Package leaflet: Information for the patient

Inluriyo® 200 mg film-coated tablets
imlunestrant

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Inluriyo is and what it is used for

Inluriyo is a cancer medicine that contains the active substance imlunestrant and belongs to a group of medicines called selective oestrogen receptor degraders.

Inluriyo is used to treat adults with a certain type of breast cancer that is locally advanced or has spread to other parts of the body (metastatic) and whose cancer has not responded to or progressed further following at least one line of hormonal treatment. It is used when the cancer cells have oestrogen receptors (ER-positive) and do not have many receptors called human epidermal growth factor receptor 2 (HER2-negative). Inluriyo can only be used in patients who have certain changes (mutations) in a gene called ESR1.

In fertile woman and women in transition to menopause, and in men, treatment with Inluriyo should be combined with a luteinising hormone-releasing hormone (LHRH) agonist.

How Inluriyo works
Oestrogen receptors are proteins in cells that activate when the hormone oestrogen binds to them. By binding to these receptors, oestrogen can in some cases cause cancer cells to grow and multiply. Imlunestrant binds to oestrogen receptors in the cancer cells, which breaks them down and stops them from working. By blocking and destroying oestrogen receptors, imlunestrant can slow down the growth and spread of breast cancer and help to kill cancer cells.

2. What you need to know before you take Inluriyo

Do not take Inluriyo
- if you are breast-feeding.
- if you are allergic to imlunestrant or any of the other ingredients of this medicine (listed in section 6).

Children and adolescents
Inluriyo should not be used in children and adolescents under 18 years of age as it is not intended to treat breast cancer in this age group.

Other medicines and Inluriyo
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because some medicines may affect the way Inluriyo works and Inluriyo may affect the way other medicines work. For example, either medicine may become less effective or you may be more likely to experience side effects.

In particular, tell your doctor or pharmacist before taking Inluriyo if you are taking the following:
- **Dabigatran etexilate** (used to treat or prevent blood clots)
- **Dextromethorphan** (used to relieve cough)
- **Digoxin** (used to treat heart disease)
- **Rosuvastatin** (used to treat high cholesterol)
- **Itraconazole** (used to treat fungal infections)
- **Carbamazepine** (anti-epileptic used to treat seizures or fits)
- **Phenytoin** (anti-epileptic used to treat seizures or fits)
- **Rifampicin** (used to treat bacterial infections)
- **St. John's wort (**used to treat depression**)**

Pregnancy, breast-feeding and fertility
Pregnancy
Inluriyo may harm an unborn baby. If you are pregnant, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you are a man, or woman of childbearing age, you must use an effective method of contraception (birth control) during treatment with Inluriyo and for at least 1 week after stopping the treatment. Ask your doctor about suitable methods. If you are a woman who could become pregnant, your doctor will confirm that you are not pregnant before starting you on treatment with Inluriyo. This may include having a pregnancy test. Tell your doctor immediately if you become pregnant.

Breast-feeding
Do not breast-feed while taking Inluriyo. It is unknown whether Inluriyo passes into breast milk.

Fertility
Inluriyo may decrease fertility in men and women. Talk to your doctor or pharmacist for advice if you are planning to have a baby.

Driving and using machines
Inluriyo has no or negligible influence on your ability to drive and use machines. However, since fatigue and weakness have been reported in some patients taking Inluriyo, if you experience these side effects, you should be careful when driving or operating machinery.

Inluriyo contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to take Inluriyo

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose of Inluriyo is 400 mg (two 200 mg film-coated tablets) taken once daily.

If you experience liver problems your doctor may lower your dose to 200 mg once daily.

If you get certain side effects while you are taking Inluriyo your doctor may lower your dose, pause your treatment until the side effects resolve, or stop treatment permanently.

Your doctor will tell you exactly how many tablets to take.

Take Inluriyo on an empty stomach; at least 2 hours before or 1 hour after food.

Inluriyo should be taken at about the same time every day. The tablets should be swallowed whole. Do not chew, crush, or split tablets before swallowing. This medicine could be harmful for people who are not taking Inluriyo.

If you take more Inluriyo than you should
If you have taken more Inluriyo than you should, contact a doctor or pharmacist immediately, or go to a hospital for advice. Take the tablets and this leaflet with you. Medical treatment may be necessary.

If you forget to take Inluriyo
- If less than 6 hours have passed since your usual time for taking a dose: Take the missed dose right away. Take the next dose at your usual scheduled time the next day.
- If more than 6 hours have passed since your usual time for taking a dose: Skip the missed dose. Take the next dose at your usual scheduled time the next day.
- If you experience vomiting: Do not take a double dose. Take the next dose at your usual scheduled time the next day.
- Do not take a double dose to make up for a forgotten tablet.

If you stop taking Inluriyo
Do not stop taking Inluriyo unless your doctor or pharmacist tells you to. Continuous treatment is important and stopping treatment without advice may worsen your condition.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor, pharmacist or nurse if you notice any of the following:

Very common (may affect more than 1 in 10 people)
- Increased levels of liver enzymes, as measured in blood tests (alanine aminotransferase (ALT) increased, aspartate aminotransferase (AST) increased)
- Tiredness (fatigue)
- Joint, bone and muscle pain
- Diarrhoea
- Increased levels of triglycerides, a type of fat in your blood
- Feeling sick (nausea)
- Back pain

Common (may affect up to 1 in 10 people)
- Constipation
- Abdominal (stomach) pain
- Cough
- Vomiting
- Headache
- Decreased appetite
- Hot flushes

- Blood clots in the veins (venous thromboembolism)

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Inluriyo

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not use this medicine if you notice that the pack is damaged or shows signs of tampering.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Inluriyo contains
The active substance is imlunestrant. Each film-coated tablet contains imlunestrant tosylate equivalent to 200 mg imlunestrant.

The other ingredients are:
- Tablet core: croscarmellose sodium (E 468), hydroxypropylcellulose (E 463), magnesium stearate (E 470b) and cellulose, microcrystalline (E 460) (see section 2 “Inluriyo contains sodium”).
- Film coating: macrogols (E 1521), poly (vinyl alcohol) (E 1203), talc (E 553b), titanium dioxide (E 171).

What Inluriyo looks like and contents of the pack
Inluriyo 200 mg is supplied as a white, capsule shaped film-coated tablet (tablet) of 14 x 7.5 mm, debossed with “LILLY” on one side and “1717” and an elongated 4-point starburst on the other side.

It is available in blister packs of 28 and 56 film-coated tablets.

Not all the pack sizes may be marketed.

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