

WHAT IS ERLEADA®?

ERLEADA® (apalutamide) is a prescription medicine used for the treatment of prostate cancer:

 that has spread to other parts of the body and still responds to a medical or surgical treatment that lowers testosterone.

OR

 that has not spread to other parts of the body and no longer responds to a medical or surgical treatment that lowers testosterone.

It is not known if ERLEADA® is safe and effective in females.

It is not known if ERLEADA® is safe and effective in children.

IMPORTANT SAFETY INFORMATION

ERLEADA® may cause serious side effects including:

- Heart disease, stroke, or mini-stroke, fractures and falls, seizure, and severe skin reactions
- The most common side effects of ERLEADA® include feeling very tired, joint pain,rash—tell your healthcare provider if you get a rash, decreased appetite, fall, weight loss, high blood pressure, hot flash, diarrhea, fracture



IMPORTANT SAFETY INFORMATION (CONTINUED)

Before taking ERLEADA®, tell your healthcare provider about all your medical conditions, including if you:

- have a history of heart disease
- have high blood pressure
- have diabetes
- have abnormal amounts of fat or cholesterol in your blood (dyslipidemia)
- have a history of seizures, brain injury, stroke, or brain tumors

TABLE OF CONTENTS

LIVING YOUR LIFE WITH PROSTATE CANCER	<u>4</u>
HOW ERLEADA® WORKS	<u>5</u>
ABOUT ERLEADA®	<u>6-9</u>
SIDE EFFECTS	<u>10-11</u>
DOSING	<u>12-13</u>
STARTING AND STAYING ON ERLEADA®	<u>14-16</u>
SUPPORT	<u>17</u>
PAYING FOR ERLEADA®	<u>18-19</u>
YOUR HEALTHCARE TEAM INFO	<u>20</u>
STOP AND REFLECT	<u>21</u>
IMPORTANT SAFETY INFORMATION	

BEING THERE IS POSSIBLE™

Click to Learn More About

Patient Support From *Janssen Compass*™





LIVING YOUR LIFE WITH PROSTATE CANCER

Prostate cancer is common and may be diagnosed early

It's important to understand your disease to help make treatment decisions with your healthcare provider. There are many factors to consider, from the type of cancer you have to the clinical study results for your medication.



mCSPC

WHAT IS METASTATIC CASTRATION-SENSITIVE PROSTATE CANCER (mCSPC)?

Prostate cancer that **HAS SPREAD** to other parts of the body and **STILL RESPONDS** to medical or surgical treatment that lowers testosterone.



nmCRPC

WHAT IS NON-METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (nmCRPC)?

Prostate cancer that **HAS NOT SPREAD** to other parts of the body and **NO LONGER** responds to medical or surgical treatment lowers testosterone.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Before taking ERLEADA®, tell your healthcare provider about all your medical conditions, including if you:

- are pregnant or plan to become pregnant. ERLEADA® can cause harm to your unborn baby and loss of pregnancy (miscarriage).
- have a partner who is pregnant or may become pregnant.

HOW ERLEADA® WORKS

ERLEADA® + ADT work together to lower androgens that can help fuel prostate cancer



How androgens help fuel prostate cancer

- Androgens are male hormones, primarily testosterone, that are needed for the prostate to function normally
- However, when androgens attach to androgen receptors they can help fuel prostate cancer cell growth



The goal of ADT* is to lower androgen† levels

- Medical or surgical treatments that lower testosterone are also referred to as androgen deprivation therapy (ADT)
- ADT includes treatment to suppress or block the production or action of male hormones called androgens



ERLEADA® + ADT fight prostate cancer together

 ERLEADA® blocks androgens from attaching to receptors to help prevent cancer cells from growing

*ADT: Medical or surgical treatments that lower testosterone.

†Androgens: Male hormones, primarily testosterone, that are needed for the prostate to function normally but can help fuel prostate cancer cell growth.

IMPORTANT SAFETY INFORMATION (CONTINUED)

- O Males who have female partners who are able to become pregnant should use effective birth control (contraception) during treatment and for 3 months after the last dose of ERLEADA®.
- Males should use a condom during sex with a pregnant female.
 Talk with your healthcare provider if you have questions about birth control.
- are breastfeeding or plan to breastfeed. It is not known if ERLEADA® passes into breast milk.



FOR MEN WITH mCSPC,

BEING THERE LONGER IS POSSIBLE™

ERLEADA® + ADT was compared with placebo + ADT in a clinical study of 1052 men with mCSPC

• In this study, men received either ERLEADA® 240 mg once daily or placebo. All men in the study received ADT

In a clinical study,

ERLEADA® + ADT reduced the risk of death by 35% vs placebo + ADT**



Here's another way to look at the results:

At 4 years, approximately 65% of men taking ERLEADA® + ADT were alive vs 52% of men taking placebo + ADT*

*Median (middle) follow-up time was 44.0 months. Median (middle) data has not been reached for ERLEADA®.

In an earlier analysis from the study, the reduction in the risk of death was 33%.

In a clinical study,

ERLEADA® + ADT reduced the risk of prostate cancer getting worse by 52% vs placebo + ADT‡



Here's another way to look at the results:

At 2 years, approximately 68% of men taking ERLEADA® + ADT lived without their disease getting worse vs 48% of men taking placebo[‡]

[†]Median (middle) data has not been reached for ERLEADA®.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. ERLEADA® can interact with many other medicines.



Reduced risk of beginning chemotherapy vs placebo + ADT

The clinical study for men with mCSPC also evaluated time to chemotherapy:

ERLEADA® + ADT reduced the risk of beginning chemotherapy by 61% vs placebo + ADT§

§Median (middle) data has not been reached.

ADT: Androgen deprivation therapy (ADT) includes medical or surgical treatment that lowers testosterone.

Chemotherapy: Type of drug(s) that kill cancer cells.

Median: The middle number in a set of numbers. For 50% of people, this value was larger, and for 50% of people, it was smaller. **mCSPC:** Metastatic castration-sensitive prostate cancer (mCSPC) is prostate cancer that HAS SPREAD to other parts of the body and STILL responds to medical or surgical treatment that lowers testosterone.

Placebo: Pronounced "pluh-see-bow": a pill that looks like "real" medicine but contains nothing to affect health.

Progression: Disease spreading further as measured by imaging studies or dying.

Time to chemotherapy: Length of time from when patients began study to starting chemotherapy.





BEING THERE LONGER IS POSSIBLE™

ERLEADA® + ADT was compared with placebo + ADT in a clinical study of 1207 men with nmCRPC

• In this study, men either received ERLEADA® 240 mg once daily or placebo. All men in the study received ADT

ERLEADA® HELPED SOME MEN WITH nmCRPC LIVE LONGER WITHOUT THE SPREAD OF CANCER

In a clinical study, ERLEADA® + ADT delayed the spread of cancer to other parts of the body or death by a median of 24.3 months compared with placebo + ADT.

40.5 months

WITH ERLEADA® + ADT

VS

16.2 months

WITH PLACEBO + ADT

Additional study results in nmCRPC

THE CLINICAL STUDY FOR MEN WITH nmCRPC ALSO EVALUATED:

Overall survival: living longer



Men taking ERLEADA® + ADT

lived 14 months longer

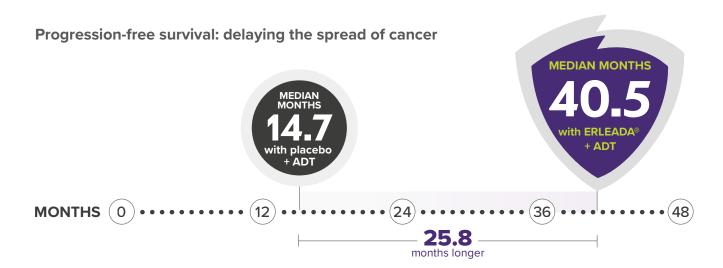
than men taking placebo + ADT

(73.9 months vs 59.9 months)

IMPORTANT SAFETY INFORMATION (CONTINUED)

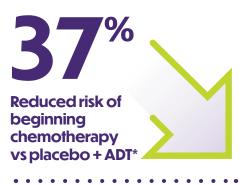
You should not start or stop any medicine before you talk with the healthcare provider that prescribed ERLEADA®.

Know the medicines you take. Keep a list of them with you to show to your healthcare provider and pharmacist when you get a new medicine.





Time to chemotherapy: delaying the start of chemotherapy



*Median data has not been reached.

ADT: Androgen deprivation therapy (ADT) includes medical or surgical treatment that lowers testosterone. **Chemotherapy:** Type of drug(s) that kill cancer cells.

Median: The middle number in a set of numbers. For 50% of people, this value was larger, and for 50% of people, it was smaller. **nmCRPC:** Non-metastatic castration-resistant prostate cancer (nmCRPC) is prostate cancer that HAS NOT SPREAD to other parts of the body and NO LONGER responds to medical or surgical treatment that lowers testosterone.

Placebo: Pronounced "pluh-see-bow": a pill that looks like "real" medicine but contains nothing to affect health.

Progression-free survival: Length of time patients lived without their prostate cancer spreading to local or distant parts of the body or death. **Time to chemotherapy:** Length of time from when patients began study to starting chemotherapy.



SIDE EFFECTS

ERLEADA® may cause serious side effects including:



Heart Disease, Stroke, or Mini-Stroke. Bleeding in the brain or blockage of the arteries in the heart or in part of the brain have happened in some people during treatment with ERLEADA® and can lead to death. Your healthcare provider will monitor you for signs and symptoms of heart or brain problems during your treatment with ERLEADA®. Call your healthcare provider or get medical help right away if you get:

- chest pain or discomfort at rest or with activity
- shortness of breath
- numbness or weakness of the face, arm, or leg, especially on one side of the body
- trouble talking or understanding
- trouble seeing in one or both eyes
- dizziness, loss of balance or coordination, or trouble walking



Fractures and Falls. ERLEADA® treatment can cause bones and muscles to weaken and may increase your risk for falls and fractures. Falls and fractures have happened in men during treatment with ERLEADA®. Your healthcare provider will monitor your risks for falls and fractures during treatment with ERLEADA®.



Seizure. Treatment with ERLEADA® may increase your risk of having a seizure. You should avoid activities where a sudden loss of consciousness could cause serious harm to yourself or others. Tell your healthcare provider right away if you have a loss of consciousness or seizure. Your healthcare provider will stop ERLEADA® if you have a seizure during treatment.



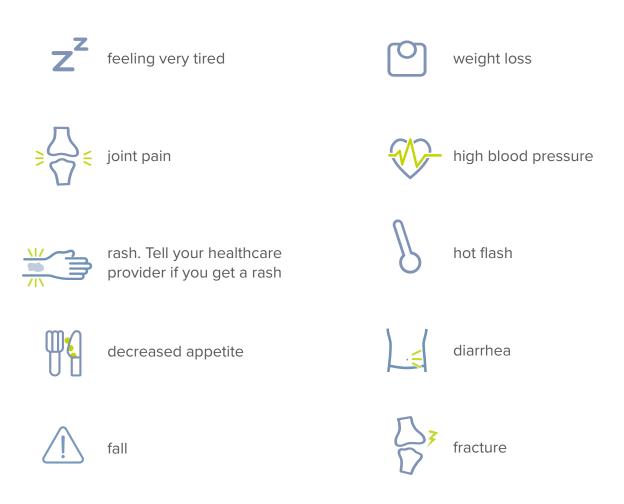
Severe Skin Reactions. Treatment with ERLEADA® may cause severe skin reactions that can be life-threatening or may lead to death. Stop taking ERLEADA® and get medical help right away if you develop any of these signs or symptoms of a severe skin reaction:

- severe rash or rash that continues to get worse
- fever or flu-like symptoms
- swollen lymph nodes

- blisters or sores in the mouth, throat, nose, eyes, or genital area
- blistering or peeling of the skin

SIDE EFFECTS (CONTINUED)

THE MOST COMMON SIDE EFFECTS OF ERLEADA® INCLUDE:



• Your healthcare provider may reduce your dose, temporarily stop, or permanently stop treatment with ERLEADA® if you have certain side effects.



ONCE-A-DAY ORAL TABLETS

Take ERLEADA® as directed by your doctor

The recommended dose of ERLEADA® is 240 mg (four 60 mg tablets) taken orally once daily.

TAKE ERLEADA®



UNABLE TO SWALLOW TABLETS WHOLE?

Learn an alternate way to take ERLEADA®

Please read the complete directions below for mixing ERLEADA® with applesauce.

Taking ERLEADA® if you are unable to swallow tablets whole:



Place your dose of ERLEADA® in a container that contains 4 ounces (120 mL) of applesauce and stir. **DO NOT** crush the tablets.



Wait 15 minutes and stir the mixture.

Wait another 15 minutes and stir the mixture until tablets are well mixed with no chunks remaining.



Swallow the mixture right away using a spoon.



Rinse the container with 2 ounces (60 mL) of water and drink the water mixture right away.

Repeat the rinse with 2 ounces (60 mL) of water one more time to make sure that you take your full dose of ERLEADA®.

Swallow all the applesauce and medicine mixture within 1 hour of preparation. DO NOT store ERLEADA® that is mixed with applesauce.





- Take ERLEADA® exactly as your healthcare provider tells you
- Do not stop taking your prescribed dose of ERLEADA® without talking with your healthcare provider first





• Take your prescribed dose of ERLEADA® 1 time a day, at the same time each day



Take ERLEADA® with or without food



- Swallow ERLEADA® tablets whole If you miss a dose of ERLEADA®, take your normal dose as soon as possible on the same day. Return to your normal schedule on the following day. You should not take extra tablets to make up the missed dose
- You should start or continue a gonadotropin-releasing hormone (GnRH) analog therapy during your treatment with ERLEADA® unless you had a surgery to lower the amount of testosterone in your body (surgical castration)



If you take too much ERLEADA®, call your healthcare provider or go to the nearest hospital emergency room



TALKING TO YOUR DOCTOR ABOUT GETTING STARTED

Always remember that your healthcare team should be your main source of treatment direction and information. You should have an open and honest conversation with them.

TO HELP GET THE MOST OUT OF YOUR TREATMENT WITH ERLEADA®



Take ERLEADA® exactly as your doctor tells you



Tell your doctor if you have any side effect that does not go away or that bothers you



Call your doctor for medical advice about side effects



Do not stop taking your prescribed dose of ERLEADA® without talking with your doctor first

QUESTIONS TO ASK YOUR HEALTHCARE TEAM

	chat your healthcare ould have an open a				allection and
ıelpful, you may	use this space to jo	ot down any go	als or questions	s about your tre	atment.
				V Er	leadautamide)60mg
				(apali	utamide)60ma

THERE ARE 2 WAYS TO RECEIVE YOUR ERLEADA® (apalutamide) PRESCRIPTION

Doctor's office pharmacy

If your doctor's office has its own pharmacy, your prescription may be available for pick up there.

OR

Specialty pharmacy

Your doctor will most likely send your prescription to a specialty pharmacy. Specialty pharmacies carry certain medications that are not available at retail pharmacies.

THE SPECIALTY PHARMACY PATH



When you receive your prescription:

 Your doctor's office will complete the necessary paperwork and then submit on your behalf to the specialty pharmacy. Before you leave the doctor's office, make sure your paperwork has been submitted



Within a few days:

 The specialty pharmacy will call you to discuss your prescription costs and arrange delivery by mail of your ERLEADA® right to your front door. If you don't receive a call, contact your doctor's office



Within 2 weeks:

• Your 30-day ERLEADA® prescription bottle should arrive by mail within 14 days. If it does not, contact your doctor's office

EVERY MONTH, YOU WILL BE CONTACTED TO COORDINATE YOUR MONTHLY REFILL.

PERSONALIZED SUPPORT. FROM PEOPLE WHO CARE.



Once you and your doctor have decided that ERLEADA® is right for you, you have access to a free, personalized support program that connects you with a dedicated Care Navigator to help you get started with your treatment and stay on track.

THROUGH THIS PROGRAM YOU CAN:



Connect...

each time to the same $Janssen\ Compass^{TM}\ Care\ Navigator\ who\ understands$ and offers education on your cancer and ERLEADA®



Learn...

about resources to support you with cost, coverage, your personal wellness, and your emotional well-being throughout your treatment journey and beyond



Simplify...

your experience through personalized education, every step of the way, to build confidence in what to expect and support in making decisions about your treatment with your doctor and loved ones

CONNECT WITH US!

Your personal Care Navigator is just a phone call away.





You can also call us at **844-NAV-1234** (844-628-1234), Monday through Friday, 8:30 AM — 8:30 PM ET



Patient Support from Janssen Compass™

PAYING FOR ERLEADA®

FOR COMMERCIALLY INSURED PATIENTS: SAVINGS PROGRAM

ELIGIBLE PATIENTS PAY AS LITTLE AS



There is a limit to savings each year. Participate without sharing your income information. See program requirements here.



Call a Care Navigator to learn more about program requirements and enroll over the phone.



You can also call us at 844-NAV-1234 (844-628-1234), Monday through Friday, 8:30 AM -8:30 PM ET

FOR MEDICARE PART D PATIENTS: EXTRA HELP AND LOW-INCOME SUBSIDY

ELIGIBLE PATIENTS PAY LESS THAN

\$10

PER MONTH

Call a Care Navigator to learn more about program requirements and how to enroll.

Download Medicare Resource Guide Medicare Part D Extra Help — Low-Income Subsidy

- You may be eligible for the Extra Help Program provided by the Social Security Administration
- The Low-Income Subsidy (LIS) program provides financial assistance for patients who may otherwise be unable to afford the costs associated with their Medicare Part D plan
- Eligible patients may be able to access brand-name drugs for less than \$10 per month

STATE HEALTH INSURANCE ASSISTANCE PROGRAMS (SHIPS)

A state program that gets money from the federal government to give free local health insurance counseling to people with Medicare.



If you use government-funded healthcare programs such as Medicare, Medicaid, or need supplemental assistance with paying for your Janssen medication

IF YOU DO NOT HAVE INSURANCE

A Care Navigator can be your guide to non-profit organizations, patient advocacy groups and state programs that may help with financial assistance.

Visit <u>janssencompass.com</u> to request your first call and learn more about how *Janssen Compass*™ can be here for you.

You can also call at 844-NAV-1234 (844-628-1234).

Monday through Friday, 8:30 AM – 8:30 PM ET.

Or text "CALL" to 844-628-1234* to request your first call!

*The personal information you provide about yourself through text message will be used by Janssen Biotech, Inc., and its affiliates and the program's service providers (collectively Janssen) to contact you by phone to describe the *Janssen Compass*™ program and complete the enrollment process. The Privacy Policy further explains how Janssen processes the personal information you provide. By texting "CALL," you indicate that you have read, understand, and agree to these terms.

By texting "CALL" to 844-628-1234, you consent to receive automated text messages from the Janssen Compass™ program to schedule a call with a dedicated Care Navigator and to learn more about the program. Please note, text message and data rates may apply. You may opt out at any time by texting "STOP" to 844-628-1234. Please do not share any unprompted personal or medical information as we are not able to reply to messages other than "CALL." If you have specific questions, please contact a Janssen Compass™ Care Navigator at 844-628-1234, Monday-Friday, from 8:30 AM - 8:30 PM. Call your doctor for medical advice about side effects. You may report side effects to the Janssen Medical Information Center by calling 800-526-7736.

(apalutamide

YOUR HEALTHCARE TEAM

Use this space to keep contact information for your healthcare team

Primary care physician's name:
Primary care physician's address:
Primary care physician's phone number:
Oncologist's name:
Oncologist's address:
Oncologist's phono number:
Oncologist's phone number:
Urologist's name:
Urologist's name:
Urologist's address:
Urologist's phone number:
Specialty pharmacy's name:
Specialty pharmacy's address:
Specialty pharmacy's phone number:

STOP AND REFLECT

Use this space to write about hopes and goals for the journey ahead of you
What is one thing you are actively trying to change or maintain this month?
What is something you are looking forward to in the near future?
What is something new you'd like to try?
How can your friends and loved ones help support you?
Additional thoughts:



IMPORTANT SAFETY INFORMATION

Before taking ERLEADA®, tell your healthcare provider about all your medical conditions, including if you:

- · have a history of heart disease
- · have high blood pressure
- have diabetes
- have abnormal amounts of fat or cholesterol in your blood (dyslipidemia)
- · have a history of seizures, brain injury, stroke, or brain tumors
- are pregnant or plan to become pregnant. ERLEADA® can cause harm to your unborn baby and loss of pregnancy (miscarriage).
- have a partner who is pregnant or may become pregnant.
 - Males who have female partners who are able to become pregnant should use effective birth control (contraception) during treatment and for 3 months after the last dose of ERLEADA®.
 - Males should use a condom during sex with a pregnant female.
 Talk with your healthcare provider if you have questions about birth control.
- are breastfeeding or plan to breastfeed. It is not known if ERLEADA® passes into breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. ERLEADA® can interact with many other medicines.

You should not start or stop any medicine before you talk with the healthcare provider that prescribed ERLEADA®.

Know the medicines you take. Keep a list of them with you to show to your healthcare provider and pharmacist when you get a new medicine.

How should I take ERLEADA®?

- Take ERLEADA® exactly as your healthcare provider tells you.
- Do not stop taking your prescribed dose of ERLEADA® without talking with your healthcare provider first.
- Take your prescribed dose of ERLEADA® 1 time a day, at the same time each day.
- Take ERLEADA® with or without food.
- Swallow ERLEADA® tablets whole.
- If you miss a dose of ERLEADA®, take your normal dose as soon as possible on the same day. Return to your normal schedule on the following day. You should not take extra tablets to make up the missed dose.
- You should start or continue a gonadotropin-releasing hormone (GnRH) analog therapy during your treatment with ERLEADA® unless you have had a surgery to lower the amount of testosterone in your body (surgical castration).
- If you take too much ERLEADA®, call your healthcare provider or go to the nearest hospital emergency room.

cp-50508v

IMPORTANT SAFETY INFORMATION

What are the possible side effects of ERLEADA®?

ERLEADA® may cause serious side effects including:

- **Heart Disease, Stroke, or Mini-Stroke.** Bleeding in the brain or blockage of the arteries in the heart or in part of the brain have happened in some people during treatment with ERLEADA® and can lead to death. Your healthcare provider will monitor you for signs and symptoms of heart or brain problems during your treatment with ERLEADA®. Call your healthcare provider or get medical help right away if you get:
 - chest pain or discomfort at rest or with activity
 - shortness of breath
 - numbness or weakness of the face, arm, or leg, especially on one side of the body
- trouble talking or understanding
- trouble seeing in one or both eyes
- dizziness, loss of balance or coordination, or trouble walking
- Fractures and Falls. ERLEADA® treatment can cause bones and muscles to weaken and may increase your risk for falls and fractures. Falls and fractures have happened in people during treatment with ERLEADA®. Your healthcare provider will monitor your risks for falls and fractures during treatment with ERLEADA®.
- **Seizure.** Treatment with ERLEADA® may increase your risk of having a seizure. You should avoid activities where a sudden loss of consciousness could cause serious harm to yourself or others. Tell your healthcare provider right away if you have a loss of consciousness or seizure. Your healthcare provider will stop ERLEADA® if you have a seizure during treatment.
- Severe skin reactions. Treatment with ERLEADA® may cause severe skin reactions that can be life-threatening or may lead to death. Stop taking ERLEADA® and get medical help right away if you develop any of these signs or symptoms of a severe skin reaction:
 - severe rash or rash that continues to get worse
 - fever or flu-like symptoms
 - swollen lymph nodes

- blisters or sores in the mouth, throat, nose, eyes, or genital area
- blistering or peeling of the skin

The most common side effects of ERLEADA® include:

- · feeling very tired
- joint pain
- rash. Tell your healthcare provider if you get a rash
- decreased appetite
- fall

- weight loss
- · high blood pressure
- · hot flash
- diarrhea
- fracture

Your healthcare provider may reduce your dose, temporarily stop, or permanently stop treatment with ERLEADA® if you have certain side effects.

ERLEADA® may cause fertility problems in males, which may affect the ability to father children. Talk to your healthcare provider if you have concerns about fertility. **Do not** donate sperm during treatment with ERLEADA® and for 3 months after the last dose of ERLEADA®.

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

These are not all the possible side effects of ERLEADA®.

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





Visit ERLEADA.com to Discover How





Please see Important Safety Information throughout and on <u>pages 22-23</u>, and <u>click here</u> for the full Prescribing Information.

Janssen Biotech, Inc. 800 Ridgeview Drive Horsham, PA 19044 USA

