

Afolia®

Recombinant human follicle stimulating hormone (follitropin alfa [rch])

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Afolia.

It does not contain all the available information.

It does not take the place of talking to your doctor, nurse or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Afolia against the benefits it is expected to have for you.

If you have any concerns about using this medicine, ask your doctor, nurse or pharmacist.

Keep this information with your medicine.

You may need to read it again later.

What is Afolia used for

Afolia contains follitropin alfa, which is similar to follicle stimulating hormone (FSH) found naturally in humans.

Afolia 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.

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

Comparability in safety, efficacy and quality between Afolia and Gonal-f® have been established.

In women

Afolia can be used to bring about the development of follicles in women who are not ovulating and

who have not responded to treatment with clomiphene citrate.

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

Afolia can be used together with another hormone called Luteinising Hormone (LH) to stimulate development of follicles in women who have been shown to produce very low levels of some of the hormones involved in the natural reproductive cycle.

In men

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

Ask your doctor if you have any questions about why Afolia has been prescribed for you.

Your doctor may have prescribed it for another reason.

Afolia is available only on a doctor's prescription.

Afolia is not habit-forming.

Before you are given Afolia

When you must not use Afolia

Do not use Afolia if you have a history of allergy to any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include:

- shortness of breath

- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not use Afolia if you have tumours of the hypothalamus or pituitary gland.

For women

Do not use Afolia if:

- you are pregnant
- you are breastfeeding
- your ovaries are enlarged
- you have an unexplained ovarian cyst
- you have unexplained vaginal or uterine bleeding
- you have cancer of the ovaries, uterus or breasts
- your ovaries have failed
- you have fibroids in your uterus which would make pregnancy impossible

For men

Do not use Afolia if:

- you have increased levels of gonadotrophins indicating failure of the testes
- your infertility is due to disorders other than hypogonadotrophic hypogonadism (low levels of gonadotrophins)

If you are not certain whether these conditions apply to you, or you are worried about anything on this list, tell your doctor.

Do not give this medicine to a child or elderly person.

Do not use this medicine after the expiry date (month/year) on the packaging has passed, or if the

packaging is torn or shows signs of tampering.

If your medicine has expired or the packaging is damaged, return it to your pharmacist / clinic for disposal.

If you are not sure whether you should start using Afolia, talk to your doctor.

Before you start to use Afolia

Your doctor will assess you and your partner's fertility. This may include tests for other medical conditions, which may interfere with your ability to become pregnant. If necessary, other medical conditions may be treated before starting infertility treatments including Afolia.

Tell your doctor if you have any allergies to any foods, dyes, preservatives or any other medicines.

Tell your doctor if you have or have had any of the following medical conditions:

- disorders of the thyroid gland
- disorders of the adrenal glands
- high prolactin levels in the blood
- porphyria or a family history of porphyria

For women

Your doctor will assess if you have any medical conditions which interfere with your ability to become pregnant.

Treatment with Afolia may increase your risk of developing a condition called ovarian hyperstimulation syndrome (OHSS). This is when the ovaries over-react to the hormonal treatment and become larger.

The most common symptom is lower abdominal pain. During stimulation your doctor will monitor your treatment by the use of ultrasound and/or blood tests to help determine if you are likely to develop OHSS. If necessary your doctor will delay or cancel your Afolia injection. You may also be advised to refrain from sexual

intercourse until the end of the cycle if this occurs.

Compared to natural conception, the frequency of multiple pregnancies and births is higher in patients receiving treatments that stimulate follicle growth for ovulation induction. The majority of these are twins. Your doctor will monitor your response to treatment to minimise the chance of multiple pregnancies, because of the greater risks they carry for mothers and babies.

Compared to natural conception, the frequency of pregnancy loss is higher in patients undergoing treatments to stimulate follicle growth for ovulation induction.

There may be a slightly increased risk of birth defects in babies of women using assisted reproductive technologies. This may be due to increased maternal age, genetic factors, multiple pregnancies or the procedures. An effect of medicines used to induce ovulation has not been excluded.

Tell your doctor if you or a family member have or have had signs of blood clots (e.g. pain, warmth, redness, numbness or tingling in the arm or leg).

Treatment with Afolia and hCG may increase the risk of blood clots forming in your blood vessels.

Talk to your doctor about any concerns you may have before undergoing treatment or before you start using Afolia.

For men

Elevated FSH blood levels are indicative of testicular failure. Your doctor may ask you for a semen analysis to assess your response to treatment.

Talk to your doctor about any concerns you may have before you start using Afolia.

Taking other medicines

Tell your doctor if you are taking any other medicines, including:

- all prescription medicines

- any medicines, vitamins, herbal supplements or natural therapies you buy without prescription from your pharmacy, supermarket, naturopath or health food shop

Some medicines may be affected by Afolia or may affect how well it works.

Your doctor has more information on medicines to be careful with or avoid while using Afolia.

How Afolia is given

Follow all directions given to you by your doctor, nurse or pharmacist carefully.

They may differ from the information contained in this leaflet.

Treatment with Afolia should be started under the supervision of a specialist doctor experienced in fertility treatment.

Afolia is given as a course of daily injections.

You should have your injection at the same time each day.

How much to inject

Your doctor will decide the correct dose of Afolia for you. Your dose of Afolia may be adjusted depending on your individual response to treatment. Please consult your doctor if you are in any doubt.

The following is a guide to the common dose.

1. Women who are not ovulating

The common dose usually starts at 75IU (5.5microgram) daily. The dose may be adjusted as your treatment progresses. The maximal daily dose is usually not higher than 225 IU (16.5 microgram).

2. Women undergoing assisted reproductive technologies

The common dose usually starts at 150 IU (11 microgram) daily,

commencing on day 2 or 3 of the cycle. The dose may be adjusted as your treatment progresses. The maximal daily dose is usually not higher than 450 IU (33 microgram).

3. Women who are not ovulating and have been diagnosed with very low levels of FSH and LH hormones

The common dose usually starts at 75IU to 150IU (5.5 to 11 microgram) together with 75 IU of lutropin alfa daily. The dose may be adjusted as your treatment progresses.

4. Men with hypogonadotropic hypogonadism

Afolia is commonly given with hCG. The common dose usually starts at 150 IU (11 microgram) three times a week.

How to inject

Afolia is given as a subcutaneous (under your skin) injection in the lower abdominal area or thigh.

Afolia is intended to be injected by you or your partner.

Alternatively your doctor or a nurse may give you these injections.

If your doctor or nurse decides you can give the injections yourself, the doctor or nurse will teach you the injection technique.

Do not self-inject until you are sure of how to do it.

Read the Instructions for Use provided in the pack carefully before commencing injections.

Your partner may be trained to give you the injection at home.

Where to inject

Afolia is usually given in the lower abdominal area (except around the navel and waistline) or the front of your thigh. The injection site should be changed daily to lessen possible injection site reactions.

Do not inject into any areas in which you feel lumps, firm knots, depressions, pain, or see any discolouration.

Talk to your doctor if you find anything unusual when injecting.

How long to use Afolia for

For women

The length of treatment varies with each patient. It is possible to have more than one treatment cycle of Afolia.

For men

The combination treatment of Afolia and hCG could continue for at least 4 months and may continue for up to 18-24 months.

If you forget to inject Afolia

If you forget an injection or are not sure what to do, contact your doctor or nurse immediately for advice.

Do not inject a double dose on any day.

Ask your doctor if you are not sure what to do or have trouble remembering to inject your medicine.

If you injected too much

Immediately contact your doctor or the Poisons Information Centre (In Australia telephone 131 126. In New Zealand telephone 0800 764 766) if you are concerned that you have given yourself too much or someone else has injected themselves with Afolia.

While you are using Afolia

Your doctor will carefully monitor your response to Afolia by using ultrasound, blood tests or semen analysis.

Things you must do

See your doctor regularly.

Your doctor will monitor you closely throughout your treatment.

If you are about to be started on any new medicine, tell your

doctor and pharmacist that you are using Afolia.

If you plan to have surgery, tell your doctor or dentist that you are using Afolia.

Tell all doctors, dentists and pharmacists who are treating you that you are using Afolia.

For Women

Tell your doctor immediately if you become pregnant while using Afolia.

Things you must not do

If you are self-injecting do not:

- **Stop using Afolia without telling your doctor.**
- **Change the dose unless your doctor tells you to.**
Changing your dose without advising your doctor can increase your risk of unwanted side effects or can prevent the drug from working properly.
- **Give this medicine to anyone else, even if their symptoms seem similar to yours or if they have the same condition as you.**

Things to be careful of

Be careful driving or operating machinery until you know how Afolia affects you.

Side Effects

Tell your doctor as soon as possible if you do not feel well while using Afolia.

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Ask your doctor or pharmacist to answer any questions you may have.

If you get any side effects, do not stop using Afolia without first talking to your doctor.

Tell your doctor immediately, or go to Accident and Emergency at

your nearest hospital if you notice any of the following:

- signs of an allergic reaction, including swelling of the face, lips, tongue, or other parts of the body; shortness of breath, wheezing or difficulty breathing; severe skin rash, itching or hives.

Tell your doctor if you notice any of the following and they worry you:

- pain, redness, itching or swelling at the site of injection during your treatment with Afolia

For women

- vaginal bleeding
- inflammation, swelling or pain in your legs
- signs of severe OHSS such as severe lower abdominal pain, severe pelvic pain, nausea, vomiting, diarrhoea followed by rapid weight gain, reduced amounts of urine and shortness of breath
- warning signs of stroke or heart attack
- warning signs of blood clots such as pain, warmth, redness, numbness or tingling in your arm or leg

Ectopic pregnancy (embryo implanted outside the womb) may occur, especially in women with prior tubal disease.

Tell your doctor if you notice any of the following and they worry you:

- headache, dizziness
- stomach pain, abdominal distension or abdominal discomfort
- nausea, vomiting
- diarrhoea

For men

- acne
- some breast development
- weight gain

These are common side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

After Using Afolia

Storage

Prior to using, store Afolia PEN in the original package at 2°C to 8°C (Refrigerate. Do not freeze.).

Protect from light.

Before opening and within its shelf-life, the medicine may be removed from the refrigerator, without being refrigerated again, for up to 3 months kept at or below 25°C.

The product if stored at or below 25°C, must be discarded if it has not been used after 3 months.

Discard used pen and needle immediately after injection.

Do not use Afolia PEN if the solution contains particles or is not clear.

Do not use the product after the expiry date printed on the label.

Do not use Afolia if you notice any visible signs of deterioration or damage to the container.

Do not use Afolia on anyone else.

It is for your use only.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half-metres above the ground is a good place to store medicines.

Disposal

If you are self-injecting, you should discard all sharps into a disposal unit.

The Afolia PEN once used should be disposed of in sharps container or return to your clinic or pharmacist for safe disposal.

If you have any Afolia that has expired or is left over from your treatment take this to your clinic.

Product description

What it looks like

Afolia Pen Injector is available in five strengths:

75 IU/0.125 mL
(5.5micrograms/0.125 mL);

150 IU/0.25 mL
(11micrograms/0.25 mL);

225 IU/0.375 mL
(16.5micrograms/0.375 mL);

300 IU/0.50 mL (22micrograms/0.5 mL); and

450 IU/0.75 mL
(33micrograms/0.75 mL).

Afolia Pen Injector is pre-filled with a clear, colourless solution of 0.125 mL (75 IU), 0.25 mL (150 IU), 0.375 mL (225 IU), 0.5mL (300 IU) or 0.75 mL (450 IU).

Each cartridge contains the following ingredients:

Active ingredient

- Recombinant human follicle stimulating hormone (follitropin alfa [rch]) 75 IU (5.5 microgram), 150 IU (11 microgram), 225IU (16.5 microgram), 300 IU(22 microgram) or 450 IU (33 microgram)

Other ingredients

- Sucrose
- Dibasic hydrogen phosphate dihydrate
- Monobasic sodium phosphate dihydrate
- Phosphoric acid
- Polaxamer

- Methionine
- Water for Injections

Pack sizes

Pack sizes of 1, 5 and 10 pre-filled pens. Not all pack sizes may be marketed. Each pack also contains the corresponding number of needles to be used with the pen for administration.

Afolia Pens are not designed to allow the cartridge to be removed.

Australian Registration Numbers:

Afolia 75 IU Pen Injector
AUST R 262645

Afolia 150 IU Pen Injector
AUST R 262646

Afolia 225 IU Pen Injector
AUST R 262647

Afolia 300 IU Pen Injector
AUST R 262648

Afolia 450 IU Pen Injector
AUST R 262649

Supplier

Afolia is supplied in Australia by:
Gedeon Richter Australia Pty Ltd
Suite 902, 15 Blue Street,
North Sydney, NSW 2060
Australia

Phone number: 1300 GEDEON
(1300 433 366)

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Instructions for Use

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1. How to use the Afolia pre-filled pen

- Before starting to use your pre-filled pen, please read these instructions the whole way through first.
- Only use this pen for you – do not let anyone else use it.
- The numbers on the dose display are measured in International Units or IU. **Your doctor will have told you how many IU to inject each day.**
- **Your doctor/pharmacist will tell you how many Afolia pens you need to use for your complete treatment course.**
- Give yourself the injection at the same time each day.

2. Before you start using your pre-filled pen

2.1. Wash your hands

- It is important that your hands and the things you use to get your pen ready are as clean as possible.

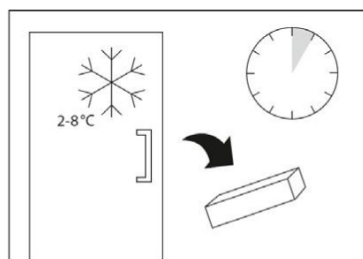
2.2. Find a clean area

- A good place is a clean table or surface.

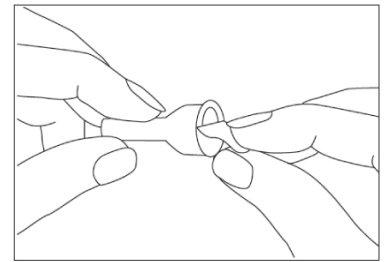
3. Getting your pre-filled pen ready for injection

Perform the injection every day at the same time. Take the pen out of the fridge 5 to 10 minutes before using it.

Note: Please check that the medicine is not frozen. If frozen, do not inject and immediately contact your pharmacist or nurse or doctor

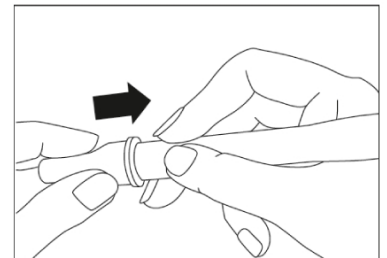


Remove the peel tab from the injection needle.

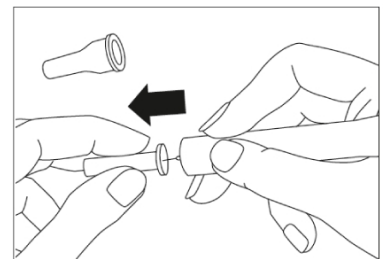


Attach the needle by pushing directly on to the pen, until you hear a 'click'. **Do not twist or screw the needle onto the pen.** Do not click on at an angle.

Caution: Do not push the dosage knob while clicking on the injection needle.

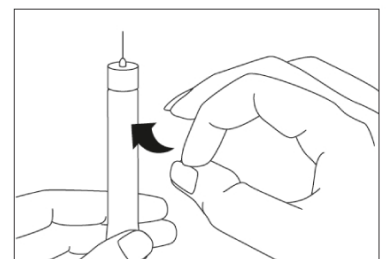


Remove the outer and inner needle protection caps.



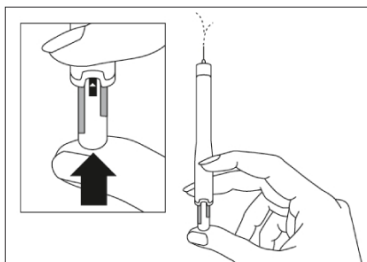
4. Setting the dose

Hold the pen with the needle pointing upright. Tap the pen slightly in order to make eventual air bubbles rise.



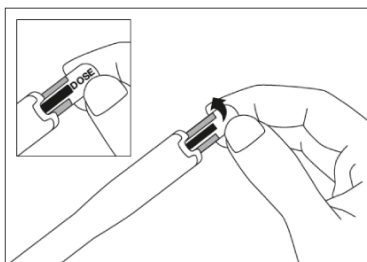
Hold the pen with needle pointing Upright. Push the dosage knob until the stop.

Note: The activation bar disappears and a small amount of liquid splashes out. If a small amount of liquid is not splashed out, the pen should not be used.



Turn the dosage knob until the desired dose (dose bar) is set in the display window.

Note: The pen is now ready for injection. Caution: Do not push the dosage knob.

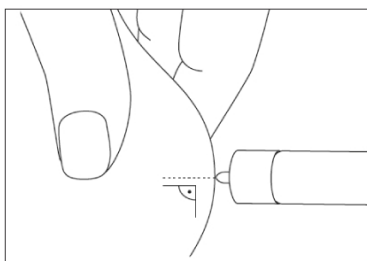


5. Injecting the dose

Immediately inject the solution: Your doctor or nurse will have already advised you where to inject (e.g. tummy, front of thigh). To minimise skin irritation, select a different injection site each day.

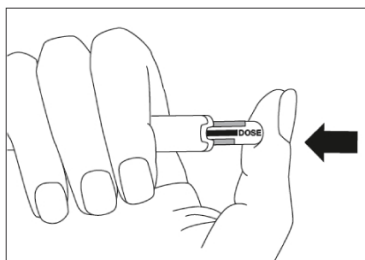
Fold the skin lightly and insert the injection needle completely at a 45° to 90° angle using a dart-like motion.

Caution: Do not push the dosage knob while inserting injection needle.

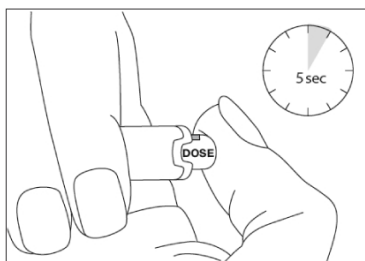


Push the dosage knob until the stop.

Note: Push slowly but continuously; the dose bar disappears.

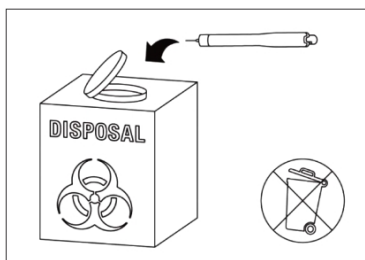


End of the injection: The dose bar has disappeared completely behind the display window (the display window shows the injected dose). Wait for 5 seconds, then pull out the injection needle.



6. After the injection

Following injection do not remove the needle. Place the needle and the used pre-filled pen into a suitable sharps container for disposal.



Throw away the packaging box, needle caps, peel tab, and the instructions for use in the household waste.

