

For care partners of people being treated with INLEXZO™



You've got their back.
WE'VE GOT YOURS.

Useful information, tips, and support to help every step of the way.

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 Important Safety Information throughout and on pages 10-11 and full [Prescribing Information](#) for INLEXZO™.



inlexzo™
gemcitabine intravesical
system | 225 mg

WE'RE HERE TO HELP YOUR LOVED ONE—AND YOU

Life after a cancer diagnosis can feel overwhelming. Especially if the initial treatment plans are not proving as effective as you'd hoped; it can add to the uncertainty and frustration.

But your loved one isn't going through it alone. Care partners play an important role in the treatment process. It's also a big commitment that can involve:



Advocating for your loved one and communicating their needs to doctors.



Potentially traveling long distances and coordinating care.



Managing day-to-day care, such as a medication schedule, meals, finances, and more.

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:

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

Males treated with INLEXZO™:

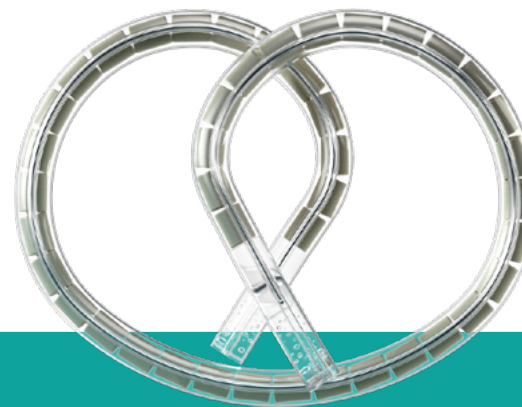
- o If you have a female partner who is able to become pregnant, you should use effective birth control (contraception) during treatment with INLEXZO™ and for 3 months after final removal of INLEXZO™.

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MEET THE PRETZEL BY INLEXZO™

INLEXZO™ is an innovative treatment delivery system for adults who have certain types of non-muscle invasive bladder cancer (NMIBC) when Bacillus Calmette-Guérin (BCG) stops working. It is a thin, flexible, curled silicone tube, shaped similar to a pretzel, which contains cancer-fighting medicine called gemcitabine.

Illustrative depiction.
Not actual size.



- A thin, flexible, curled silicone tube
- Designed to release a cancer-fighting medicine into the bladder overtime
- Administered by a healthcare provider during a brief office procedure through a urinary catheter
- Stays in the bladder for about 3 weeks at a time

If you would like additional tips and support, visit [INLEXZOwithMe.com/signup](https://www.inlexzowithme.com/signup) to sign up for helpful emails from INLEXZO withMe.

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THE INLEXZO™ DOSING SCHEDULE

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

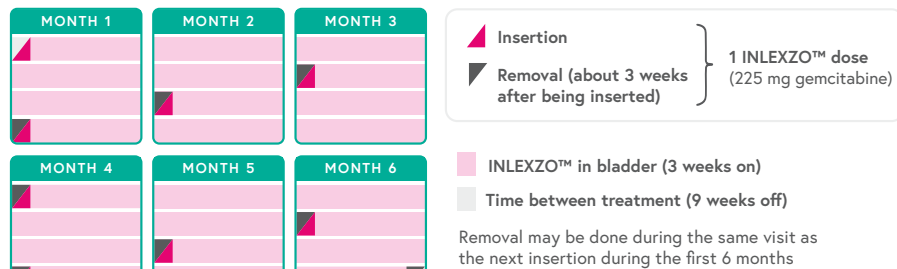
INLEXZO™ is given in 14 doses over about 2 years

- INLEXZO™ is inserted into the 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

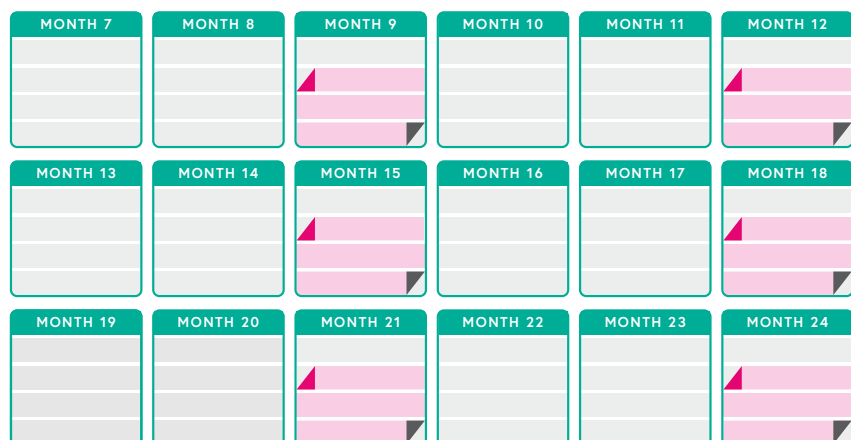


Initial period provides 6 months of continuous dosing

Continuation Period

Next 18 months

Once every
12 weeks | 6 doses



Dosing is quarterly after 6 months

It is very important that your loved one goes to all of their appointments. If they miss any appointments, call their healthcare provider as soon as possible to schedule their appointment.

Please read Important Safety Information throughout and on pages 10-11 and full [Prescribing Information](#) for INLEXZO™.

THINGS TO KNOW DURING TREATMENT

INSTRUCTIONS FOR YOUR LOVED ONE:

BEFORE RECEIVING INLEXZO™

- Do not empty their bladder right before INLEXZO™ insertion procedure

AFTER RECEIVING INLEXZO™

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

AFTER THE HEALTHCARE PROVIDER REMOVES INLEXZO™

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

MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION CARD

Your loved one's healthcare provider will give them a Magnetic Resonance Imaging (MRI) Safety Information Card.

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

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TREATMENT DAY CHECKLIST

Caregiving can feel overwhelming at times. Beyond the concern for your loved one, there are a lot of other things to manage. This checklist can help you prepare for treatment days.



Make a schedule

Knowing where the treatment takes place and when your loved one needs to be there can help make the day smoother.



Help your loved one feel comfortable

Even small things, like encouraging them to wear comfortable clothes and bringing snacks, can help. Always talk with their care team about snacks or drinks to make sure they won't impact the treatment.



Adjust your schedule

Treatment days can disrupt your usual schedule. It helps to block out time in advance—and to let your friends, family, and coworkers know if you need help with any errands while you're helping your loved one.

Remember, if your loved one misses an appointment, be sure to schedule another one as soon as possible.

IMPORTANT SAFETY INFORMATION *(continued)*

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

- 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 Important Safety Information throughout and on pages 6 10-11 and full [Prescribing Information](#) for INLEXZO™.

POSSIBLE SIDE EFFECTS WHILE TAKING INLEXZO™

As with any treatment, side effects can occur. Taking notes of which ones your loved one experiences, when they occur, and how often can help at the next doctor appointment.

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 pancreas function blood tests (increased lipase)
- Increased potassium level in the blood

- Changes in kidney function blood tests (increased creatinine)
- Changes in 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

In a clinical study of 85 people with certain NMIBC that did not respond to BCG, 7% of people permanently stopped INLEXZO™ treatment due to side effects.

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DAY-TO-DAY CARE



Ask your loved one how they're feeling

Taking notes on how their treatment is going and which side effects they may experience will help when talking with their healthcare provider.



Watch for signs of infection

One of the potential side effects while being treated with INLEXZO™ are urinary tract infections. Keep an eye out for certain signs, such as a fever. If you suspect your loved one may have a urinary tract infection, contact their healthcare provider immediately. Your loved one's healthcare provider may give them antibiotics before INLEXZO™ is inserted or removed.



Set goals to stay hydrated

While INLEXZO™ is in the bladder, your loved one should drink plenty of non-alcoholic, caffeine-free fluids (at least 1500 mL or 6-7 cups per day). This helps produce urine in the bladder so that INLEXZO™ can work properly.

DON'T FORGET TO TAKE CARE OF YOURSELF

While you want to do everything you can to help your loved one—it can sometimes feel overwhelming. It helps to practice self-care along the way.



Ask for help
when you need it



Sleep and
eat well



Take time
for yourself

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.

Please read Important Safety Information throughout and on pages 8 10-11 and full [Prescribing Information](#) for INLEXZO™.

ADDITIONAL SUPPORT FOR YOU AND THE PERSON YOU'RE SUPPORTING

PATIENT & CARE PARTNER RESOURCES



Bladder Cancer Advocacy Network (BCAN)

A group that advocates for better today's and more tomorrow's for everyone impacted by bladder cancer by focusing on four critical areas: education, support, research, and policy.

[Click here to find out more](#)



Urology Care Foundation

A nonprofit dedicated to advancing urologic health—educating patients, funding research, and raising awareness to improve care.

[Click here to find out more](#)

CARE PARTNER RESOURCES



The Mighty Caregiver Toolkit

Explore a digital toolkit for care partners, provided by The Mighty.

[Click here to find out more](#)

PATIENT RESOURCES



Imerman Angels

A community that provides free, personalized one-on-one cancer support for cancer fighters, survivors, previvors, and caregivers.

[Click here to find out more](#)

You can find advocacy groups and resources near you at advocacyconnector.com



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- 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:

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

Males treated with INLEXZO™:

- o 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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- 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).

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 | • decreased lymphocytes |
| • urinary tract infection | • blood in urine |
| • pain or burning sensation when passing urine | • increased creatinine |
| • urgent need to pass urine | • increased potassium |
| • decreased hemoglobin | • increased aspartate aminotransferase |
| • increased lipase | • decreased sodium |
| • pain in the urinary tract (felt in the lower stomach area or lower back) | • 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 full [Prescribing Information](#) for INLEXZO™.

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Once your loved one and their doctor have decided that INLEXZO™ is right for them, sign up for INLEXZO withMe

inlexzo withMe



SUPPORT IS WITH YOU ALONG THE WAY

You and your loved one have access to free, dedicated support. A Care Navigator is here to help guide you both to support solutions throughout treatment with INLEXZO™. Upon a patient's consent, care partners can participate in check-ins with your dedicated Care Navigator.

Not actual patient.

WE ARE HERE TO HELP.

Starting a new treatment can be overwhelming and you may still have questions.



Free 1-on-1 Dedicated Care Navigator Support



Cost Support Options Regardless of Insurance Type



Additional Resources and Community Connections

To sign up, visit INLEXZOwithMe.com/signup
or call 833-JNJ-wMe1 (833-565-9631),
Monday through Friday, 8:00 AM—8:00 PM ET.

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

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