Merional

75 IU and 150 IU
powder and solvent for solution for injection
Menotrophin

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Patient Information Leaflet

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours

As Merional can be used by both women and men, information specific to women or men only is identified with the following symbols:

Woman - ♀ Man - ♂

Information without a symbol alongside is equally applicable to women and men.

In this leaflet:

1. What Merional is for
2. Before you use Merional
3. How to use Merional
4. Possible side effects
5. How to store Merional
6. Further information.

1. What Merional is for

Merional belongs to a group of medicines called sex hormones or gonadotropins.

Benefits of using Merional
Merional works by helping the reproductive organs in both males and females work normally. Merional is used to treat infertility in women and men in the following situations:

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- Women who are not ovulating (producing eggs) who have not responded to clomiphene citrate or other similar medicine
- Women having treatment to stimulate their ovaries to produce eggs in assisted conception procedures such as in-vitro fertilisation (IVF).

♂
- Men who have little or no sperm production due to very low hormone levels.

Merional is presented as a powder (in a vial) and a solvent (in an ampoule).

Risks of using Merional

♀ Becoming pregnant whilst using Merional does have some risks:
- There is a risk that overstimulation of the ovaries (Ovarian Hyperstimulation Syndrome or OHSS) will become more severe or prolonged if pregnancy occurs
- There is an increased chance of multiple births (more than one baby). With these, there is a higher risk of problems for the mother during the pregnancy and at or around the time of birth
- Chances of miscarriage are higher than the normal fertile population, but similar to those with other fertility treatments
- There is a slightly higher risk of an embryo (fertilised egg) implanting outside of the womb (ectopic pregnancy), particularly if you have a history of damaged fallopian tubes
- There have been reports of ovarian and other reproductive system tumours in women having infertility treatment
- There may be a slightly higher risk of your baby being born with physical defects especially if you conceive a multiple pregnancy
- Pregnancy carries a risk of blood clots forming in your blood vessels. Your family history and treatment with infertility hormonal medicines may further increase risk.

If you have any further questions about the benefits and risks of using this medicine, speak with your doctor.

2. Before you use Merional

Do not use Merional if:
- You are allergic to menotrophin
- You are allergic to any of the other ingredients of Merional
- You have tumours of your hypothala mus or pituitary gland (parts of your brain).

Do not use Merional if

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- You have tumours of your uterus, ovaries or breasts
- You have a larger than normal ovary or cyst not caused by polycystic ovarian disease (a hormonal disorder)
- Your ovaries are not capable of working properly
- You have premature menopause
- You have a physical defect of your reproductive organs (uterus, fallopian tubes, ovaries or cervix) that mean you should not become pregnant
- You suffer from unexplained bleeding from your vagina
- You are pregnant or breast-feeding.

♂ **Do not use Merional if**
- You have low testosterone levels.

If any of the above applies to you, do not use Merional and talk to your doctor or pharmacist.

Check with your doctor before using Merional if:
- You have had any previous treatment for infertility
- You or your close family members have ever had blood clots in your blood vessels.

♀
- You have a history of blocked or damaged fallopian tubes (tubal disease).

Tell your doctor if you are taking any of the following medicines:

Your doctor may give you other medicines as part of your fertility treatment. These medicines may have an effect on Merional. If you have any further questions about these medicines, ask your doctor

Tell your doctor if you are taking any other medicine, including medicines obtained without a prescription.

Pregnancy and breast-feeding

♀ Do not take Merional if you are pregnant or breast-feeding.

Important information about some of the ingredients of Merional
This medicine contains (when made up in 1 ml of liquid) less than 1 mmol of sodium (23 mg) i.e. it is essentially 'sodium-free'.

Medical check-ups before your treatment
Your doctor will normally check:
- Your infertility and the effect of any previous fertility treatment
- Your thyroid and adrenal glands are working properly
- You do not have tumours of the pituitary gland or hypothalamus

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- You do not have high prolactin levels in the blood.

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- Your sperm analysis including sperm count.

3. How to use Merional

Always use Merional exactly as your doctor has shown you.
Your medicine can be given to you by a doctor. However after suitable training by your doctor or another healthcare professional you may be able to administer this medicine yourself.

Important:
Your doctor will choose the dose that is right for you. Use your medicine as directed by your doctor. If you are not sure, ask your doctor or pharmacist.

Remember: Merional should only be used for the treatment of infertility under the supervision of a doctor or nurse.

How much Merional to use

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- **Women not ovulating and who have not responded to clomiphene citrate or a similar medicine:**

The usual dose is 75 - 150 IU per day. Your doctor may change your dose depending on how you have responded.

The maximum daily dose is usually 225 IU per day.
If your doctor cannot see a response after 4 weeks of treatment, that treatment cycle will probably be stopped and restarted at a higher dose.

When your follicles are at the correct size for ovulation to be induced, a single injection of another medicine called human chorionic gonadotrophin (hCG) is usually given. This will be given 24 to 48 hours after your last Merional injection and will ensure that you ovulate approximately 36 hours later. You should have sexual intercourse the day hCG is given and again on the following day. Alternatively, your doctor will be able to advise you on artificial insemination procedures.

If you have too great a response treatment will be stopped and hCG will not be given (see Possible side effects). For the following cycle, your doctor will prescribe a lower starting dose.

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- **Women having treatment to stimula te their ovaries to produce eggs in assisted conception procedures such as IVF**

The usual dose is 150 – 225 IU per day, starting on days 2 or 3 of the menstrual cycle.

The maximum daily dose is usually 450 IU.

Development of several follicles containing eggs is usually achieved by the tenth day of treatment although this can happen anywhere from 5-20 days. A single injection of another medicine (human chorionic gonadotrophin-hCG) is usually given 24 to 48 hours after your last Merional injection to complete the maturation of the eggs and allow them to be collected for the IVF procedure. This will normally occur 35-36 hours after the hCG injection.

If you have too great a response treatment will be stopped and hCG will not be given (see Possible side effects). For the following cycle, your doctor will prescribe a lower starting dose.

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- **Men who have little or no sperm production:**

The usual dose is 75 – 150 IU given 2-3 times per week.

Your doctor will start your treatment with injections of another medicine called human chorionic gonadotrophin (hCG) followed by injections of Merional. You will need to have Merional for at least 3 months before any increase in sperm count can be expected. Your doctor may continue your treatment for at least 18 months to maintain satisfactory levels of sperm.

Medical check-ups during your treatment
While you are taking this medicine, your doctor or nurse will be measuring how your body is responding. This is to make sure that your medicine is working properly and that the dose you are taking is right for you. Your body's response could be measured in different ways including:
- Clinical check-ups

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- Scanning the ovaries using ultrasound to see the number and size of the follicles (sacs) containing the eggs that are developing
- Measuring the level of hormones such as oestradiol in blood or urine

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- Sperm counts.

It is very important that you are closely monitored during treatment with Merional and your doctor will decide on the most appropriate way for you.

What you need to administer Merional
Merional is usually administered under your skin (subcutaneously), after training you will normally be able to inject Merional subcutaneously. Merional can also be injected into a muscle (intramuscularly), this is normally done by a healthcare professional.

To administer Merional you will need:
- One syringe
- One large needle (for mixing the solvent with the powder)
- One fine needle (for injecting yourself with the reconstituted product)
- A bin called a 'sharps bin' to dispose safely of the used needles and glass containers.

Preparing your subcutaneous injection

1. **It is important to keep everything as clean as possible**, so start by washing your hands thoroughly and drying them on a clean towel.

2. Choose a clean area and set out all the items you need including the appropriate number of containers of powder and solvent required for the dose your doctor has chosen for you.

   - Each Merional 75 IU vial contains 75 IU of Menotrophin or
   - Each Merional 150 IU vial contains 150 IU of Menotrophin
   - Each solvent ampoule contains 1 ml of solution



3. Attach the large needle to the end of the syringe, leaving the needle's protective cover in place.



4. Carefully break the top off the solvent ampoule by snapping it where the red dot is. Remove needle cover.



Withdraw all the liquid from the ampoule with the large needle and a syringe. Remove syringe with needle, care should be taken not to touch the needle. Replace cover on needle.



5. Remove coloured plastic cap on the powder vial by gently pushing it upwards.



6. Remove syringe cover. Push the needle through the rubber stopper and slowly inject all the solvent into the vial as shown to you by your doctor.

7. The product will normally dissolve immediately. It is important to ensure that all of the powder is completely dissolved, including that near the stopper. If however some of the white powder is stuck to the vial stopper or has not dissolved immediately, keeping the needle in place in the vial slowly and gently roll the vial between your fingers until all the powder dissolves. Do not shake the vial as this will cause foaming. If there is excessive foaming discard vial and start again.

8. Withdraw all the Merional solution by gently drawing the solution back into the syringe. Do this slowly. Ensure solution is clear and particlefree.

9. When reconstituting more than 1 vial of Merional slowly re-inject the solution into a second vial of powder and repeat until the contents of the required number of vials are dissolved. You may dissolve up to 5 vials of Merional in the contents of 1 ampoule of solvent.

Once the powder has all dissolved draw the solution back into the syringe. Inspect solution to ensure it is clear and particle-free.

10. To get ready for the injection replace the large needle on the syringe with the smaller needle as shown to you by your doctor. Do not touch the needle.



11. Remove any air bubbles by pointing the syringe upwards and flicking the syringe so that any air bubbles collect at the top. The plunger is then gently pushed in sufficiently to expel the air bubbles.

12. **Use the reconstituted solution immediately.**

Injecting your medicine subcutaneously
- Your doctor will have already advised you where on your body to inject your medicine. The usual places for subcutaneous injection are the front of thigh and the lower tummy below the navel.
- Ensure the skin has been thoroughly cleaned.
- Inject your medicine as shown by your doctor. **Do not inject into a vein.**
- Pinch the skin together and insert the needle at a 45-90 degree angle using a dart like motion. Inject directly under the skin by pushing gently on the plunger. Ensure that you inject all of the solution.
- Withdraw the needle and wipe the injection site with a clean swab.
- Dispose of all the items including the syringes, needles, ampoules and vials in the sharps bin.

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

Injecting your medicine intramuscularly
For intramuscular injections your healthcare provider will prepare and then inject Merional into the side of your thigh or buttock.

Stopping Merional treatment
Your doctor will tell you when to stop using Merional.

4. Possible side effects

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

♀ **Using Merional can cause overstimulation of the ovaries. The first signs of this are:**
- **Lower stomach pain,**
- **Feeling thirsty and sick and sometimes being sick,**
- **Passing reduced quantities of concentrated urine**
- **Weight gain.**

Seek immediate medical help if you have any of these symptoms.

The condition is characterised by:
- Swelling of the ovaries with large ovarian cysts
- More rarely, enlarged ovaries
- Fluid collecting in the abdomen
- Thickening of the blood resulting in blood clots can occur.

Very common side effects (affect more than 1 in 10 people):
- Ovarian cysts
- Pain and/or inflammation at the injection site
- Headache.

Common side effects (affect less than 1 in 10 people):
- Mild to moderate over-stimulation of the ovaries
- Stomach pain, bloating or discomfort
- Feeling and being sick
- Diarrhoea.

Uncommon side effects (affect less than 1 in 100 people):
- Severe over-stimulation of the ovaries.

Rare side effects (affect less than 1 in 1000 people)
- Twisting of the ovary (ovarian torsion) seen as extreme lower stomach pain.

Very rare side effects (affect less than 1 in 10,000 people)
- Blood clots in blood vessels
- Mild allergic reactions such as redness of skin, rash or facial swelling.

♂ **Common side effects** (affect less than 1 in 10 people):
- Breast enlargement
- Weight gain
- Acne.

Very rare side effects (affect less than 1 in 10,000 people)
- Blood clots in blood vessels
- Mild allergic reactions such as redness of skin, rash or facial swelling.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Merional

Keep out of the reach and sight of children.

Do not use Merional after the expiry date on the label. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original pack to protect from light.

Do not use the Merional if you notice particles in the solution or it is not clear.

The solution must be used immediately after reconstitution.

Medicines should not be disposed of via wastewater or household waste. Return any medicines you no longer need to your doctor or pharmacist.

6. Further information.

What Merional contains
The active substance is menotrophin. One 75 IU container of powder has 75 IU of follicle stimulating hormone and 75 IU of lutenising hormone. One 150 IU container of powder has 150 IU of follicle stimulating hormone and 150 IU of lutenising hormone.

The other ingredient in the powder is lactose monohydrate.

The solvent contains 1 ml of saline (sodium chloride 0.9% w/v solution).

What Merional looks like
Merional is presented as a powder and a solvent for solution for injection.

The powder is white and comes in a small glass container (vial). The solvent is a clear colourless solution that comes in small glass container (ampoule).

Merional comes in a carton containing 1 vial of powder and 1 ampoule of solvent or 10 vials of powder and 10 ampoules of solvent. Not all pack sizes may be marketed.

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