

Indication

FIRMAGON® (degarelix for injection) is a prescription medicine used in the treatment of advanced prostate cancer.

Important Safety Information

- Do not take FIRMAGON if you are allergic to any of the ingredients in FIRMAGON. FIRMAGON can cause serious allergic reactions. Get medical help right away if you get any of these symptoms;
 - Trouble breathing or wheezing
 - Severe itching
 - Swelling of your face, lips, mouth, or tongue





Important Safety Information (continued)

- Women who are pregnant or may become pregnant should not take FIRMAGON. FIRMAGON can harm an unborn baby when given to a pregnant woman.
- Before receiving FIRMAGON, tell your healthcare provider about all your medical conditions, including if you have any heart problems including a condition called long QT syndrome, have problems with blood levels such as sodium, potassium, calcium, and magnesium, have kidney or liver problems.



Welcome to your advanced prostate cancer (APC) treatment guide

If you've been diagnosed with APC, there is a lot to think about.

You have a well-informed treatment team that will partner with you in all important decisions on your APC journey, including choosing the ADT that's right for you.

Not all ADTs work the same way. That's why it's important for you to talk with your doctor to learn all about your ADT. You have a voice, and you deserve to be heard. Stay involved in your treatment decisions and keep talking with your healthcare team. Ask your doctor if FIRMAGON is the right ADT for you.

This brochure is designed to help you have a voice in your ADT decision.

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ADVANCED PROSTATE CANCER

An overview for you

Take a quick look at these APC facts

Many men diagnosed with prostate cancer receive different types of treatments, all with the goal of slowing progression of their disease—and very often the result is that people can live productive lives while on treatment.

- Prostate cancer is the most common cancer in men¹
- Approximately 220,800 men are diagnosed with prostate cancer every year—that's more than 604 men every day²
- Approximately 1 in 7 men in the United States will get prostate cancer in their lifetime³
- The majority of prostate cancers are dependent on testosterone for growth^{2,4}

Understanding APC: why testosterone (T) matters

The prostate is usually the size and shape of a walnut and grows bigger as you get older.



Testosterone is a hormone that can stimulate prostate cancer growth.⁵

- Growth and function of the prostate gland depend on testosterone, a male sex hormone (or androgen) made mainly in the testicles
- Cancer of the prostate gland develops when cells of the prostate show uncontrolled growth
- High levels of testosterone help fuel prostate cancer growth
- The goal of ADT is to stop the production or effects of testosterone in prostate cancer⁶
- FIRMAGON is a type of ADT that lowered testosterone nearly 90% on the first day⁷

Important Safety Information (continued)

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FIRMAGON works differently than an agonist (leuprolide) in suppressing testosterone (T)

Steps to Testosterone Suppression

FIRMAGON is an antagonist^{8,9}

Blocks a receptor, called the GnRH receptor, in an area of the brain called the pituitary

Rapidly decreases testosterone production at its main source, eliminating the possibility of an initial testosterone "surge"

Time to goal castrate levels10

1 to 3 days

Day 1: Over 50% of patients achieved castrate levels vs 0% with leuprolide. 10

Day 3: 96% of FIRMAGON patients achieved castrate levels vs 0% with leuprolide.¹⁰

FSH = follicle-stimulating hormone; GnRH = gonadotropin-releasing hormone; LH = luteinizing hormone; LHRH = luteinizing hormone-releasing hormone.

Leuprolide is an agon<u>ist</u>8

Binds to a receptor, called the LHRH receptor, in an area of the brain called the pituitary

Promotes temporary release of the hormones LH and FSH

Dramatically increases testosterone production

In some patients, this surge of testosterone may increase symptoms

Continued administration leads to decreased LH and FSH

Decreases testosterone production

Time to goal castrate levels10

Up to 28 days

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FIRMAGON® (degarelix for injection) 120 mg, 80 mg

FIRMAGON dropped T fast

Testosterone Levels in the First 28 Days of FIRMAGON vs Leuprolide^{7*}



■ FIRMAGON

■ Leuprolide

- FIRMAGON dropped T by 88%, 94%, 96%, 97%, and 98% on day 1, 3, 7, 14, and 28, respectively⁷
- Leuprolide increased T by 43%, 65%, and 8% on day 1, 3, and 7, respectively, and dropped T by 75% and 97% on day 14 and 28, respectively⁷
- By day 28, both FIRMAGON and leuprolide achieved similar testosterone levels¹⁰

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^{*}In a controlled trial of FIRMAGON compared to leuprolide, FIRMAGON was shown to reduce and maintain testosterone levels below castration level (50 ng/dL) throughout the full 12-month study.°

WHAT TO KNOW ABOUT PROSTATE-SPECIFIC ANTIGEN (PSA)

Know your level

While no particular PSA level is considered "normal" or "abnormal," the classifications below are often used. 11



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Understanding PSA levels

- Testosterone levels may affect PSA levels
- PSA is a protein produced by cells in the prostate gland¹²
- When PSA levels are high, it can be due to prostate cancer or other noncancerous conditions⁸
- As ADT lowers testosterone levels, typically the PSA levels will start to drop as well¹⁰
- PSA is used to help diagnose and track the progress of your APC treatment, so you will likely have regular tests to check your PSA level^{11,12}

FIRMAGON began reducing testosterone on day 1 by 88% and maintained PSA reduction over 12 months of treatment.7,10*

*PSA is a measure that may indicate that your prostate cancer has gotten worse. These results, which show a reduction of PSA, should be interpreted carefully. There is no proof that how quickly PSA drops has clinical benefit. 10

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FIRMAGON dropped PSA levels, too

- Testosterone levels can affect PSA levels
- FIRMAGON reduced median PSA levels by 64% by week 2, 85% by month 1, and 95% by month 3¹⁰*
- FIRMAGON is proven to maintain PSA suppression through 12 months of treatment¹⁰

PSA Levels After Starting Treatment¹⁰



*PSA is a measure that may indicate that your prostate cancer has gotten worse. These results, which show a reduction of PSA, should be interpreted carefully. There is no proof that how quickly PSA drops has clinical benefit.¹⁰

Typically, PSA levels will drop after testosterone levels drop.

Important Safety Information (continued)

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HAVE A VOICE

Get involved in your treatment decisions

The diagnosis of APC probably gave you a lot to think about—and raised lots of questions

Let your voice be heard when you connect with your treatment team. Keeping in touch with your treatment team is one important way to stay on top of your health and be involved in your treatment decisions.

You and your loved ones will learn all you need to know by keeping the line of communication open and active.

Questions you may find useful when talking with your treatment team

- What is the main goal of therapy?
- How soon does FIRMAGON get me to my testosterone and PSA goals?
- How will I know my ADT is working?
- How do I track my ADT progress?
- How long will I be taking this medicine?
- How do I keep regular contact with my treatment team?
- What resources are available to me to cope with feeling nervous and anxious about my APC diagnosis?
- How frequently can we touch base?

You may also want to know about testosterone and PSA.

- Checking your testosterone and PSA levels monthly when starting ADT can help track the progress of your APC treatment¹
- Ask your doctor about what to expect with monthly monitoring of testosterone and PSA

Every month is a chance for you to connect with your treatment team.

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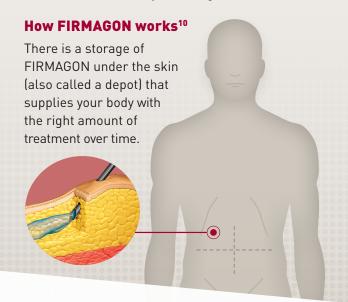
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PREPARING FOR TREATMENT Your FIRMAGON injections

FIRMAGON is given in your doctor's office monthly (every 28 days) in a deep subcutaneous (below the skin) injection in the abdomen.¹⁰

Your doctor should change the place in your abdomen where the injection is given on each visit.



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Simple ways to take care of the injection site



Keep the injection site clean



Wear comfortable, loose-fitting clothing that does not rub against the injection site



Avoid rubbing or scratching the area



Make sure your healthcare provider chooses a different injection location from last time

Postinjection tips!

- Make sure that belts or waistbands do not rub against the injection site
- Take time to ask your treatment team any questions before leaving. Write down the answers so you can refer back to them anytime
- Make sure you set up your next appointment for your monthly check-in with your treatment team and FIRMAGON injection

If you have any concerns between visits, create a list of questions to ask your treatment team.

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FIRMAGON has a proven safety profile.9

Important Safety Information (continued)

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Here's what to know

FIRMAGON is an ADT, and as with any ADT you may notice aftereffects of the medicine. If you have any questions or concerns, speak with your treatment team immediately.

Possible Side Effects of ADT¹⁰

- Flushing of the skin
- Increased weight
- Decreased sex drive
- Difficulties with erectile function
- Redness, swelling, and itching at the injection site
- Increase in some liver enzymes

These are not all the possible side effects. For more information, ask your healthcare provider or pharmacist. For full side effects, please see the full Prescribing Information.

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

You may report side effects to the FDA at 1-800-FDA-1088.

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Support is important for you and your loved ones

Together with your family and treatment team, you will have the support you need to stay on top of your progress.

Here are some organizations that you may find useful.

Prostate Cancer Advocacy & Support

Prostate Cancer Foundation

1-800-757-CURE (2873) / www.pcf.org

Us T00 International

1-800-80-US-T00 (808-7866) / www.ustoo.org

ZER0

1-888-245-9455 / www.zerocancer.org

Patient & Caregiver Support

Help for Cancer Caregivers

www.helpforcancercaregivers.org

Cancer.Net

www.cancer.net

Cancer Care

1-800-813-HOPE (4673) / www.cancercare.org

United States Department of Agriculture www.usda.gov

Cancer Education & Research Organizations

American Cancer Society

1-800-227-2345 / www.cancer.org

National Cancer Institute

1-800-4-CANCER (422-6237) / www.cancer.gov

These resources are provided solely for your information and convenience. This should not be considered an endorsement by Ferring of any of the organizations listed.

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Staying in touch with your treatment team, month by month, keeps you informed on your APC progress

- Start achieving your testosterone (T) suppression goal today with FIRMAGON
- Now that you've learned about APC and the importance of discussing your ADT options with your doctor, it's time to use that information and have your voice heard

Ask your doctor about FIRMAGON to find out if it's the right ADT choice for you. Visit FIRMAGON.com for more information.

References: 1. Centers for Disease Control and Prevention. Cancer among men. http://www. cdc.gov/cancer/dcpc/data/men.htm. Accessed February 29, 2016. 2. National Institute of Health, National Cancer Institute, Surveillance, Epidemiology, and End Results Program. SEER stat fact sheets: Prostate cancer. http://seer.cancer.gov/statfacts/html/prost.html. Accessed February 29, 2016. 3. Prostate Cancer Foundation. Prostate cancer FAQs. http://www.pcf.org/ site/c.leJRIROrEpH/b.5800851/k.645A/Prostate_Cancer_FAQs.htm. Accessed February 29, 2016. 4. National Institute of Health, National Cancer Institute. Hormone therapy for prostate cancer fact sheet. http://www.cancer.gov/types/prostate/prostate-hormone-therapy-fact-sheet. Accessed February 29, 2016. **5.** Gomella L.G. Effective testosterone suppression for prostate cancer: Is there a best castration therapy? Rev Urol. 2009;11[2]:52-60. 6. American Cancer Society. Hormone therapy for prostate cancer. http://www.cancer.org/cancer/ prostatecancer/detailedguide/prostate-cancer-treating-hormone-therapy. Accessed April 6, 2016. 7. Data on file. Ferring Pharmaceuticals Inc. 8. Mottet N, Bastian PJ, Bellmunt RC, et al. Guidelines on prostate cancer. http://uroweb.org/wp-content/uploads/1607-Prostate-Cancer_ LRV3.pdf. Accessed February 29, 2016. 9. Klotz L, Boccon-Gibod L, Shore ND, et al. The efficacy and safety of degarelix: a 12-month, comparative, randomized, open-label, parallel-group phase III study in patients with prostate cancer. BJU Int. 2008;102(11):1531-1538. 10. FIRMAGON [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc. 11. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology. Prostate Cancer v2.2014. http://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed May 11, 2015. 12. Velonas VM, Woo HH, dos Remedios CG, Assinder SJ. Current status of biomarkers for prostate cancer. Int J Mol Sci. 2013;14(6):11034-11060.

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