

THE NEXT STEP WHEN BCG STOPS WORKING

Meet "The Pretzel"

<2 in



A breakthrough in **bladder cancer** treatment

INLEXZO™ is a treatment for adult patients with certain NMIBC that did not respond to BCG.

BCG, Bacillus Calmette-Guérin; NMIBC, non-muscle invasive bladder cancer.
Illustrative depiction. Not actual size.

WHAT IS INLEXZO™?

INLEXZO™ 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 Important Safety Information throughout and on pages 15-17 and full [Prescribing Information](#) for INLEXZO™.


gemcitabine intravesical
system | 225 mg

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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™.

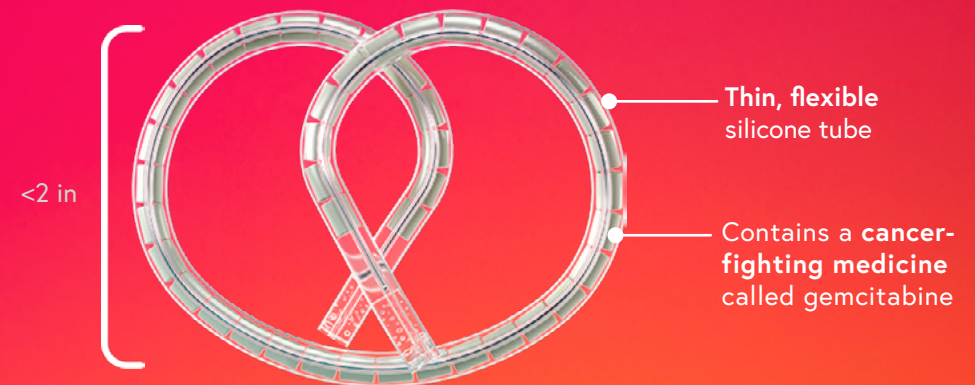
Males treated with INLEXZO™:

- 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™.

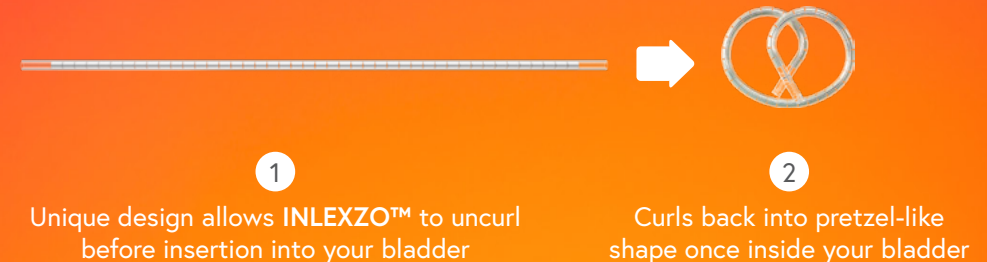
Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

INLEXZO™

True innovation for a different kind of treatment



Illustrative depiction. Not actual size.



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A one-of-a-kind treatment approach

INLEXZO™ releases medicine directly into your bladder over time.

Not actual patients.

WHAT MAKES INLEXZO™ UNIQUE?



The pretzel-like shape is designed to keep INLEXZO™ in your bladder



Administered by a healthcare provider in a brief office procedure



Stays in your bladder for about 3 weeks at a time



If you cannot or do not want to undergo bladder removal surgery, ask your doctor if INLEXZO™ is right for you

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™:

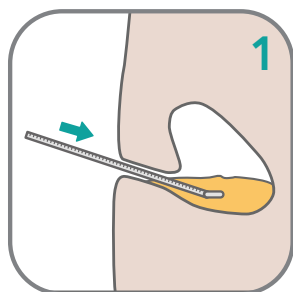
- Do not empty your bladder right before your procedure to insert INLEXZO™.

Please read Important Safety Information throughout and on pages 15-17 and full [Prescribing Information](#) for INLEXZO™.

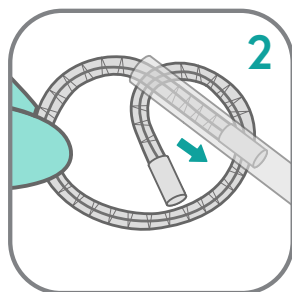
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HOW IS INLEXZO™ GIVEN?

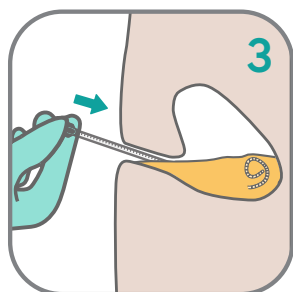
INSERTING INLEXZO™



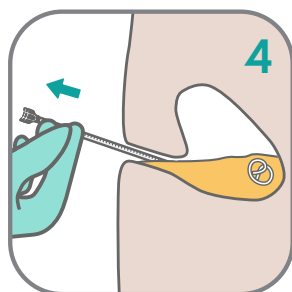
A healthcare provider will pass a tube (urinary catheter) via the urethra into your bladder.



As INLEXZO™ is passed into the tube, it uncurls and straightens.



Once inside your bladder, INLEXZO™ resumes its curled shape.



The tube will then be removed, and INLEXZO™ will remain inside your bladder.

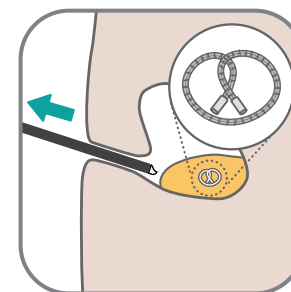
INLEXZO™ is always inserted and removed by a healthcare provider

IMPORTANT SAFETY INFORMATION *(continued)*

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.

REMOVING INLEXZO™



A healthcare provider will remove INLEXZO™ using a tube-like instrument (cystoscope). During removal, your healthcare provider may use the cystoscope's camera to check inside your bladder and see how INLEXZO™ has been working. Your healthcare provider may insert a new INLEXZO™ immediately after removing the previously inserted INLEXZO™. See [dosing information](#) on page 11.

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



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THINGS TO KNOW DURING TREATMENT

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

MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION CARD

Your healthcare provider will give you a Magnetic Resonance Imaging (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

In line with your routine

There is no need to hold your urine after treatment,
and you may urinate normally.

Not actual patients.



Please read Important Safety Information
throughout and on pages 15-17 and full
[Prescribing Information](#) for INLEXZO™.

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A treatment that goes with you

Each dose of INLEXZO™ stays in your bladder for about 3 weeks at a time.



Not actual patient.

IMPORTANT SAFETY INFORMATION (continued)

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).

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.

YOUR JOURNEY WITH INLEXZO™:

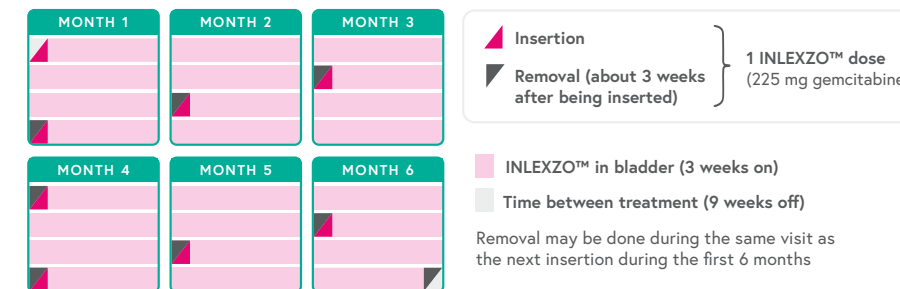
INLEXZO™ is given in 14 doses over about 2 years

- 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)

Initial Period

First 6 months

Once every 3 weeks | 8 doses

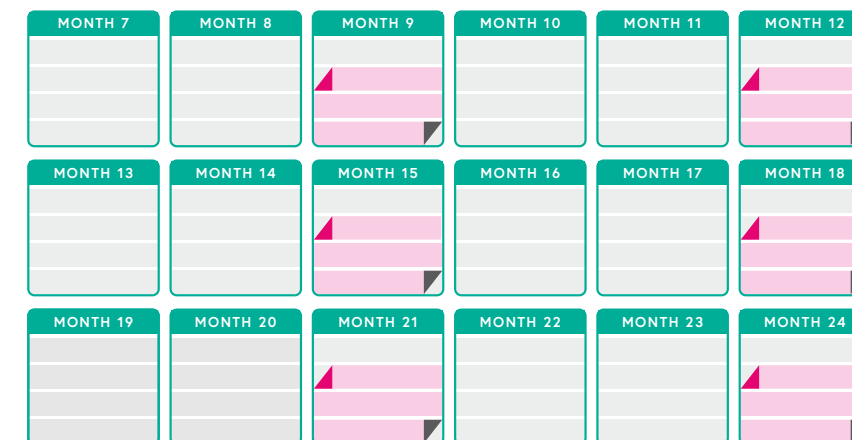


Initial period provides 6 months of continuous dosing

Continuation Period

Next 18 months

Once every 12 weeks | 6 doses



Dosing is quarterly after 6 months

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 Important Safety Information throughout and on pages 15-17 and full [Prescribing Information](#) for INLEXZO™.



INLEXZO™ WAS STUDIED IN A CLINICAL TRIAL

Who participated in this study?

- 83 adults with a certain type of NMIBC that had not spread to other parts of the body
- Their cancer remained or came back within 12 months of completing multiple rounds of BCG
- They could not or did not want to undergo bladder removal surgery



Designed for patients with certain NMIBC not wanting or able to have bladder removal surgery

What were the goals of the study?

- See if the cancer **completely responded** to treatment (the person did not show any signs of cancer)
- See how long the patients responded to treatment (**duration of response**)

How did patients receive INLEXZO™?



- Once every 3 weeks for 6 months



- Then, once every 12 weeks for the next 18 months



- Once inserted, INLEXZO™ stayed in the bladder for 3 weeks and was then removed

IMPORTANT SAFETY INFORMATION (continued)

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

INLEXZO™ was effective in helping to treat certain NMIBC

In a clinical trial of 83 people with a certain NMIBC,

82% of people who received INLEXZO™ did not show any signs of bladder cancer at any time during the study (complete response)

51% of those people who responded maintained a complete response for 12 months or longer (duration of response)

See the most common [side effects](#) on page 14.



Not actual patients.

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WHAT SHOULD I LOOK OUT FOR WHILE ON INLEXZO™?

Most common bladder-related side effects 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



Pain in the urinary tract (felt in the lower stomach area or lower back)



Blood in urine



Bladder irritation

Most common blood test–related side effects include:



- Decreases in blood cell counts (hemoglobin, white blood cells)
- Changes in your pancreas function blood tests (increased lipase)
- Decreased potassium level in the blood
- Changes in your kidney function blood tests (increased creatinine)
- Changes in your liver function blood tests (increased aspartate aminotransferase, increased alanine transaminase)
- Decreased sodium level in the blood

These are not all the possible side effects, and they can vary from person to person.

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

In the clinical study, **7% of people** permanently stopped INLEXZO™ treatment due to side effects.

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:

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- 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.

How will I receive INLEXZO™?

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- 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.

(Continued on next page)

Please read additional Important Safety Information on pages 16-17 and full [Prescribing Information](#) for INLEXZO™.



IMPORTANT SAFETY INFORMATION (continued)

How will I receive INLEXZO™? (continued)

- 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).

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.

IMPORTANT SAFETY INFORMATION (continued)

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

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.

cp-520100v1

Please read additional Important Safety Information on page 15 and full [Prescribing Information](#) for INLEXZO™.



Once you and your doctor have decided that INLEXZO™ is right for you, sign up for

inlexzo withMe

PERSONALIZED 1-ON-1 SUPPORT

You have access to free, dedicated support. Your Care Navigator is here to help guide you to support solutions throughout your treatment journey.

Starting a new treatment can be overwhelming and you may still have questions. We are here to help.



Free, 1-on-1 Personalized Care Navigator Support



Cost Support Options Regardless of Your Insurance Type



Additional Support and Community Connections

Sign up for [support](#)

OR Call 833-JNJ-wMe1 (833-565-9631),
Monday through Friday, 8:00 AM–8:00 PM ET



If you're prescribed INLEXZO™, when you sign up for INLEXZO withMe, you'll get a free Patient Starter Kit with resources to help you start your treatment.

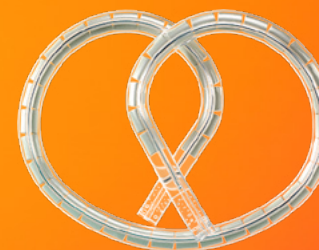
The support and resources provided by INLEXZO withMe are not intended to provide medical advice, replace a treatment plan you receive from your doctor or nurse, or serve as a reason for you to start or stay on treatment.

CHOOSE INLEXZO™

INNOVATIVE DESIGN

IMPACTFUL RESULTS

IN LINE WITH YOUR ROUTINE



Illustrative depiction. Not actual size.

After BCG stops working, take the next step.
Ask your urologist if INLEXZO™ is right for you.

IMPORTANT SAFETY INFORMATION *(continued)*

What are the possible side effects of INLEXZO™? *(continued)*

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.

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

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