

# Your journey with **INLEXZO™** starts here

 **inlexzo™**  
gemcitabine intravesical  
system | 225 mg

What to know when you begin  
treatment with INLEXZO™



## **BEFORE**

Things to know before your INLEXZO™ appointment



## **DURING**

Things to know when INLEXZO™ is inserted  
or removed by your healthcare provider



## **AFTER**

Things to know after insertion or removal

Not actual patient.



## **WHAT IS INLEXZO™?**

INLEXZO™ (gemcitabine intravesical system) is a prescription medicine for the treatment of adults with a type of cancer of the lining of the bladder called non-muscle invasive bladder cancer (NMIBC), that has not spread to other parts of the body, and that did not respond to treatment with Bacillus Calmette-Guérin (BCG).

## **IMPORTANT SAFETY INFORMATION**

**Do not receive INLEXZO™ if you:**

- have a tear or hole (perforation) of your bladder.
- have had an allergic reaction to gemcitabine or any of the ingredients in INLEXZO™. See the end of this Patient Information for a complete list of ingredients in INLEXZO™.

Please read full Important Safety Information on pages 5-7 and full [Prescribing Information](#) for INLEXZO™.

# WHAT TO KNOW BEFORE STARTING TREATMENT



## Some information to help you get ready:



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



Before receiving INLEXZO™, tell your healthcare provider about all of your medical conditions, including if you are:

- Pregnant or plan to become pregnant
- A female who is able to become pregnant
- A male with a female partner who is able to become pregnant
- Breastfeeding or plan to breastfeed

**Please refer to the Important Safety Information on this page and pages 5-7 for additional details.**

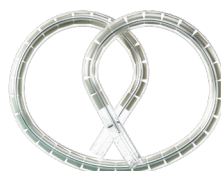


Your healthcare provider may give you antibiotics before INLEXZO™ is inserted or removed



Do not empty your bladder right before an insertion of INLEXZO™

INLEXZO™



Illustrative depiction. Not actual size.

## IMPORTANT SAFETY INFORMATION *(continued)*

**Before receiving INLEXZO™, tell your healthcare provider about all of your medical conditions, including if you:**

- are pregnant, or plan to become pregnant. INLEXZO™ can harm your unborn baby. You should not become pregnant during treatment with INLEXZO™. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with INLEXZO™.

### **Females who are able to become pregnant:**

- Your healthcare provider will check to see if you are pregnant before starting treatment with INLEXZO™.
- Use effective birth control (contraception) during treatment with INLEXZO™ and for 6 months after final removal of INLEXZO™.

### **Males treated with INLEXZO™:**

- If you have a female partner who is able to become pregnant, you should use effective birth control (contraception) during treatment with INLEXZO™ and for 3 months after final removal of INLEXZO™.
- are breastfeeding, or plan to breastfeed. It is not known if INLEXZO™ passes into your breastmilk. Do not breastfeed during treatment with INLEXZO™ and for 1 week after final removal of INLEXZO™.

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

**Please read full Important Safety Information on pages 5-7 and full [Prescribing Information](#) for INLEXZO™.**

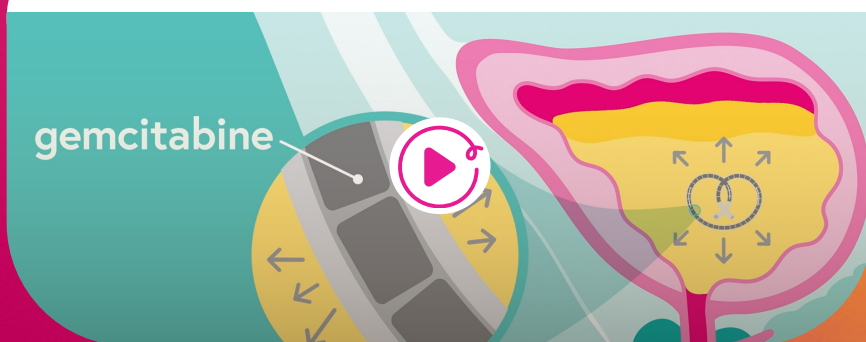
# WHAT TO KNOW DURING TREATMENT



## DURING INSERTION

- INLEXZO™ will be inserted by a healthcare provider uncurled and straightened into your bladder through a tube called a urinary catheter
- Once inside your bladder, INLEXZO™ resumes its curled shape and the tube (urinary catheter) will be removed
- INLEXZO™ is inserted into your bladder once every 3 weeks for up to 6 months (8 doses) and then once every 12 weeks for up to 18 months (6 doses)
- INLEXZO™ is removed after 3 weeks of being inserted (3-week indwelling period)
- Your healthcare provider will decide how many INLEXZO™ treatments you will receive

To watch a video about how INLEXZO™ is given, visit [INLEXZO.com](https://www.inlexzo.com)



## DURING REMOVAL

- A healthcare provider will remove INLEXZO™ using a viewing tube (cystoscope)
- The cystoscope's camera can also look around your bladder and see how INLEXZO™ has been working
- Your healthcare provider may insert a new INLEXZO™ immediately after removing the previously inserted INLEXZO™

It is very important that you go to all of your appointments. If you miss any appointments, call your healthcare provider as soon as possible to schedule your appointment.

Please read full Important Safety Information on pages 5-7 and full [Prescribing Information](#) for INLEXZO™.

# WHAT TO KNOW AFTER INSERTION



## AFTER RECEIVING INLEXZO™

- Drink about 6 to 7 cups (1500 mL) of fluids per day during treatment with INLEXZO™ to make sure you produce enough urine for the medicine to be released into the bladder
- You can urinate normally. There is no need to hold your urine
- Avoid contact between your skin and urine
- To urinate, **males and females** should sit on the toilet and flush after each use
- Wash your hands with soap and water and wash your genital area with water after each time you urinate
- Wash clothing soiled with urine right away and separately from other clothing



## AFTER YOUR HEALTHCARE PROVIDER REMOVES INLEXZO™

- Avoid contact between your skin and urine for at least 24 hours after INLEXZO™ is removed



## MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION CARD

Your healthcare provider will give you an MRI Safety Information Card

- Show it to your healthcare providers, who will determine the conditions in which they can safely do an MRI scan if needed while INLEXZO™ is in your bladder

# IMPORTANT SAFETY INFORMATION



## WHAT IS INLEXZO™?

INLEXZO™ (gemcitabine intravesical system) is a prescription medicine for the treatment of adults with a type of cancer of the lining of the bladder called non-muscle invasive bladder cancer (NMIBC), that has not spread to other parts of the body, and that did not respond to treatment with Bacillus Calmette-Guérin (BCG).

## IMPORTANT SAFETY INFORMATION

**Do not receive INLEXZO™ if you:**

- have a tear or hole (perforation) of your bladder.
- have had an allergic reaction to gemcitabine or any of the ingredients in INLEXZO™. See the end of this Patient Information for a complete list of ingredients in INLEXZO™.

**Before receiving INLEXZO™, tell your healthcare provider about all of your medical conditions, including if you:**

- are pregnant, or plan to become pregnant. INLEXZO™ can harm your unborn baby. You should not become pregnant during treatment with INLEXZO™. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with INLEXZO™.

**Females who are able to become pregnant:**

- Your healthcare provider will check to see if you are pregnant before starting treatment with INLEXZO™.
- Use effective birth control (contraception) during treatment with INLEXZO™ and for 6 months after final removal of INLEXZO™.

**Males treated with INLEXZO™:**

- If you have a female partner who is able to become pregnant, you should use effective birth control (contraception) during treatment with INLEXZO™ and for 3 months after final removal of INLEXZO™.
- are breastfeeding, or plan to breastfeed. It is not known if INLEXZO™ passes into your breastmilk. Do not breastfeed during treatment with INLEXZO™ and for 1 week after final removal of INLEXZO™.

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

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Please read additional Important Safety Information on pages 6-7 and full [Prescribing Information](#) for INLEXZO™.

# IMPORTANT SAFETY INFORMATION



## IMPORTANT SAFETY INFORMATION (*continued*)

### How will I receive INLEXZO™?

- INLEXZO™ will be inserted and removed by your healthcare provider.
- INLEXZO™ is inserted into your bladder through a tube called a urinary catheter 1 time every 3 weeks for up to 6 months (8 doses) and then 1 time every 12 weeks for up to 18 months (6 doses).
- INLEXZO™ is removed after 3 weeks of being inserted (3-week indwelling period).
- Your healthcare provider will decide how many INLEXZO™ treatments you will receive.
- Your healthcare provider may give you antibiotics before INLEXZO™ is inserted or removed.
- It is very important that you go to all of your appointments. If you miss any appointments, call your healthcare provider as soon as possible to schedule your appointment.

### Before receiving INLEXZO™:

- Do not empty your bladder right before your procedure to insert INLEXZO™.

### After receiving INLEXZO™:

- Drink about 6 to 7 cups (1500 mL) of fluids per day during treatment with INLEXZO™ to make sure you produce enough urine for the medicine to be released into the bladder.
- You can urinate normally. There is no need to hold your urine.
- Avoid contact between your skin and urine.
- To urinate, **males and females** should sit on the toilet and flush after each use.
- Wash your hands with soap and water and wash your genital area with water after each time you urinate.
- Wash clothing soiled with urine right away and separately from other clothing.

### After your healthcare provider removes INLEXZO™:

Avoid contact between your skin and urine for at least 24 hours after INLEXZO™ is removed.

### What should I avoid after INLEXZO™ is inserted?

Tell your healthcare provider that you have INLEXZO™ before having a type of scan called Magnetic Resonance Imaging (MRI).

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Please read additional Important Safety Information on pages 5 and 7 and full [Prescribing Information](#) for INLEXZO™.

# IMPORTANT SAFETY INFORMATION



## IMPORTANT SAFETY INFORMATION (*continued*)

**INLEXZO™ may be used under specific conditions.** Your healthcare provider will give you an MRI Safety Information Card. Keep the card in a safe place and show it to all of your healthcare providers. The card contains important information in case you need to have an MRI. Your healthcare provider will review the information on the MRI Safety Information Card and determine the conditions they can safely do an MRI scan while INLEXZO™ is in your bladder.

### What are the possible side effects of INLEXZO™?

**The most common side effects of INLEXZO™ include:**

- frequent need to pass urine more often than usual
- urinary tract infection
- pain or burning sensation when passing urine
- urgent need to pass urine
- decreased hemoglobin
- increased lipase
- pain in the urinary tract (felt in the lower stomach area or lower back)
- decreased lymphocytes
- blood in urine
- increased creatinine
- increased potassium
- increased aspartate aminotransferase
- decreased sodium
- bladder irritation
- increased alanine transaminase

INLEXZO™ may cause fertility problems in males, which may affect your ability to have children. It is unknown if these side effects of fertility are reversible. Talk to your healthcare provider if this is a problem for you.

Tell your healthcare provider if you have any side effect that bothers you or does not go away.

These are not all the possible side effects of INLEXZO™.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

### What are the ingredients in INLEXZO™?

**Active ingredient:** gemcitabine hydrochloride

**Inactive ingredients for gemcitabine component:** polyethylene glycol 8000, povidone K30, and urea.

**Inactive ingredients for osmotic components:** FD&C Blue No.1, polyethylene oxide 600,000, and urea.

Please read additional Important Safety Information on pages 5-6 and full [Prescribing Information](#) for INLEXZO™.



VISIT [INLEXZO.COM](https://www.inlexzo.com)  
TO LEARN MORE.

Please read full Important Safety Information on pages 5-7 and full [Prescribing Information](#) for INLEXZO™.

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