Your FASLODEX treatment guide

Select Safety Information About FASLODEX

You should not receive FASLODEX if you have had an allergic reaction to fulvestrant or any of the ingredients in FASLODEX. Talk to your health care provider if you experience symptoms of an allergic reaction to FASLODEX, which may include itching or hives; swelling of your face, lips, tongue, or throat; and trouble breathing.

Approved Uses for FASLODEX

FASLODEX is a prescription medicine used to treat advanced breast cancer or breast cancer that has spread to other parts of the body (metastatic).

FASLODEX may be used alone, if you have gone through menopause, and your advanced breast cancer is:

- hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative and has not been previously treated with endocrine therapy or
- HR-positive and has progressed after endocrine therapy

FASLODEX may be used in combination with ribociclib, if you have gone through menopause, and your advanced or metastatic breast cancer is HR-positive and HER2-negative, and has not been previously treated with endocrine therapy or has progressed after endocrine therapy.

FASLODEX may be used in combination with palbociclib or abemaciclib if your advanced or metastatic breast cancer is HR-positive and HER2-negative, and has progressed after endocrine therapy.

When FASLODEX is used in combination with palbociclib, abemaciclib, or ribociclib, also read the Patient Information for the prescribed product.

It is not known if FASLODEX is safe and effective in children or in people with severe liver problems.

Please see additional Important Safety Information on page 32 and FASLODEX Prescribing Information with Patient Information (Medication Guide).
Understanding why your doctor prescribed FASLODEX for you

You have received this brochure because your doctor has prescribed FASLODEX, FASLODEX with Ibrance® (palbociclib), FASLODEX with Verzenio™ (abemaciclib), or FASLODEX with Kisqali® (ribociclib) for you.

FASLODEX is a prescription medicine used to treat advanced breast cancer or breast cancer that has spread to other parts of the body (metastatic).

FASLODEX may be used alone, if you have gone through menopause, and your advanced breast cancer is:
• hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative and has not been previously treated with endocrine therapy or
• HR-positive and has progressed after endocrine therapy

FASLODEX may be used in combination with ribociclib, if you have gone through menopause, and your advanced or metastatic breast cancer is HR-positive and HER2-negative, and has not been previously treated with endocrine therapy or has progressed after endocrine therapy.

FASLODEX may be used in combination with palbociclib or abemaciclib if your advanced or metastatic breast cancer is HR-positive and HER2-negative, and has progressed after endocrine therapy.

FASLODEX is a hormonal therapy that can be used in 6 ways: alone as your first hormonal medicine; alone after your disease has progressed after endocrine therapy; with Kisqali® (ribociclib) as your first hormonal medicine; or with Ibrance® (palbociclib), Verzenio™ (abemaciclib), or Kisqali after your disease has progressed after endocrine therapy. However it is used, FASLODEX targets the estrogen receptor to help inhibit tumor growth in HR-positive advanced breast cancer.

The How FASLODEX Works section (pages 25-26) of this guide can help you understand more about how FASLODEX may be able to help.

See the Glossary (page 31) for definitions of underlined terms.

Select Safety Information About FASLODEX

Before receiving FASLODEX, tell your health care provider about all of your medical conditions, including if you:
• Have a low level of platelets in your blood or bleed easily. Especially tell your health care provider if you take a blood thinner medicine (anticoagulant)
• Have liver problems
• Are pregnant or plan to become pregnant, because FASLODEX can harm your unborn baby. Your health care provider may perform a pregnancy test within 7 days before starting FASLODEX. Women who are able to become pregnant should use effective birth control during treatment with FASLODEX and for 1 year after the last dose. Tell your health care provider right away if you become pregnant or think you are pregnant while on FASLODEX
• Are breastfeeding or plan to breastfeed. It is not known if FASLODEX passes into breast milk. Do not breastfeed during treatment with FASLODEX and for 1 year after the final dose. Talk to your health care provider about the best way to feed your baby during this time
Why FASLODEX?

FASLODEX is a hormonal therapy that has been available since 2002.

FASLODEX works differently than other medicines that may have been prescribed for you in the past, such as aromatase inhibitors.

Before prescribing FASLODEX, FASLODEX with Verzenio™ (abemaciclib), FASLODEX with Ibrance® (palbociclib), or FASLODEX with Kisqali® (ribociclib), your doctor may have reviewed the following:

- If you are premenopausal or postmenopausal
- If your cancer has spread to other parts of your body far from the original tumor (also known as advanced or metastatic cancer)
- Your hormone receptor status
- What kind(s) of breast cancer medicine you were previously given

Select Safety Information About FASLODEX

Tell your health care provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. FASLODEX may affect the way other medicines work, and other medicines may affect how FASLODEX works.

FASLODEX is administered by your health care provider as an injection into the muscle of each buttock. Your health care provider may change your dose of FASLODEX if needed.

FASLODEX may cause serious side effects, including injection site–related nerve damage. Call your health care provider if you develop any of the following symptoms in your legs following a FASLODEX injection: numbness, tingling, or weakness.

Please see additional Important Safety Information on page 32 and FASLODEX Prescribing Information with Patient Information.
The MONARCH 2 study: FASLODEX with Verzenio™ (abemaciclib)

FASLODEX with Verzenio was approved based on results from a clinical trial called MONARCH 2. The goals of the MONARCH 2 study were to see how well FASLODEX with Verzenio worked vs FASLODEX and placebo, the control group, in helping to treat advanced or metastatic breast cancer after endocrine therapy and to examine what types of side effects women in the study experienced.

The MONARCH 2 study included 669 women who had either been through menopause or had been given medication that began menopause. These women had HR-positive, HER2-negative advanced or metastatic breast cancer. Their cancer had spread while receiving prior endocrine therapy, meaning that they were endocrine therapy-resistant.

The median age of patients in this study was 60 years.

Over half (59.2%) of patients received this treatment as their first endocrine therapy for advanced or metastatic breast cancer, while over one-third of patients (38.3%) received it as their second treatment.

Visit FASLODEX.com for more information on the MONARCH 2 study.

Select Safety Information About FASLODEX

Common side effects of FASLODEX include injection site pain; nausea; muscle, joint, and bone pain; headache; back pain; tiredness; pain in arms, hands, legs or feet; hot flashes; vomiting; loss of appetite; weakness; cough; shortness of breath; constipation; increased liver enzymes; and diarrhea.

Tell your health care provider if you have any side effect that bothers you or does not go away. These are not all of the possible side effects with FASLODEX. For more information, ask your health care provider or pharmacist. You may report side effects to the FDA at 1-800-FDA-1088.

Please see additional Important Safety Information on page 32 and FASLODEX Prescribing Information with Patient Information.
FASLODEX in combination with Verzenio significantly extended the length of time during and after treatment that patients lived without their cancer getting worse, compared with FASLODEX and placebo. This measure, known as progression-free survival time, is one way to see how well a treatment works. Progression-free survival can be displayed as the middle of a range of months, also known as the median.

Median progression-free survival time for FASLODEX with Verzenio vs FASLODEX and placebo was 16.4 months vs 9.3 months, respectively, a 76% improvement.

These results were shown to be statistically significant. Statistically significant results are important in studies like MONARCH 2—this means that it is highly likely that the results are related to treatment rather than something else.

See page 8 for information on side effects seen in the MONARCH 2 study.

Select Safety Information About FASLODEX

You should not receive FASLODEX if you have had an allergic reaction to fulvestrant or any of the ingredients in FASLODEX. Talk to your health care provider if you experience symptoms of an allergic reaction to FASLODEX, which may include itching or hives; swelling of your face, lips, tongue, or throat; and trouble breathing.

Please see additional Important Safety Information on page 32 and FASLODEX Prescribing Information with Patient Information.
What you may have in common with women in MONARCH 2

If you have received a diagnosis of HR-positive, HER2-negative advanced or metastatic breast cancer and your cancer has spread after endocrine therapy, you and your doctor may consider whether FASLODEX with Verzenio™ (abemaciclib) is right for you. You may have more things in common with the women in MONARCH 2—review the information below to learn more, and talk with your doctor about what to expect from your FASLODEX with Verzenio treatment.

Women in the MONARCH 2 study

If you have been through menopause or have been given medication that begins menopause, you may still have something in common with the women in this study. You do not need to have gone through menopause to be considered for this medication.

All patients in MONARCH 2 had disease progression after prior endocrine therapy. Disease progression during or after endocrine therapy is also known as endocrine therapy resistance. Talk to your doctor about what endocrine therapy resistance means for your treatment.

The MONARCH 2 study was not designed to suggest use in patients with specific disease characteristics, although you may have some things in common with the women in the study. The MONARCH 2 results applied to all patients in the study.

Select Safety Information About FASLODEX

Before receiving FASLODEX, tell your health care provider about all of your medical conditions, including if you:

- Have a low level of platelets in your blood or bleed easily. Especially tell your health care provider if you take a blood thinner medicine (anticoagulant)
- Have liver problems
- Are pregnant or plan to become pregnant, because FASLODEX can harm your unborn baby. Your health care provider may perform a pregnancy test within 7 days before starting FASLODEX. Women who are able to become pregnant should use effective birth control during treatment with FASLODEX and for 1 year after the last dose. Tell your health care provider right away if you become pregnant or think you are pregnant while on FASLODEX
- Are breastfeeding or plan to breastfeed. It is not known if FASLODEX passes into breast milk. Do not breastfeed during treatment with FASLODEX and for 1 year after the final dose. Talk to your health care provider about the best way to feed your baby during this time
As with any medication, you may experience side effects while taking FASLODEX with Verzenio. If you are concerned about any symptoms you may be experiencing, you should contact your doctor’s office right away. The common side effects below were observed in the MONARCH 2 study, and were seen more often in women receiving FASLODEX with Verzenio than in those in the control group.

Serious side effects occurred in 22.4% of patients participating in the FASLODEX with Verzenio arm and 10.8% for the control arm in the MONARCH 2 study. The most frequently reported serious side effect was the formation of clots in the blood vessels, occurring in 2% of patients in the FASLODEX with Verzenio arm and in 0.4% in the control group.

Because FASLODEX is metabolized, or broken down, primarily in the liver, a monthly dose of 250 mg is recommended for patients with moderate liver problems.

It is not known if FASLODEX is effective in patients with severe liver problems.

When FASLODEX is used in combination with Verzenio, also read the Verzenio Patient Information.

Please see additional Important Safety Information on page 32 and FASLODEX Prescribing Information with Patient Information.
FASLODEX with Ibrance was approved in 2016, based on results from a clinical trial called PALOMA-3. The goals of the study were to see how well FASLODEX with Ibrance worked vs FASLODEX plus placebo, the control group, in advanced or metastatic breast cancer and to examine what types of side effects women in the study experienced. Reading about PALOMA-3 may help you understand why FASLODEX with Ibrance was prescribed for you.

The PALOMA-3 study included 521 women who had either been through menopause or had been given medication that began menopause. These women had HR-positive, HER2-negative advanced or metastatic breast cancer. Their cancer had spread on or after previous endocrine therapy.

Women in the PALOMA-3 study had cancer that spread from 1 to more than 3 locations. These locations included organs (including lungs and liver) and bones.

All women (100%) had been given prior treatment. Most (75%) had been given previous chemotherapy.

Visit FASLODEX.com for more information on the PALOMA-3 study.

Select Safety Information About FASLODEX

Tell your health care provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. FASLODEX may affect the way other medicines work, and other medicines may affect how FASLODEX works.

FASLODEX is administered by your health care provider as an injection into the muscle of each buttock. Your health care provider may change your dose of FASLODEX if needed.

FASLODEX may cause serious side effects, including injection site–related nerve damage. Call your health care provider if you develop any of the following symptoms in your legs following a FASLODEX injection: numbness, tingling, or weakness.
Select Safety Information About FASLODEX

Common side effects of FASLODEX include injection site pain; nausea; muscle, joint, and bone pain; headache; back pain; tiredness; pain in arms, hands, legs or feet; hot flashes; vomiting; loss of appetite; weakness; cough; shortness of breath; constipation; increased liver enzymes; and diarrhea.

Tell your health care provider if you have any side effect that bothers you or does not go away. These are not all of the possible side effects with FASLODEX. For more information, ask your health care provider or pharmacist. You may report side effects to the FDA at 1-800-FDA-1088.

Please see additional Important Safety Information on page 32 and FASLODEX Prescribing Information with Patient Information.

Results of the PALOMA-3 study showed that the 347 women who received FASLODEX 500 mg with Ibrance 125 mg lived a significantly extended length of time during and after treatment without their cancer getting worse, compared with the 174 women who received FASLODEX and placebo. This measure, known as progression-free survival time, is one way to see how well a treatment works. Progression-free survival can be displayed as the middle of a range of months, also known as the median.

Median progression-free survival time for FASLODEX with Ibrance vs FASLODEX and placebo was 9.5 months vs 4.6 months, respectively, showing that women who received FASLODEX with Ibrance experienced roughly double the progression-free survival time than did women who received FASLODEX and placebo.

These results were shown to be statistically significant. Statistically significant results are important in studies like PALOMA-3—this means that it is highly likely that the results are related to treatment rather than something else.
If you have received a diagnosis of HR-positive, HER2-negative advanced or metastatic breast cancer and your cancer has spread after previous hormonal therapy, you and your doctor may consider whether FASLODEX with Ibrance® (palbociclib) is right for you. You may have more things in common with the women in PALOMA-3—review the information below to learn more, and talk with your doctor about what to expect from your FASLODEX with Ibrance treatment.

**Women in the PALOMA-3 study**

If you have been through menopause or have been given medication that begins menopause, you may still have something in common with the women in this study. You do not need to have gone through menopause to be considered for this medication.

All women (100%) in the PALOMA-3 study experienced disease progression during or after prior endocrine therapy.

Most women (75%) in the PALOMA-3 study were previously given chemotherapy.

The PALOMA-3 study was not designed to suggest use in patients with specific disease characteristics, although you may have some things in common with the women in the study. The PALOMA-3 results applied to all patients in the study.

**Select Safety Information About FASLODEX**

You should not receive FASLODEX if you have had an allergic reaction to fulvestrant or any of the ingredients in FASLODEX. Talk to your health care provider if you experience symptoms of an allergic reaction to FASLODEX, which may include itching or hives; swelling of your face, lips, tongue, or throat; and trouble breathing.
Side effects of FASLODEX with Ibrance® (palbociclib)

As with any medication, you may experience side effects while taking FASLODEX with Ibrance. If you are concerned about any symptoms you may be experiencing, you should contact your doctor's office right away. The common side effects below were reported in the PALOMA-3 study, and were seen more often in women receiving FASLODEX with Ibrance than in those in the control group.

- Infections
- Tiredness
- Nausea
- Fever
- Sore mouth
- Sudden hair loss
- Diarrhea
- Decreased red blood cells, white blood cells, and/or platelets
- Vomiting
- Rash
- Loss of appetite

The most frequently reported serious side effect in patients receiving FASLODEX with Ibrance was decreased white blood cells.

In the PALOMA-3 study, 6% of patients receiving FASLODEX with Ibrance and 3% of patients in the control group withdrew from treatment due to side effects.

Because FASLODEX is metabolized, or broken down, primarily in the liver, a monthly dose of 250 mg is recommended for patients with moderate liver problems.

It is not known if FASLODEX is effective in patients with severe liver problems.

When FASLODEX is used in combination with Ibrance, also read the Ibrance Patient Information.

Please see additional Important Safety Information on page 32 and FASLODEX Prescribing Information with Patient Information.
FASLODEX with Kisqali was approved in 2019, based on results from a clinical trial called MONALEESA-3. The goals of the MONALEESA-3 study were to see how well FASLODEX worked with Kisqali vs FASLODEX with placebo (no medication), the control group, in helping to treat advanced or metastatic breast cancer as the initial endocrine-based therapy or following disease progression on endocrine therapy and to examine what types of side effects women in the study experienced. Reading about MONALEESA-3 study may help you understand why FASLODEX with Kisqali was prescribed for you.

The MONALEESA-3 study included 726 postmenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer who haven’t received or have received only 1 line of endocrine therapy.

50.6% of patients received this treatment as their first endocrine therapy for advanced or metastatic breast cancer, while 47.5% of patients received it as their second treatment.

Women in this study had cancer that had spread to other locations, ranging from 1 to more than 5 locations, including the lungs, liver, and bones.

The median age of patients in this study was 63 years.

Visit FASLODEX.com for more information on the MONALEESA-3 study.
Results of the MONALEESA-3 study showed that the 484 women who received FASLODEX 500 mg with Kisqali 600 mg lived a significantly extended length of time during and after treatment without their cancer getting worse, compared with the 242 women who received FASLODEX with placebo. This measure, known as progression-free survival, is one way to see how well a treatment works. Progression-free survival can be displayed as the middle of a range of months, also known as the median.

Median progression-free survival time for FASLODEX with Kisqali vs FASLODEX with placebo was **20.5 months** vs **12.8 months**, respectively, resulting in a 41% reduction in the risk of progression. This indicates that women who received FASLODEX with Kisqali experienced a greater progression-free survival time than those women who received FASLODEX with placebo, irrespective of prior endocrine therapy for advanced disease.

These results were shown to be statistically significant. Statistically significant results are important in studies such as MONALEESA-3—this means that it is highly likely that the results are related to treatment rather than something else.

See page 18 for information on side effects seen in the MONALEESA-3 study.

**Select Safety Information About FASLODEX**

**Common side effects of FASLODEX include** injection site pain; nausea; muscle, joint, and bone pain; headache; back pain; tiredness; pain in arms, hands, legs, or feet; hot flashes; vomiting; loss of appetite; weakness; cough; shortness of breath; constipation; increased liver enzymes; and diarrhea.

Tell your health care provider if you have any side effect that bothers you or does not go away. These are not all of the possible side effects with FASLODEX. For more information, ask your health care provider or pharmacist. You may report side effects to the FDA at 1-800-FDA-1088.

Please see additional Important Safety Information on page 32 and FASLODEX Prescribing Information with Patient Information.
If you have received a diagnosis of HR-positive, HER2-negative advanced or metastatic breast cancer and you have never received hormonal therapy OR your cancer has spread after previous hormonal therapy, you and your doctor may consider whether FASLODEX with Kisqali® (ribociclib) is right for you. You may have more things in common with the women in MONALEESA-3 study—review the information below to learn more, and talk with your doctor about what to expect from your FASLODEX with Kisqali treatment.

**Women in the MONALEESA-3 study**

If you have been through menopause, you may have something in common with the women in this study. You need to have gone through menopause to be considered for this medication.

In MONALEESA-3 study,
- 50.6% of patients were treatment-naïve (not received endocrine therapy before)
- 47.5% of patients had disease progression after prior endocrine therapy. Disease progression during or after endocrine therapy is also known as endocrine therapy resistance. Talk to your doctor about what endocrine therapy resistance means for your treatment
- More than half (56%) of the patients were previously treated with chemotherapy

The MONALEESA-3 study was not designed to suggest use in patients with specific disease characteristics, although you may have some things in common with the women in the study. The MONALEESA-3 study results applied to all patients in the study.

**Select Safety Information About FASLODEX**

You should not receive FASLODEX if you have had an allergic reaction to fulvestrant or any of the ingredients in FASLODEX. Talk to your health care provider if you experience symptoms of an allergic reaction to FASLODEX, which may include itching or hives; swelling of your face, lips, tongue, or throat; and trouble breathing.

Before receiving FASLODEX, tell your health care provider about all of your medical conditions, including if you:
- Have a low level of platelets in your blood or if you bleed easily. Especially, tell your health care provider if you take a blood-thinner medicine (anticoagulant)
- Have liver problems
- Are pregnant or plan to become pregnant, because FASLODEX can harm your unborn baby. Your health care provider may perform a pregnancy test within 7 days before starting FASLODEX. Women who are able to become pregnant should use effective birth control during treatment with FASLODEX and for 1 year after the last dose. Tell your health care provider right away if you become pregnant or think you are pregnant while on FASLODEX
- Are breastfeeding or planning to breastfeed. It is not known if FASLODEX passes into breast milk. Do not breastfeed during treatment with FASLODEX and for 1 year after the final dose. Talk to your health care provider about the best way to feed your baby during this time
As with any medication, you may experience side effects while taking FASLODEX with Kisqali. If you are concerned about any symptoms you may be experiencing, you should contact your doctor's office right away. The common side effects below were observed in the MONALEESA-3 study, and were seen more often in women receiving FASLODEX with Kisqali than in those in the control group.

- Decreased white blood cells
- Cough
- Diarrhea
- Constipation
- Rash
- Infections
- Nausea
- Vomiting
- Pruritus (itchy skin)
- Increased liver enzymes

The serious side effects occurred in 138 (28.6%) women receiving FASLODEX with Kisqali and 40 (16.6%) women in the control group.

The most frequently reported serious side effects were decreased white blood cells and abnormal liver function tests.

In the MONALEESA-3 study, 8% of patients receiving FASLODEX with Kisqali and 4% of patients in the control group withdrew from treatment due to side effects.

Because FASLODEX is metabolized or broken down primarily in the liver, a monthly dose of 250 mg is recommended for patients with moderate liver problems.

It is not known if FASLODEX is effective in patients with severe liver problems.

When FASLODEX is used in combination with Kisqali, also read the Kisqali Patient Information.

Please see additional Important Safety Information on page 32 and FASLODEX Prescribing Information with Patient Information.
WHY FASLODEX?

FASLODEX WITH IBRANCE® (palbociclib)

TAKING FASLODEX

HOW FASLODEX WORKS

RESOURCES

GLOSSARY AND SAFETY INFORMATION
The results of FALCON, a clinical trial that studied FASLODEX, were published in 2016. The goals of the study were to see how well FASLODEX worked when compared with anastrozole, another drug used to treat HR-positive advanced breast cancer and to examine what types of side effects women in the study experienced. Reading about FALCON may help you understand why FASLODEX was prescribed for you.

The FALCON study included 462 postmenopausal women with locally advanced or metastatic breast cancer. All women tested HR-positive, and nearly all tested HER2-negative.

Women in the study had cancer that spread to 1 or more parts of their body, such as organs (including lungs and liver), lymph nodes, and/or bones in addition to another location.

In nearly all cases, their cancer had not previously been treated with hormonal therapy.

Visit FASLODEX.com for more information on the FALCON study.

Select Safety Information About FASLODEX

Before receiving FASLODEX, tell your health care provider about all of your medical conditions, including if you:

- Have a low level of platelets in your blood or bleed easily. Especially tell your health care provider if you take a blood thinner medicine (anticoagulant)
- Have liver problems
- Are pregnant or plan to become pregnant, because FASLODEX can harm your unborn baby. Your health care provider may perform a pregnancy test within 7 days before starting FASLODEX. Women who are able to become pregnant should use effective birth control during treatment with FASLODEX and for 1 year after the last dose. Tell your health care provider right away if you become pregnant or think you are pregnant while on FASLODEX
- Are breastfeeding or plan to breastfeed. It is not known if FASLODEX passes into breast milk. Do not breastfeed during treatment with FASLODEX and for 1 year after the final dose. Talk to your health care provider about the best way to feed your baby during this time
FALCON study results

FALCON compared 2 treatments for postmenopausal patients’ first hormonal therapy for HR-positive, HER2-negative advanced breast cancer: FASLODEX 500 mg vs anastrozole 1 mg.

Among other measurements, the study used progression-free survival to see how well FASLODEX works. Progression-free survival is the length of time during and after treatment that patients lived without their cancer getting worse. Progression-free survival can be displayed as the middle of a range of months, also known as the median.

Results showed that FASLODEX 500 mg significantly extended the length of time during and after treatment that patients lived without their cancer getting worse, compared with anastrozole 1 mg. The 230 women who were given FASLODEX experienced a median progression-free survival time of 16.6 months vs 13.8 months in the 232 women who were given anastrozole.

The results of the FALCON study were shown to be statistically significant. Statistically significant results are important in studies like FALCON—this means that it is highly likely that the results are related to treatment rather than something else.

See page 24 for information on side effects seen in the FALCON study.

Select Safety Information About FASLODEX

Tell your health care provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. FASLODEX may affect the way other medicines work, and other medicines may affect how FASLODEX works.
What you may have in common with women in FALCON

If you are postmenopausal, have received a diagnosis of HR-positive, HER2-negative advanced breast cancer, and have not been previously treated with endocrine therapy, you and your doctor may consider whether FASLODEX is right for you. You may have more things in common with the women in FALCON—review the information below to learn more, and talk with your doctor about what to expect from your FASLODEX treatment.

**Women in the FALCON study**

Most women (99%) were not given endocrine therapy before the study began.

Some women were given other kinds of medicine (such as chemotherapy) or radiotherapy before the study began.

The FALCON study was not designed to suggest use in patients with specific disease characteristics, although you may have some things in common with the women in the study. The FALCON results applied to all patients in the study.

**Select Safety Information About FASLODEX**

FASLODEX is administered by your health care provider as an injection into the muscle of each buttock. Your health care provider may change your dose of FASLODEX if needed.

FASLODEX may cause serious side effects, including injection site–related nerve damage. Call your health care provider if you develop any of the following symptoms in your legs following a FASLODEX injection: numbness, tingling, or weakness.

Please see additional Important Safety Information on page 32 and FASLODEX Prescribing Information with Patient Information.
WHY FASLODEX?

FASLODEX WITH IBRANCE® (palbociclib)

TAKING FASLODEX

FASLODEX WITH KISQALI® (ribociclib)

HOW FASLODEX WORKS

RESOURCES

GLOSSARY AND SAFETY INFORMATION
As with any medication, you may experience side effects while taking FASLODEX. If you are concerned about any symptoms you may be experiencing, you should contact your doctor’s office right away. Results indicated that women in the FALCON study experienced similar side effects whether they received FASLODEX or anastrozole.

In the FALCON study, 1.8% of patients receiving FASLODEX 500 mg and 1.3% of patients receiving anastrozole 1 mg withdrew from treatment because of drug-related side effects.

Because FASLODEX is metabolized, or broken down, primarily in the liver, a monthly dose of 250 mg is recommended for patients with moderate liver problems.

It is not known if FASLODEX is effective in patients with severe liver problems.

These are not all the side effects of FASLODEX. If you are concerned about any additional symptoms you may be experiencing, contact your doctor’s office immediately.

Select Safety Information About FASLODEX

Tell your health care provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. FASLODEX may affect the way other medicines work, and other medicines may affect how FASLODEX works.

FASLODEX is administered by your health care provider as an injection into the muscle of each buttock. Your health care provider may change your dose of FASLODEX if needed.

FASLODEX may cause serious side effects, including injection site–related nerve damage. Call your health care provider if you develop any of the following symptoms in your legs following a FASLODEX injection: numbness, tingling, or weakness.

Please see additional Important Safety Information on page 32 and FASLODEX Prescribing Information with Patient Information.
The role of estrogen receptors in ER+ metastatic breast cancer

It’s important to discuss your hormone receptor status with your doctor. Estrogen receptors play a critical role in certain types of breast cancer, such as HR-positive advanced or metastatic breast cancer. HR-positive cancer cells depend on hormone receptors, such as estrogen receptors, to grow. Your doctor may also use the term “estrogen receptor-positive” (ER+).

Estrogen receptors can play a role in the spread of ER+ metastatic breast cancer by:

- Connecting with estrogen, which is a hormone that can send signals leading to the growth of cancer
- Sending signals that do not rely on estrogen inside cancer cells
- Participating in the cell cycle, which leads to tumor cell division

FASLODEX, a hormonal medicine designed to target the estrogen receptor, may be able to help. When the estrogen receptor is blocked, estrogen’s ability to influence cancer growth is reduced.

Select Safety Information About FASLODEX

Common side effects of FASLODEX include injection site pain; nausea; muscle, joint, and bone pain; headache; back pain; tiredness; pain in arms, hands, legs or feet; hot flashes; vomiting; loss of appetite; weakness; cough; shortness of breath; constipation; increased liver enzymes; and diarrhea.

Tell your health care provider if you have any side effect that bothers you or does not go away. These are not all of the possible side effects with FASLODEX. For more information, ask your health care provider or pharmacist. You may report side effects to the FDA at 1-800-FDA-1088.

Please see additional Important Safety Information on page 32 and FASLODEX Prescribing Information with Patient Information.
FASLODEX targets the estrogen receptor

FASLODEX works differently than other medicines that may have been prescribed for you in the past. It is the only approved hormonal medicine that has been shown to interact with the estrogen receptor in the following ways:

Connects with the estrogen receptor

When FASLODEX connects with estrogen receptors,* those estrogen receptors can react by:

- Losing stability, meaning that they will not work as well
- Changing shape, affecting their ability to connect with estrogen

*As demonstrated in laboratory studies.

Blocks† estrogen receptor activation

Estrogen receptors that are connected to FASLODEX have a reduced ability to activate or communicate with estrogen. Inactive estrogen receptors cannot participate in the process of cancer growth.

†FASLODEX does not block 100% of estrogen receptors.

Breaks down the estrogen receptor

Estrogen receptors connected to FASLODEX break down quickly, resulting in fewer estrogen receptors in cancer cells. Broken-down estrogen receptors cannot participate in the process of cancer growth.

Decreases the number of estrogen receptors

FASLODEX is associated with a decrease in Ki67, a marker of cancer growth.

When FASLODEX decreases the number of available estrogen receptors in breast cancer cells, estrogen receptors’ ability to cause cancer cells to divide and multiply is impacted. Having fewer available estrogen receptors makes it more difficult for estrogen receptors to support cancer growth.

Visit howFASLODEXworks.com for more information on how FASLODEX targets the estrogen receptor and what that means for your treatment.

Select Safety Information About FASLODEX

You should not receive FASLODEX if you have had an allergic reaction to fulvestrant or any of the ingredients in FASLODEX. Talk to your health care provider if you experience symptoms of an allergic reaction to FASLODEX, which may include itching or hives; swelling of your face, lips, tongue, or throat; and trouble breathing.
Whether you are taking FASLODEX alone or in combination with Ibrance® (palbociclib), Verzenio™ (abemaciclib) or Kisqali® (ribociclib), FASLODEX requires 3 doses during the first month of treatment to allow the drug to reach and maintain steady levels within your body. **FASLODEX is given on Days 1, 15, and 29 of the first month and then once a month thereafter.**

Your treatment consists of 2 injections into your buttock muscle, administered by a health care professional.

The 500 mg dose is given as 2 injections of 250 mg each, 1 into each buttock. Your health care provider may change your dose of FASLODEX if needed.

**FASLODEX may cause serious side effects, including injection site–related nerve damage.** Call your health care provider if you develop any of the following symptoms in your legs following a FASLODEX injection: numbness, tingling, weakness.

A 250 mg dose (given as 1 injection into the buttock) is recommended if your liver function is moderately impaired.

Please see additional Important Safety Information on page 32 and FASLODEX Prescribing Information with Patient Information.
A diagnosis of metastatic breast cancer can come as a shock, but AstraZeneca is here to help. We hope the educational resources below can provide support during your treatment journey.

**My MBC Story**
www.mymbcstory.com
A community that provides educational resources and support to women living with metastatic breast cancer and their caregivers

**Metastatic Breast Cancer Network**
www.mbcn.org
An independent, patient-led group that supports nationwide research and advocacy efforts

**National Breast Cancer Foundation, Inc.®**
www.nationalbreastcancer.org
A foundation that works with national groups and government agencies to promote breast cancer awareness and increase screening accessibility

**Breastcancer.org**
www.breastcancer.org
An online education group, including chat rooms, discussion boards, and online conferences

**SHARE Cancer Support**
www.sharecancersupport.org
A network that aims to support and empower women who have breast or ovarian cancer

This list of resources is provided as a convenience. Some of these resources are not maintained, sponsored, or reviewed by AstraZeneca.

For additional information and resources during your treatment, visit yourMBCresources.com.
The AstraZeneca Access 360™ program is here for you

AstraZeneca has created a program called AstraZeneca Access 360™ that may be able to assist you as you go through your metastatic breast cancer journey. AstraZeneca Access 360™ provides you with free personal support, so you can have access to the medicines you need, and helps you work through difficult financial and insurance questions that can make accessing your medicines worrisome.

Our knowledgeable and compassionate Reimbursement Counselors can help you with:

- Insurance coverage
- Patient assistance programs
- Out-of-pocket costs

Call today to meet your AstraZeneca Reimbursement Counselor at 1-844-ASK-A360 (1-844-275-2360), Monday-Friday, 8 AM-8 PM ET.

AstraZeneca Access 360 is a trademark of the AstraZeneca group of companies.
**Anastrozole**
A type of **aromatase inhibitor** that can be used in advanced breast cancer.

**Aromatase inhibitor**
A type of **endocrine therapy** that prevents the formation of estradiol, a hormone in the body.

**Chemotherapy**
Treatment that travels throughout the body to weaken and destroy cancer cells.

**Clinical trial**
Also referred to as **clinical study**; a type of research study that tests how well new medical approaches work in people.

**Endocrine therapy**
A type of **hormone therapy** that adds, blocks, or removes hormones to treat the disease.

**Endocrine therapy resistance**
The removal of hormones to treat diseases can eventually lead to the body resisting the therapy, which causes the treatment to stop working. In a large number of patients, endocrine therapy resistance eventually occurs and causes a significant issue for optimal treatment.

**Estrogen**
A hormone that can play a role in tumor growth when present in women with breast cancer.

**Estrogen receptor**
A protein found in and on breast cancer cells. Estrogen receptors are activated by estrogen hormones and may signal cancer cells to grow.

**Hormonal therapy**
A type of therapy used in breast cancer to block the body’s ability to produce hormones or to interfere with the effects of hormones on breast cancer cells. FASLODEX and **aromatase inhibitors** are hormonal therapies.

**HR-positive cancer**
A type of cancer that depends on hormone receptors, such as the **estrogen receptor**, to grow. **Estrogen receptor-positive breast cancer** is a type of HR-positive breast cancer.

**HER2-negative breast cancer**
A type of cancer that does not depend on HER2 to grow.

**Ibrance® (palbociclib)**
A medication that can be used with FASLODEX in **HR-positive, HER2-negative** advanced or **metastatic breast cancer** that has progressed after **endocrine therapy**. Please review the Ibrance Prescribing Information with Patient Information for more information about Ibrance.

**Kisqali® (ribociclib)**
A medication that can be used with FASLODEX in **HR-positive, HER2-negative** advanced or **metastatic breast cancer** in postmenopausal women as initial endocrine-based therapy or following disease progression on **endocrine therapy**. Please review the Kisqali Prescribing Information with Patient Information for more information about Kisqali.

**Lymph nodes**
Small glands located throughout the body that filter lymph fluid and help the body fight infection and disease.

**Metastatic breast cancer**
Also referred to as **advanced or stage IV breast cancer**; cancer that has spread from the breast to other parts of the body.

**Placebo**
An inactive substance or treatment that looks the same and is given the same way as an active drug or treatment being tested.

**Premenopausal**
The time before menopause (the permanent stop of menstrual activity).

**Postmenopausal**
The time after menopause (the permanent stop of menstrual activity).

**Radiotherapy**
A type of treatment that uses high-energy waves or streams of particles to hinder the growth of or kill cancer cells.

**Statistically significant results**
Results of a **clinical trial** allowing researchers to demonstrate that the results are related to the medical approach being studied instead of something else.

**Verzenio™ (abemaciclib)**
A medication that can be used with FASLODEX in **HR-positive, HER2-negative** advanced or **metastatic breast cancer** that has progressed after endocrine therapy. Please review the Verzenio Prescribing Information with Patient Information for more information about Verzenio.
You should not receive FASLODEX if you have had an allergic reaction to fulvestrant or any of the ingredients in FASLODEX. Talk to your health care provider if you experience symptoms of an allergic reaction to FASLODEX, which may include itching or hives; swelling of your face, lips, tongue, or throat; and trouble breathing.

Before receiving FASLODEX, tell your health care provider about all of your medical conditions, including if you:

- Have a low level of platelets in your blood or bleed easily. Especially tell your health care provider if you take a blood thinner medicine (anticoagulant)
- Have liver problems
- Are pregnant or plan to become pregnant, because FASLODEX can harm your unborn baby. Your health care provider may perform a pregnancy test within 7 days before starting FASLODEX. Women who are able to become pregnant should use effective birth control during treatment with FASLODEX and for 1 year after the last dose. Tell your health care provider right away if you become pregnant or think you are pregnant while on FASLODEX
- Are breastfeeding or plan to breastfeed. It is not known if FASLODEX passes into breast milk. Do not breastfeed during treatment with FASLODEX and for 1 year after the final dose. Talk to your health care provider about the best way to feed your baby during this time

Tell your health care provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. FASLODEX may affect the way other medicines work, and other medicines may affect how FASLODEX works.

FASLODEX is administered by your health care provider as an injection into the muscle of each buttock. Your health care provider may change your dose of FASLODEX if needed.

FASLODEX may cause serious side effects, including injection site–related nerve damage. Call your health care provider if you develop any of the following symptoms in your legs following a FASLODEX injection: numbness, tingling, or weakness.

Common side effects of FASLODEX include injection site pain; nausea; muscle, joint, and bone pain; headache; back pain; tiredness; pain in arms, hands, legs or feet; hot flashes; vomiting; loss of appetite; weakness; cough; shortness of breath; constipation; increased liver enzymes; and diarrhea.

Tell your health care provider if you have any side effect that bothers you or does not go away. These are not all of the possible side effects with FASLODEX. For more information, ask your health care provider or pharmacist. You may report side effects to the FDA at 1-800-FDA-1088.

Approved Uses for FASLODEX

FASLODEX is a prescription medicine used to treat advanced breast cancer or breast cancer that has spread to other parts of the body (metastatic). FASLODEX may be used alone, if you have gone through menopause, and your advanced breast cancer is:

- hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative and has not been previously treated with endocrine therapy or
- HR-positive and has progressed after endocrine therapy

FASLODEX may be used in combination with ribociclib, if you have gone through menopause, and your advanced or metastatic breast cancer is HR-positive and HER2-negative, and has not been previously treated with endocrine therapy or has progressed after endocrine therapy.

FASLODEX may be used in combination with palbociclib or abemaciclib if your advanced or metastatic breast cancer is HR-positive and HER2-negative, and has progressed after endocrine therapy.

When FASLODEX is used in combination with palbociclib, abemaciclib, or ribociclib, also read the Patient Information for the prescribed product. It is not known if FASLODEX is safe and effective in children or in people with severe liver problems.

Please see FASLODEX Prescribing Information with Patient Information (Medication Guide).
AstraZeneca is here to help

FASLODEX is a hormonal therapy that has been available since 2002; however, AstraZeneca’s commitment to patient care goes beyond developing medicines. One of our most important goals is to support both patients and health care professionals in the advanced and metastatic breast cancer community.

Visit FASLODEX.com for valuable resources and treatment information, including:

- Additional information about FASLODEX or FASLODEX with Verzenio™ (abemaciclib) or Ibrance® (palbociclib) or Kisqali® (ribociclib) treatment
- Details on how FASLODEX is thought to work
- Metastatic breast cancer information, resources, and support

Please see Important Safety Information on page 32 and FASLODEX Prescribing Information with Patient Information.