Consumer Medicine Information

This leaflet provides important information about using OVALEAP. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using OVALEAP.

Where to find information in this leaflet:

- 1. Why am I using OVALEAP?
- 2. What should I know before I use OVALEAP?
- 3. What if I am taking other medicines?
- 4. How do I use OVALEAP?
- 5. What should I know while using OVALEAP?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using OVALEAP?

OVALEAP contains the active ingredient follitropin alfa which is similar to follicle stimulating hormone (FSH) found naturally in humans. OVALEAP belongs to a class of hormones called gonadotrophins. FSH is necessary for the growth and development of egg cells (follicles) in women, and sperm production in men.

OVALEAP is an approved biosimilar to the reference product Gonal-f®.

In women OVALEAP is used to bring about the development of follicles in women who are not ovulating and who have not responded to treatment with clomiphene citrate.

OVALEAP is also used to stimulate the development of several follicles in women undergoing assisted reproductive technologies (ART) such as in vitro fertilisation (IVF).

In men OVALEAP is used in combination with human chorionic gonadotrophin (hCG) to stimulate the production of sperm.

2. What should I know before I use OVALEAP?

Warnings

Do not use OVALEAP if:

- you are allergic to follitropin Alfa, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.