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LINADEX PREGNANCY PREVENTION PROGRAMME
PATIENT MEDICATION GUIDE (PMG)

What is the most important information I should know about Linadex?
Linadex is expected to cause birth defects (deformed babies) and harm to an unborn child. Because of this, Linadex is only made available to you through a restricted program called the Linadex Pregnancy Prevention Program. It is important that before taking Linadex, you must read and agree to all the instructions in the Linadex Pregnancy Prevention Program which will include the need to comply with pregnancy testings, contraception requirements and follow-ups. These will be explained to you by your healthcare providers. Please make sure you read and understand the following information before you start taking Linadex and ask your healthcare provider if you have any questions.

For women taking Linadex:

- You must not take Linadex if you are pregnant, as it is expected to be harmful to an unborn baby.
- You must not become pregnant while taking Linadex. Therefore you must use effective methods of contraception if you can become pregnant.
- If you do become pregnant during your treatment with Linadex, you must stop the treatment and inform your doctor immediately.

Females who can become pregnant:

- Will have pregnancy tests under the supervision of your doctor (before every treatment, at least every 4 weeks during treatment, and at least 4 weeks after the treatment has finished) except where it has been confirmed that the fallopian tubes have been severed and sealed, to stop eggs from reaching the uterus (tubal sterilisation).
- If you miss your period or have unusual bleeding, you will need to have a pregnancy test and receive counseling
- Must agree to use effective methods of birth control for at least 4 weeks before starting treatment, during treatment, during any breaks (interruptions) in your treatment, and for at least 4 weeks after stopping Linadex.

Talk with your healthcare provider to find out about options for appropriate forms of birth control

- **If you become pregnant while taking Linadex, stop taking it right away and call your healthcare provider, as Linadex is expected to be harmful to an unborn child.**

For men taking Linadex:

- Linadex can pass into human semen. Males, including those who have had a vasectomy, must always use a latex or synthetic condom during any sexual contact with a pregnant female or a female who can become pregnant while taking Linadex, during any breaks (interruptions) in your treatment with Linadex, and for at least 4 weeks after stopping Linadex.
- Do not have unprotected sexual contact with a female who is or could become pregnant.
- **Tell your healthcare provider immediately if your female partner becomes pregnant whilst you are taking Linadex or up to four weeks after you have stopped taking Linadex.**

It is recommended that she be referred to a physician specialised or experienced in teratology for evaluation and advice.
Do not donate sperm while taking Linadex, during any breaks (interruptions) in your treatment, and for 4 weeks after stopping Linadex. If a female becomes pregnant with your sperm, the baby may be exposed to Linadex and may be born with birth defects.

What should I avoid while taking Linadex?

- See “What is the most important information I should know about Linadex?”
- Females: Do not get pregnant and do not breastfeed while taking Linadex.

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- Males: Condoms must be used during treatment and for at least 4 weeks after the end of treatment, even if you have had a vasectomy, if your female partner is pregnant or able to become pregnant, and she does not use effective methods of contraception. Do not donate sperm.
- Do not share Linadex with other people. It may cause birth defects and other serious problems.
- Do not have unprotected sexual intercourse during treatment and for at least 4 weeks after the end of treatment.
- Women who are pregnant or suspect they may be pregnant should not handle the blister or capsule.

Adverse Event Reporting
If you experience side effects while taking Linadex, inform your healthcare provider.

This document has been approved by HSA as of 18-Apr-2023

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