment.
        - Use an effective method of birth control during treatment, for 3 months after your last dose of durvalumab, for 6 months after your last dose of gemcitabine, and for 14 months after your last dose of cisplatin.
        - If you think you might be pregnant or if you become pregnant, tell your care team right away.
    - If your partner is able to become pregnant, use an effective method of birth control—such as condoms—during treatment, for 3 months after your last dose of gemcitabine, and for 11 months after your last dose of cisplatin.
- **Do not breastfeed** during treatment, for 3 days after your last dose of cisplatin, for 1 week after your last dose of gemcitabine, and for 3 months after your last dose of durvalumab.

Handling Body Fluids and Waste

Some drugs you receive may stay in your urine, stool, sweat, or vomit for many days after treatment. Because many cancer drugs are toxic, your body waste may also be dangerous to touch. To help protect yourself, your loved ones, and the environment, **follow these instructions** for at least **48 hours** after each dose of **cisplatin** and **gemcitabine**: (Note: Durvalumab does not require special handling of body fluids and waste.)

- People who are pregnant should avoid touching anything that may be soiled with body fluids from the patient.
- You can use your usual toilet. Always close the lid and flush to discard all waste. If you have a low-flow toilet, flush twice.
- If the toilet or seat is soiled with urine, stool, or vomit, clean the surface after each use before others use it.
- Wash your hands with soap and water for at least 20 seconds after using the toilet.
- If you need a bedpan, inform your caregiver so they can wear gloves and assist with cleanup. Wash the bedpan with soap and water daily.
- If you cannot control your bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb waste.
- Wash any skin exposed to body waste with soap and water.
- Wash soiled linens or clothing separately from other laundry. If you don’t have a washer, place them in a plastic bag until they can be washed.
- Wash your hands with soap and water after touching soiled linens or clothing.

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Additional Information

- **Tell your care team about all the medicines you take**.
  This includes prescriptions, over-the-counter drugs, vitamins, and herbal products. Before starting any new medicine, supplement, or vaccine, ask your care team first.
- **Your treatment may cause side effects that need medicine or a break from treatment.** Your care team may give you corticosteroids or hormone medicines to help. Sometimes, they may need to delay or stop your treatment if you have certain side effects.
- **Tell your care team about all your health problems.** This includes issues with your immune system, like Crohn's disease, ulcerative colitis, or lupus. Also, tell them if you have had an organ transplant, like a kidney or eye transplant. Let them know if you had a stem cell transplant from a donor, had radiation to your chest, or have a nerve problem like myasthenia gravis or Guillain-Barré syndrome.
- **Worsening side effects from radiation treatment**. Tell your care team if you have had or are planning to receive radiation therapy.
- **This Patient Education Sheet may not describe all possible side effects.**
  Call your care team for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Notes

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