

**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS:** S4

**MERIONAL HG 75 IU** powder for solution for injection and diluent

**Menotrophin**

Contains sugar (lactose monohydrate 10 mg/mL).

**Read all of this leaflet carefully before you start receiving MERIONAL HG**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- MERIONAL HG has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

**What is in this leaflet**

1. What MERIONAL HG is and what it is used for
2. What you need to know before you receive or use MERIONAL HG
3. How to use MERIONAL HG
4. Possible side effects
5. How to store MERIONAL HG
6. Contents of the pack and other information.

## 1. What MERIONAL HG is and what it is used for

MERIONAL HG belongs to a group of medicines called sex hormones or gonadotrophins.

MERIONAL HG contains follicle stimulating hormone (FSH) activity and luteinising hormone (LH) activity; two natural hormones obtained from the urine of post-menopausal women. MERIONAL HG is used to treat infertility in women in the following situations:

- Women who are not ovulating (producing eggs) and who have not responded to clomifene citrate (medicine to induce ovulation).
- Women having treatment to stimulate their ovaries to produce eggs in assisted conception procedures such as *in vitro* fertilisation (IVF).

## 2. What you need to know before you receive or use MERIONAL HG

**You should not receive or use MERIONAL HG if:**

- You are hypersensitive (allergic) to menotrophin or any of the other ingredients of MERIONAL HG (listed in section 6).
- You have a tumour of your hypothalamus or pituitary gland (parts of your brain).
- You are a child.
- You are pregnant or breastfeeding (see "Pregnancy and breastfeeding").
- You have tumours of your uterus, ovaries or breasts.
- You have a larger than normal ovary or cyst not caused by polycystic ovarian disease (PCOD, which is a hormonal disorder).
- Your ovaries are incapable of working properly.
- You have a physical defect of your reproductive organs (uterus, fallopian tubes, ovaries or cervix) that makes you unable to become pregnant.

- 47 • You suffer from unexplained bleeding from your vagina.

48

49 **Warnings and precautions**

50 Take special care with MERIONAL HG if:

- 51 • You have had any previous treatment for infertility.
- 52 • You or your close family members have ever had blood clots in your or their blood vessels.
- 53 • You have a history of blocked or damaged Fallopian tubes (tubal disease).

54

55 The use of MERIONAL HG may cause harmful over stimulation of the ovaries (ovarian  
56 hyperstimulation syndrome [OHSS]). If you notice pain in the abdomen (stomach region), bloating,  
57 weight gain, nausea (feeling sick), vomiting (being sick) or diarrhoea, tell your doctor immediately,  
58 even if the symptoms develop some days after the last injection has been given.

59 If these symptoms become severe, the infertility treatment should be stopped and you should  
60 receive treatment in hospital.

61 Keeping to your recommended dose and careful monitoring of your treatment will reduce your  
62 chances of getting these symptoms.

63

64 If you stop using MERIONAL HG, you might still experience these symptoms. Please contact your  
65 doctor immediately if any of these symptoms occur.

66

67 While you are being treated with MERIONAL HG, your doctor will normally arrange for you to have  
68 ultrasound scans and sometimes blood tests to monitor your response to treatment.

69

If MERIONAL HG treatment results in pregnancy, there is a higher than usual chance of:

- Ectopic pregnancy (pregnancy outside of the womb) if you have a history of fallopian tube disease.
- Multiple pregnancy (having twins or multiple births).
- Miscarriage.
- Congenital malformations (physical defects present in baby at birth).

Some women who have been given infertility treatment with multiple medicines have developed tumours in the ovaries and other reproductive organs.

## Children

MERIONAL HG should not be used in children (see **What you need to know before you receive or use MERIONAL HG**).

## Other medicines and MERIONAL HG

Always tell your health care provider if you are taking any other medicines. (This includes all complementary or traditional medicines). The use of MERIONAL HG with these medicines may cause undesirable interactions.

Please consult with your doctor, pharmacist or health care provider for advice if you need to take any other medicines.

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

## 94 **Pregnancy and breastfeeding**

95 You should not be given MERIONAL HG if you are pregnant or breastfeeding.

96 If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby,  
97 please consult your doctor, pharmacist or other health care provider for advice before using or  
98 receiving MERIONAL HG.

99

## 100 **Driving and using machinery**

101 MERIONAL HG may make you feel dizzy, which may influence your ability to drive and use  
102 machinery.

103 Symptoms associated with OHSS (such as pain in the abdominal area, bloating, increased waist  
104 size, nausea (feeling sick), vomiting (being sick) or diarrhoea), may also impair your ability to drive  
105 a vehicle or to use machinery.

106 Do not drive a vehicle or use machinery until you know how MERIONAL HG affects you.

107

## 108 **MERIONAL HG contains lactose monohydrate**

109 MERIONAL HG contains lactose monohydrate, which is a type of sugar. If you have been told by  
110 your doctor that you have an intolerance to some sugars, contact your doctor before using or  
111 receiving MERIONAL HG.

112

## 113 **3. How to use MERIONAL HG**

114 Do not share medicines prescribed for you with any other person.

115 Always use MERIONAL HG exactly as your doctor has instructed you. You should check with your  
116 doctor or pharmacist if you are unsure.

117

118 MERIONAL HG will be administered by your doctor. However, after suitable training by your doctor  
119 or other health care provider you may be able to administer MERIONAL HG yourself.

120 MERIONAL HG can be injected intramuscularly (IM) (in your buttock, thigh or upper arm), or  
121 subcutaneously (SC) (in your stomach or thigh).

122 Intramuscular injections of MERIONAL HG must be performed by your doctor or health care  
123 provider.

124 MERIONAL HG should only be used for the treatment of infertility under the supervision of a  
125 doctor.

126

127 **Dosage for women not ovulating and who have not responded to clomifene citrate:**

128 The usual dose is 75 – 150 IU MERIONAL HG per day. Your doctor may change your dose  
129 depending on how you have responded.

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

132 When your follicles are at the correct size for ovulation to be induced, a single injection of another  
133 medicine called human chorionic gonadotrophin (hCG) is usually given. This will be given 24 – 48  
134 hours after your last MERIONAL HG injection and will ensure that you ovulate approximately 36  
135 hours later.

136 You should have sexual intercourse the day hCG is given and again on the following day.

137 Alternatively, your doctor will be able to advise you on artificial insemination procedures.

138 If you have a too great response, MERIONAL HG treatment will be stopped and hCG will not be  
139 given. For the following cycle, your doctor will prescribe a lower starting dose.

140

**Dosage for women having treatment to stimulate their ovaries to produce eggs in assisted conception procedures such as IVF:**

The usual dose is 150 – 220 IU MERIONAL HG per day starting on day 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 called human chorionic gonadotrophin (hCG) is usually given. This will be given 24 – 48 hours after your last MERIONAL HG injection to complete the maturation of the eggs. This will allow the eggs to be collected for the IVF procedure. This will normally occur 35 – 36 hours after the hCG injection.

If you have a too great response MERIONAL HG treatment will be stopped and hCG will not be given. For the following cycle, your doctor will prescribe a lower starting dose.

**Medical check-ups during your treatment with MERIONAL HG:**

While you are using MERIONAL HG, your doctor will be measuring how your body is responding. This is to make sure that MERIONAL HG is working properly and that the dose you are taking is right for you.

Your doctor will scan your ovaries using ultrasound to see the number and size of the follicles containing the eggs that are developing. Your doctor will also measure the level of certain hormones in your blood or urine.

Your doctor will tell you how long your treatment with MERIONAL HG will last. If you have the impression that the effect of MERIONAL HG is too strong or too weak, tell your doctor or pharmacist.

**165 Preparing your injection:**

166 MERIONAL HG is provided as a powder and must be dissolved before it is injected. The liquid  
167 (diluent) which you should use to dilute MERIONAL HG is provided with the powder. The diluent  
168 can be provided either in an ampoule or in a pre-filled syringe. MERIONAL HG should only be  
169 diluted immediately before use.

170

**171 For vial and diluent provided in an ampoule:****172 *You will need the following:***

- 173 • 1 vial of MERIONAL HG
- 174 • 1 ampoule with diluent
- 175 • 2 disinfectant swabs
- 176 • 1 syringe for administration of MERIONAL HG
- 177 • 1 thick needle (drawing up needle)
- 178 • 1 fine needle for the subcutaneous injection.

179

**180 *Procedure:***

- 181 1. Wash your hands thoroughly and dry them on a clean towel.
- 182 2. Firmly attach a long, thick needle (drawing up needle) to the syringe, leaving the needle's  
183 protective cover in place.
- 184 3. Carefully break the top off the liquid ampoule by snapping it where the red dot is. Remove the  
185 needle cover.
- 186 4. Insert the needle into the diluent ampoule and withdraw all the diluent from the ampoule into  
187 the syringe.



- 188 5. Remove syringe with needle. Do not touch the needle. Replace the protective cover on the  
189 needle.
- 190 6. Remove the coloured plastic cap on the powder vial by gently pushing it upwards. Disinfect the  
191 rubber stopper with the disinfectant swab.
- 192 7. Remove the syringe cover. Push the needle through the rubber stopper and slowly inject all  
193 the diluent into the vial. Aim at the side of the vial, to avoid creating bubbles.
- 194 8. The powder should dissolve immediately to form a clear solution. It is important to ensure that  
195 all of the powder is completely dissolved, including that near the stopper.
- 196 9. If however some of the powder is stuck to the vial stopper or has not dissolved immediately,  
197 keep the needle in place in the vial, then slowly and gently roll the vial between your fingers  
198 until all the powder dissolves. **Do not shake the vial as this will cause foaming. If there is**  
199 **excessive foaming, discard the vial and start again. If the solution is not clear or if it**  
200 **contains particles it should not be used.**
- 201 10. Withdraw all the MERIONAL HG solution by gently drawing the solution back into the syringe.  
202 Do this slowly.
- 203 11. When reconstituting more than one vial of MERIONAL HG slowly re-inject the solution into a  
204 second vial of powder and repeat until the contents of the required number of vials are  
205 dissolved. You may dissolve up to 5 vials of MERIONAL HG in the contents of 1 ampoule of  
206 diluent. Once the powder has dissolved draw the solution back into the syringe. Inspect the  
207 solution to ensure it is clear and particle free.
- 208 12. Use the reconstituted solution immediately.

210 **For vial and diluent provided in a pre-filled syringe:**

211 ***You will need the following:***

- 212 • 1 vial of MERIONAL HG
- 213 • 1 pre-filled syringe with diluent
- 214 • 2 disinfectant swabs
- 215 • 1 thick needle (drawing up needle)
- 216 • 1 fine needle for the subcutaneous injection.

217

218 **Procedure:**

- 219 1. Wash your hands thoroughly and dry them on a clean towel.
- 220 2. Remove the cap from the pre-filled syringe and attach the thick needle (drawing up needle) on  
221 the pre-filled syringe, leaving the needle's protective cover in place.
- 222 3. Remove the coloured plastic cap on the powder vial by gently pushing it upwards. Disinfect the  
223 rubber stopper with the disinfectant swab.
- 224 4. Take the pre-filled syringe, remove the needle's protective cover and push the needle through  
225 the rubber stopper and slowly inject all the diluent into the vial. Aim at the side of the vial, to  
226 avoid creating bubbles.
- 227 5. The powder should dissolve immediately to form a clear solution. It is important to ensure that  
228 all of the powder is completely dissolved, including that near the stopper.
- 229 6. If however some of the powder is stuck to the vial stopper or has not dissolved immediately,  
230 keep the needle in place in the vial, then slowly and gently roll the vial between your fingers  
231 until all the powder dissolves. **Do not shake the vial as this will cause foaming. If there is**  
232 **excessive foaming, discard the vial and start again. If the solution is not clear or if it**  
233 **contains particles it should not be used.**
- 234 7. Once the powder has completely dissolved, withdraw the solution into the pre-filled syringe  
235 again. Do this slowly.

236 8. When reconstituting more than one vial of MERIONAL HG slowly re-inject the solution into a  
237 second vial of powder and repeat until the contents of the required number of vials are  
238 dissolved. You may dissolve up to 5 vials of MERIONAL HG in the contents of 1 pre-filled  
239 syringe with diluent. Once the powder has dissolved draw the solution back into the pre-filled  
240 syringe. Inspect the solution to ensure it is clear and particle free.

241 9. Use the reconstituted solution immediately.

242

243 **Injecting MERIONAL HG subcutaneously:**

- 244 • To get ready for the injection, replace the large needle on the syringe with a smaller needle as  
245 shown to you by your doctor. Do not touch the needle.
- 246 • Remove any air bubbles by pointing the syringe upwards and flicking the syringe so that any air  
247 bubbles collect at the top. The plunger is then gently pushed in sufficiently to expel the air  
248 bubbles.
- 249 • Your doctor will have advised you where to inject MERIONAL HG. The usual places are the  
250 front of the thigh and the lower stomach below the navel.
- 251 • Ensure the skin has been thoroughly cleaned with the disinfectant swab.
- 252 • To inject MERIONAL HG pinch the skin together and insert the needle at a 45 – 90 degree  
253 angle using a dart like motion. Inject directly under the skin by pushing gently on the plunger.  
254 Ensure that you inject all of the solution.
- 255 • Withdraw the needle and swipe the injection site with a clean swab.
- 256 • Any remaining solution must be disposed of and cannot be reused.
- 257 • Do not put used items into normal domestic waste. Please dispose appropriately.

258

259 **If you use more MERIONAL HG than you should**

260 In event of an overdosage or if you think you have used too much MERIONAL HG, consult your  
261 doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

262 If your doctor administers MERIONAL HG he/she will control the dosage. However, in the event of  
263 an overdosage your doctor will manage any symptoms of the overdosage.

264

#### 265 **If you forget to use MERIONAL HG**

266 If you have missed a dose of MERIONAL HG please tell your doctor.

267 Do not use/receive a double dose to make up for forgotten individual doses.

268

#### 269 **4. Possible side effects**

270 MERIONAL HG can have side effects.

271 Not all side effects reported for MERIONAL HG are included in this leaflet. Should your general  
272 health worsen or if you experience any untoward effects while using MERIONAL HG, please  
273 consult your health care provider for advice.

274

275 If any of the following happens, stop using MERIONAL HG and tell your doctor immediately or go  
276 the casualty department at your nearest hospital:

- 277 • Swelling of your hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in  
278 swallowing or breathing.
- 279 • Rash or itching.
- 280 • Fainting.

281 These are all very serious side effects. If you have them, you may have had a serious reaction  
282 to MERIONAL HG. You may need urgent medical attention or hospitalisation.

283

284 Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice  
285 any of the following:

- 286 • Pain or swelling of the stomach, nausea (feeling sick), vomiting (being sick), diarrhoea, weight  
287 gain, difficulty breathing, feeling more thirsty than usual, producing less urine when you go to  
288 the toilet, or going to the toilet less often. It may mean that you have OHSS (ovarian  
289 hyperstimulation), because your ovaries have been stimulated too much as a result of  
290 MERIONAL HG treatment.
- 291 • Swelling of your leg, including swelling in your ankle or foot, pain in your leg, ankle or foot, or  
292 the skin on the leg, ankle or foot feeling warm. Shortness of breath, chest pain or discomfort or  
293 feeling lightheaded or dizzy. These may all be signs of a thromboembolism, a serious condition  
294 where a blood clot has formed and cause a blockage.

295 These are all serious side effects. You may need urgent medical attention.

296

297 Tell your doctor if you notice any of the following:

298 *Frequent side effects:*

- 299 • Headache.
- 300 • Stomach pain, nausea (feeling sick), vomiting (being sick), diarrhoea, stomach cramps, bloating.
- 301 • Acne.
- 302 • Ovarian cysts (sacs of fluid within the ovaries).
- 303 • Weight gain.
- 304 • Pain and/or inflammation at the injection site (redness, bruising, swelling and/or itching).

305

306 *Less frequent side effects:*

- 307 • Twisting of the ovary (ovarian torsion), where you will experience extreme lower pain in your  
308 abdominal area.

- 309 • Dizziness.

310

311 If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

312

### 313 **Reporting of side effects**

314 If you get side effects, talk to your doctor or pharmacist. You can also report side effects to  
315 SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org)  
316 found on SAHPRA's website.

317 By reporting side effects, you can help provide more information on the safety of MERIONAL HG.

318

### 319 **5. How to store MERIONAL HG**

- 320 • Store at or below 25 °C.
- 321 • Do not freeze.
- 322 • Store in the original container, protected from light.
- 323 • Discard any unused portion.
- 324 • STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- 325 • Do not use after the expiry date printed on the label or carton.
- 326 • Return all unused medicine to your pharmacist.
- 327 • Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

328

### 329 **6. Contents of the pack and other information**

#### 330 **What MERIONAL HG contains**

331 The active substance is menotrophin (human menopausal gonadotropin, HMG) equivalent to 75 IU  
332 FSH activity and 75 IU LH activity.

333

334 The other ingredients are:

335 Powder: Lactose monohydrate.

336 Diluent: 0,9 % *m/v* sodium chloride, water for injection.

337

338 **What MERIONAL HG looks like and contents of the pack**

339 Powder: White freeze-dried plug.

340 Diluent: Clear colourless and odourless solution.

341 The reconstituted solution is a clear colourless solution free from any foreign particles.

342

343 MERIONAL HG 75 IU (vial and ampoule):

344 Powder: One 4 mL Type I clear glass vial, fitted with a grey bromobutyl rubber stopper and an  
345 aluminium seal with a dark green coloured flip-off cap.

346 Diluent (ampoule): One 1 mL Type I clear glass ampoule, coded with yellow and blue coloured  
347 bands and a red dot.

348 Pack size: Each pack contains either 1 vial and 1 ampoule or 10 vials and 10 ampoules in an  
349 outer carton.

350 **OR**

351 MERIONAL HG 75 IU (vial and pre-filled syringe):

352 Powder: One 4 L Type I clear glass vial, fitted with a grey bromobutyl rubber stopper and an  
353 aluminium seal with a dark green coloured flip-off cap.

354 Diluent (pre-filled syringe): One Type I colourless glass syringe, with a grey tip cap at one end and  
355 a siliconised plunger stopper at the other end.

Signed:



25 August 2025

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Pack size: Each pack contains 1 vial, 1 pre-filled syringe with diluent and 2 needles (1 needle for reconstitution/intramuscular injection [0,8 x 40 mm] and 1 needle for subcutaneous injection [0,4 x 12 mm]) placed in a plastic tray packaged in an outer carton.

359

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