

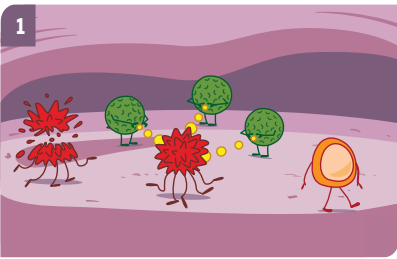


MY THERAPY GUIDE

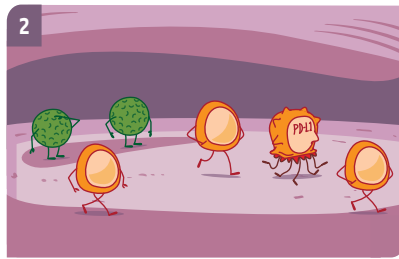
Information brochure for patients who have
been prescribed IMFINZI (durvalumab)
as treatment for advanced biliary tract
cancer in combination with chemotherapy
(gemcitabine-cisplatin)

WHAT IS IMFINZI AND HOW DOES IT WORK?

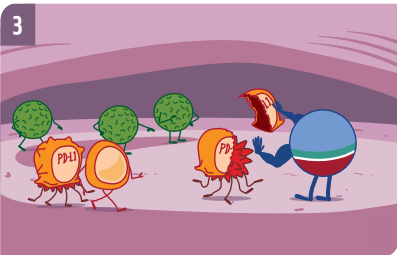
IMFINZI is an anti-PD-L1 monoclonal antibody, a so-called checkpoint inhibitor, and belongs to the class of immunotherapy. Immunotherapy uses the body's own immune system to destroy cancer cells. IMFINZI specifically attaches itself to the PD-L1, which is found on the surface of cancer cells. This is how cancer cells are targeted and attacked by your own immune system.



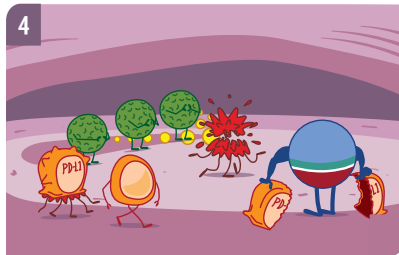
Cancer cells can be recognized and attacked by the immune system.



PD-L1 is a protein that cancer cells use to camouflage themselves so that they can't be recognized by the immune system.



IMFINZI can "unmask" the camouflaged cancer cells by binding to and blocking PD-L1.



This allows the immune system to recognize and attack the cancer cells again.



healthy cell



cancer cell



immune system



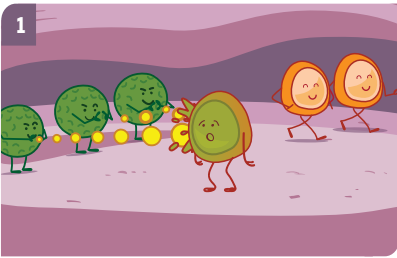
IMFINZI



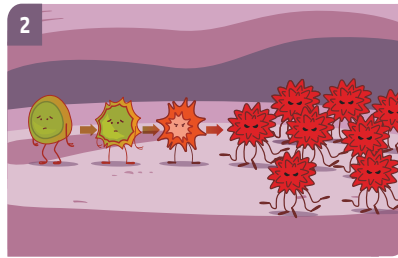
PD-L1-camouflaged cancer cell

WHAT IS CHEMOTHERAPY AND HOW DOES IT WORK?

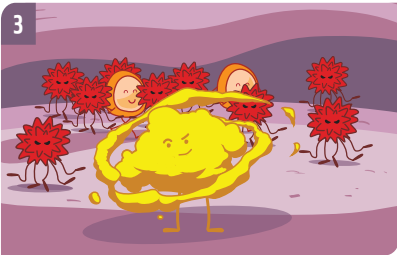
Chemotherapy consists of drugs (given intravenous or per os) that directly attack cancer cells. In patients with advanced biliary tract cancer the drugs gemcitabine and cisplatin (gem-cis) are usually used as chemotherapy.



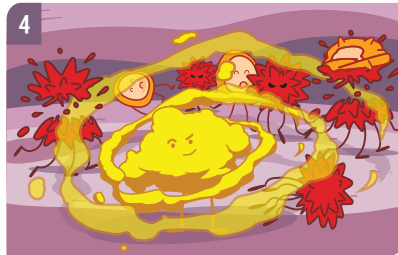
The immune system serves as your body's defense system against infections and diseases, and can typically detect and destroy unhealthy cells.



Unhealthy cells, if not detected and destroyed by the immune system, may eventually turn into cancer cells.



Cancer cells grow abnormally and multiply quickly. This is where chemotherapy, a type of cancer treatment, can help.



Chemotherapy has the ability to destroy rapidly growing cells – such as cancer cells – throughout the body. Since chemotherapy can destroy fast-growing cells, healthy cells may also be affected.



healthy cell



unhealthy cell



immune system



cancer cell



chemotherapy

HOW IS YOUR TREATMENT ADMINISTERED?

IMFINZI is administered with two different chemotherapies: gemcitabine and cisplatin. You will be given treatment as an "infusion" into your vein ("IV"). The infusion for IMFINZI takes approx. 60 minutes.

CHEMOTHERAPY (GEM-CIS)



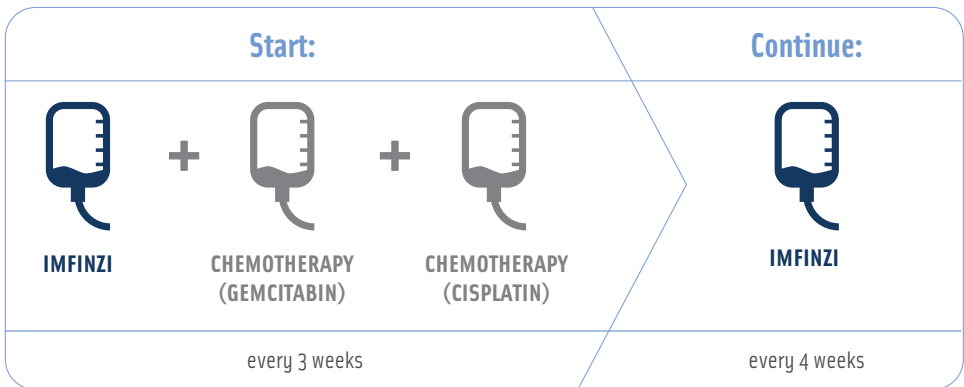
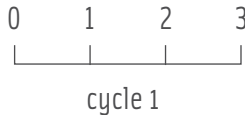
They are administered every 3 weeks for usually 8 cycles. Your doctor will decide how many cycles you will be given.

IMFINZI



Then you will receive IMFINZI alone (monotherapy) every 4 weeks. Your doctor will decide how long to continue IMFINZI, depending on the condition of your cancer.

week

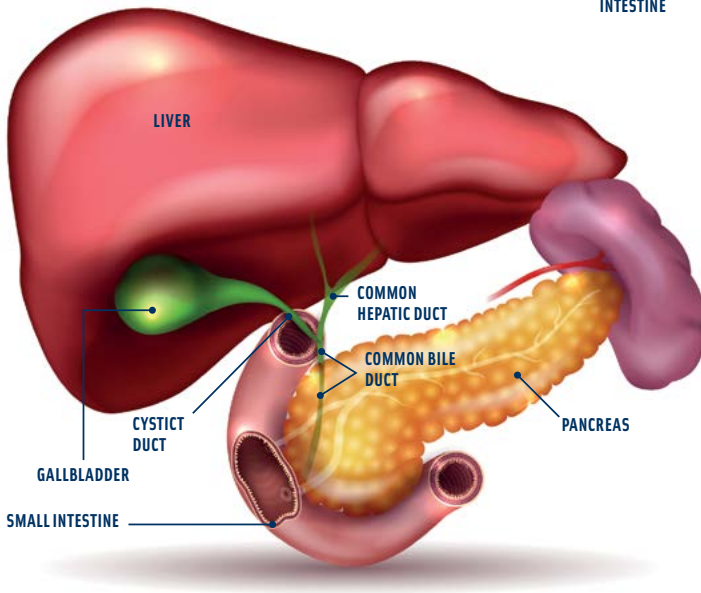
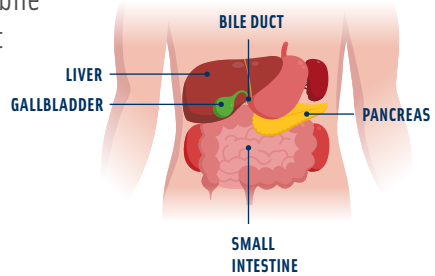


Duration of the IMFINZI infusion: ~ 60 minutes

WHAT IS BILIARY TRACT CANCER?

There are different types of biliary tract cancers, bile duct cancers and gallbladder cancer.

Bile duct cancer forms in the cells of the **bile ducts**. These are a series of tubes that bring bile from the liver to the small intestine, where it helps with digestion.



Bile duct cancer can form in parts of the bile ducts that are inside of the liver (**intrahepatic cholangiocarcinoma**) or in parts outside of the liver (**extrahepatic cholangiocarcinoma**).

Gallbladder cancer forms in the cells of the **gallbladder**, where bile is stored.

WHAT ARE THE RISK FACTORS FOR BILIARY TRACT CANCER?

Risk factors for biliary tract cancer include certain diseases like Primary sclerosing cholangitis (PSC), Liver Cirrhosis, inflammatory bowel disease (IBD) and Diabetes.

Infections with hepatitis b or c and bile duct stones are also associated with a higher risk for biliary tract cancer.

Other factors like old age, alcohol consumption and smoking also increase the probability for biliary tract cancer.

WHAT ARE THE SYMPTOMS OF BILIARY TRACT CANCER?

When biliary tract cancer has spread within your gallbladder or bile ducts, you may notice certain sign and symptoms. While these are not all of the signs and symptoms, they are very common:

- Yellowing of the skin or eyes
- Dark urine or pale bowel movements
- Abdominal pain
- Weight loss
- Fever

WHAT SHOULD YOU DO BEFORE STARTING TREATMENT?

Before starting treatment, please discuss the following with your doctor:

EXISTING DISEASES:

Especially if you:

- Are suffering from an autoimmune disease e. g. chronic bowel diseases (Crohns disease, ulcerative colitis), chronic skin diseases (psoriasis, vitiligo), rheumatic diseases, diabetes
- Had an organ transplantation
- Have problems with your lungs or breathing
- Have problems with your liver
- Are being treated for an infection or receive anti infective-treatment

Medications

Any medications you are taking or have recently taken. This applies to both prescription drugs and herbal, complementary and non-prescription medicines.

More information

IMFINZI should not be used during pregnancy or breastfeeding. For more information, please consult your physician or see the Information in the leaflet.

WHAT SHOULD YOU DO DURING TREATMENT?

In some patients, the way IMFINZI works can cause the immune system to attack healthy body tissue. In this case one speaks of an "immune-mediated adverse reaction". Sometimes the affected organs are restricted in their function and serious complications can develop.

It's very important that you watch out for signs of immune-mediated adverse reactions. If you have any suspicions, contact your attending physician or a specialist so that they can intervene at an early stage.

The most important things to remember for handling adverse reactions



WRITE DOWN HOW YOU FEEL

Write down how you feel now and keep a diary regularly during treatment. This will help you notice changes that may indicate adverse reactions.



DETECT ADVERSE REACTIONS EARLY

Early detection allows for equally early intervention. This helps to prevent side adverse reactions from becoming severe.



INFORM YOUR PHYSICIAN IMMEDIATELY

Contact your treatment team as soon as you experience an adverse reaction or if existing symptoms worsen. Do not wait for your next appointment.

WHAT KINDS OF IMMUNE-MEDIATED ADVERSE REACTIONS ARE POSSIBLE?

Inform your doctor immediately if you notice any of the following symptoms or if any existing symptoms worsen. Please note that adverse reactions may also be caused by concomitant medications or previous therapies. It is therefore especially important that you contact your treatment team and have possible adverse reactions clarified.



LUNGS (PNEUMONITIS)

Possible symptoms

- Occurrence or worsening of coughing
- Shortness of breath
- Chest pain



LIVER (HEPATITIS)

Possible symptoms

- Yellowing of the skin or eyes
- Severe nausea or vomiting
- Right-sided abdominal pain
- Tiredness
- Dark brownish urine
- Increased bleeding or bruising



INTESTINES (COLITIS)

Possible symptoms

- Diarrhea
- More frequent bowel movements
- Black tarry stool
- Constipation
- Mucus or blood in the stool
- Abdominal pain
- Nausea or difficulties to eat



SKIN (RASH, DERMATITIS)

Possible symptoms

- Rash
- Itching
- Blisters



KIDNEYS (NEPHRITIS, KIDNEY FAILURE)

Possible symptoms

- Decreased urine quantity
- Blood in urine
- Swelling of the ankles
- Loss of appetite



ENDOCRINE SYSTEM (ESPECIALLY THYROID, PITUITARY AND ADRENAL GLANDS)

Possible symptoms

- Headache (persistent)
- Extreme fatigue
- Weight changes
- Dizziness or fainting
- Increased hunger or thirst
- Chills
- Hair loss
- Deepening of the voice
- More frequent urination
- Change in mood or behavior (e.g. irritability, altered libido, forgetfulness)



HEART (MYOCARDITIS)

Possible symptoms

- Shortness of breath during physical exertion
- Fatigue
- Palpitations
- Chest pain



OTHER AFFECTED ORGANS

Possible symptoms

- Stiff neck
- Fever
- Increased susceptibility to infections
- Chills
- Confusion
- Vision problems
- Pain or redness of the eyes
- Inflammation of the oral mucosa
- Low blood pressure
- Swollen lymph nodes



REACTIONS TO THE INFUSION

Possible symptoms

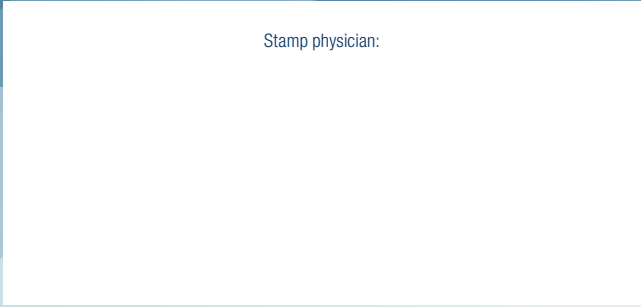
- Chills
- Itching or rash
- Flushing
- Shortness of breath
- Fever
- Dizziness or fainting
- Back or neck pain
- Swelling of the face

Please consider:

Other complaints not described here may also occur. In any case, inform your physician to clarify possible adverse reactions.

Immune-mediated adverse reactions may occur during treatment and up to 3 months after treatment.

Stamp physician:



The information in this brochure is provided by AstraZeneca for educational purposes only and should not replace a discussion with your physician or healthcare professional. It should not be used for the diagnosis or treatment of any health problem or disease. If you have any questions about your health condition, talk to your physician.

The contents of this brochure have been discussed with the treating physician during patient consultation.

This brochure is intended only for distribution by the treating physician to IMFINZI patients.

