

Elonva (ell-on-va) is a medicine which is used in female infertility. Elonva contains Corifollitropin alfa. It is supplied by Organon Laboratories Limited.

#### Your medicine

Elonva is a type of a hormone and belongs to a group of medicines called gonadotrophins. Elonva is used in the treatment of infertility or as part of a programme of treatment in assisted reproduction. Assisted reproduction increases the chances of having a multiple pregnancy. You should discuss multiple pregnancy with your prescriber if you are considering having Elonva as part of a programme of treatment of assisted reproduction.

#### Other information about Elonva:

- this medicine may need to be taken as part of a treatment programme along with other hormones. It is important to start have this medicine on a particular day so carefully follow the instructions given to you by your prescriber

Elonva needs to be injected. Your prescriber will show you how to inject this medicine yourself.

There should also be instructions on how to inject this medicine in the Patient Information Leaflet that comes with this medicine or on the pharmacy label.

The pharmacy label on your medicine tells you how much medicine you should use. It also tells you how often you should use your medicine. This is the dose that you and your prescriber have agreed you should use. You should not change the dose of your medicine unless you are told to do so by your prescriber.

Do not share your medicine with other people. It may not be suitable for them and may harm them.

If you feel that the medicine is making you unwell or you do not think it is working, then talk to your prescriber.

#### When to take your medicine

Some medicines work best if they are taken at a specific time of day. If someone is giving you this injection, the person with responsibility for giving you your medicine will make sure that you have your medicine at the prescribed times.

If you are injecting this medicine yourself, make sure that you find out from your prescriber the best time to have Elonva.

#### How to take your medicine

This medicine needs to be injected. Your medical team will train you how to inject the medicine yourself. For more information see the Patient

Information Leaflet or contact one of your medical team.

If you have any concerns about this medicine or about the process of using it you should talk to someone who is involved in your medical care.

#### Taking too much of your medicine

Taking extra doses of some medicines can be harmful. In some cases even one extra dose can cause you problems.

The person who is responsible for giving you your medicine will make sure that you are given the correct dose of your medicine. If you inject the medicine yourself, make sure that you do not take any extra doses as this could cause you problems. If you take extra doses of your medicine, you must get medical advice immediately. You may need a test to assess the effect of taking extra doses. This is because the effects of taking too much medicine are very complex so it is very important that you seek medical advice.

Contact your prescriber, pharmacist, specialist clinic or NHS Direct on 0845 46 47 for advice.

Make sure you take all of your medicine containers with you if you are advised to go to hospital.

#### Stopping your medicine

The person in charge of your care will make the decision about when you should stop this medicine. If you experience any problems while having this medicine talk to someone who is involved in your care. If you are injecting this medicine yourself, and are not having any problems with the medicine, do not stop having it unless advised to do so by your prescriber.

If you are in any doubt, contact your prescriber, pharmacist, specialist clinic or NHS Direct on 0845 46 47.

#### Looking after your medicine

If you are injecting this medicine yourself, read the pharmacy label to find out how you should look after your medicine. It is a good idea to keep your medicine in the original container. This will help to keep your medicine in the best condition and also allow you to check the instructions.

Do not use the medicine if the packaging appears to have been tampered with or if the medicine shows any signs of damage. Specific information about how to look after Elonva can be found in the Patient Information Leaflet that comes with this medicine. Make sure that the medicine is out of the sight and reach of children.

#### In the case of Elonva:

- store in a fridge at temperatures between 2-8°C
- if removed from a fridge, Elonva may be stored at room temperatures up to 25° C but it must be used within one month
- you must not freeze this medicine
- store the medicine in the outer carton to protect it from light

Do not use the medicine after the expiry date shown on the packaging. If you have any unused medicine, return it to your pharmacist who will dispose of it safely.

#### Whether this medicine is suitable for you

Elonva is not suitable for everyone and some people should never use it. Other people should only use it with special care. It is important that the person prescribing this medicine knows your full medical history.

*Your prescriber may only prescribe this medicine with special care or may not prescribe it at all if you:*

- are allergic or sensitive to or have had a reaction to any of the ingredients in the medicine
- have kidney problems
- have a tumour of the ovary, breast, uterus, pituitary or hypothalamus
- have vaginal bleeding and the cause of the bleeding is not known
- have an enlarged ovary, ovarian cyst or other ovarian problems
- have fibroids in the uterus
- have a malformation of the sexual organs
- have polycystic ovary syndrome
- have had blood clots or have risk factors for developing blood clots such as having a family history of blood clots or being obese
- have risk factors for, or have a history of ovarian hyperstimulation syndrome

Elonva is not used in children.

*As part of the process of assessing suitability to take this medicine a prescriber may also arrange tests:*

- to determine whether or not the medicine is suitable and whether it must be prescribed with extra care
- to check that this medicine is having the desired effect
- to check that this medicine is not having any undesired effects

Over time it is possible that Elonva can become unsuitable for some people, or they may become

unsuitable for it. If at any time it appears that Elonva has become unsuitable, it is important that the prescriber is contacted immediately.

#### Side-effects

A medicine is only made available to the public if the clinical trials have shown that the benefits of taking the medicine outweigh the risks.

Once a medicine has been licensed, information on the medicine's effects, both intended and unintended, is continuously recorded and updated.

Some side-effects may be serious while others may only be a mild inconvenience.

Everyone's reaction to a medicine is different. It is difficult to predict which side-effects you will have from taking a particular medicine, or whether you will have any side-effects at all. The important thing is to tell your prescriber or pharmacist if you are having problems with your medicine.

*Common: More than 1 in 100 people who use Elonva*

- breast problems
- headaches
- nausea - seek medical advice if you get nausea
- ovarian hyperstimulation syndrome which may lead to thromboembolism - seek immediate medical advice if you get symptoms such as stomach pain, nausea, diarrhoea, breathing difficulties, decreased urine production or weight gain
- pelvic pain - seek medical advice if you get pelvic pain
- tiredness

*Uncommon: More than 1 in 1000 people who use Elonva*

- constipation
- diarrhoea - seek medical advice if you get diarrhoea
- distension of the stomach
- feeling dizzy
- ovarian torsion
- stomach pain
- vomiting

*The frequency of these side-effects is unknown*

- ectopic pregnancy
- miscarriage
- multiple pregnancy
- neoplasms

If you feel unwell or if you have concerns about a side-effect, you will need to seek advice. If you feel very ill, get medical help straight away. Contact your

prescriber, pharmacist, nurse or call NHS Direct on 0845 46 47.

### Taking other medicines

If you are taking more than one medicine they may interact with each other. At times your prescriber may decide to use medicines that interact, in other cases this may not be appropriate.

The decision to use medicines that interact depends on your specific circumstances. Your prescriber may decide to use medicines that interact, if it is believed that the benefits of taking the medicines together outweigh the risks. In such cases, it may be necessary to alter your dose or monitor you more closely.

Tell your prescriber the names of all the medicines that you are taking so that they can consider all possible interactions. This includes all the medicines which have been prescribed by your GP, hospital doctor, dentist, nurse, health visitor, midwife or pharmacist. You must also tell your prescriber about medicines which you have bought over the counter without prescriptions.

*The following types of medicine may interact with Elonva:*

- gonadorelin agonists

If you are taking Elonva and one of the above types of medicines, make sure your prescriber knows about it.

### Complementary preparations and vitamins

Medicines can interact with complementary preparations and vitamins. In general, there is not much information available about interactions between medicines and complementary preparations or vitamins.

If you are planning to take or are already taking any complementary preparations and vitamins you should ask your prescriber whether there are any known interactions with Elonva.

Your prescriber can advise whether it is appropriate for you to take combinations that are known to interact. They can also discuss with you the possible effect that the complementary preparations and vitamins may have on your condition.

If you experience any unusual effects while taking this medicine in combination with complementary preparations and vitamins, you should tell your prescriber.

### Driving and operating machinery

When taking any medicine you should be aware that it might interfere with your ability to drive or operate machinery safely.

*In the case of Elonva:*

- this medicine could affect your ability to drive or operate machinery

You should see how this medicine affects you before you judge whether you are safe to drive or operate machinery. If you are in any doubt about whether you should drive or operate machinery, talk to your prescriber.

### Diet

Medicines can interact with certain foods. In some cases, this may be harmful and your prescriber may advise you to avoid certain foods.

*In the case of Elonva:*

- there are no specific foods that you must exclude from your diet when using Elonva

### Alcohol

Alcohol can interact with certain medicines.

*In the case of Elonva:*

- there are no known interactions between alcohol and Elonva

### Family planning and pregnancy

Most medicines, in some way, can affect the development of a baby in the womb. The effect on the baby differs between medicines and also depends on the stage of pregnancy that you have reached when you take the medicine.

*In the case of Elonva:*

- it is used to help women with fertility problems to become pregnant

Elonva is not used during pregnancy, so concerns about its use during pregnancy are not relevant.

### Breast-feeding

Certain medicines can pass into breast milk and may reach your baby through breast-feeding.

*In the case of Elonva:*

- Elonva is not used during breast-feeding, so concerns about its use during breast-feeding are not relevant

### Ingredients of your medicine

Medicines contain active ingredients. They may also contain other, additional ingredients that help ensure the stability, safety and effectiveness of the medicine. Some may be used to prolong the life of the medicine.

*Elonva contains:*

- Corifollitropin alfa
- sodium citrate
- sucrose
- polysorbate 20
- methionine
- sodium hydroxide
- hydrochloric acid
- water for injections

If you are not able to take any of the ingredients in your medicine, talk to your prescriber or pharmacist to see if they can suggest an alternative medicine. If you have reacted badly to Elonva before, do not use Elonva. Talk to your prescriber, pharmacist or nurse as soon as possible.