PROFESSIONAL INFORMATION

SCHEDULING STATUS

S4

1 NAME OF THE MEDICINE

FIRMAGON® 120 mg powder for solution for injection.

FIRMAGON® 80 mg powder for solution for injection.

FIRMAGON® SOLVENT for solution for injection.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

FIRMAGON® 120 mg: Each vial contains degarelix acetate equivalent to 120 mg degarelix. After reconstitution the concentration is 40 mg/ml.

Contains sugar (160 mg mannitol per vial).

FIRMAGON® 80 mg: Each vial contains degarelix acetate equivalent to 80 mg degarelix. After reconstitution the concentration is 20 mg/ml.

Contains sugar (220,5 mg mannitol per vial).

FIRMAGON® SOLVENT: Each pre-filled syringe contains water for injection 3,0 ml or 4,2 ml.

Sugar free.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder and solvent for solution for injection.

FIRMAGON® 80 mg & 120 mg: white to off-white lyophilisation cake.

FIRMAGON® SOLVENT: clear, colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

FIRMAGON® is a gonadotrophin releasing hormone (GnRH) receptor blocker indicated for treatment of patients with prostate cancer in whom androgen deprivation is warranted.

4.2 Posology and method of administration

Posology

Dosage for adult males:

Starting dose	**Maintenance dose – monthly administration**
240 mg administered as two subcutaneous (s.c.) injections of 120 mg each	80 mg administered as one subcutaneous (s.c.) injection

The first maintenance dose should be given one month after the starting dose.

The therapeutic effect of FIRMAGON® should be monitored by clinical parameters and by measuring prostate specific antigen (PSA) serum levels. Testosterone (T) suppression occurs immediately after administration of the starting dose and 96 % of the patients would have plasma testosterone at medical castration levels (T ≤ 0,5 ng/ml) after three days and 100 % after one month with long term treatment with the maintenance dose up to 1 year shows that 97 % of the patients would have sustained suppressed testosterone levels (T ≤ 0,5 ng/ml).

In case the patient's clinical response appears to be sub-optimal, it should be confirmed that serum testosterone levels are remaining sufficiently suppressed.

Since FIRMAGON® does not induce a testosterone surge it is not necessary to add an anti-androgen as surge protection at initiation of therapy.

Special populations

Elderly, hepatically or renally impaired:

There is no need to adjust the dose for the elderly or in patients with mild or moderate liver or kidney function impairment (see section 5.2). Safety and efficacy in patients with severe liver or kidney dysfunction have not been established (see section 4.4).

Women:

There is no relevant indication for FIRMAGON® in women.

Paediatric population

There is no relevant indication for FIRMAGON® in children and adolescents.

Method of administration

FIRMAGON® must be reconstituted prior to administration. For instructions on reconstitution and administration, please see section 6.6.

FIRMAGON® is for subcutaneous use ONLY, not to be administered intravenously.

FIRMAGON® is administered as a subcutaneous injection in the abdominal region. The injection site should vary periodically. Injections should be given in areas where the patient will not be exposed to pressure e.g., not close to waistband or belt and not close to the ribs.

The reconstituted solution should be a clear liquid, free of undissolved matter.

4.3 Contraindications

- Hypersensitivity to degarelix, or to any of the excipients listed in section 6.1.
- FIRMAGON® is not indicated in women or paediatric patients. In addition, due to its pharmacological effects FIRMAGON® may cause foetal harm if administered to a pregnant woman (see section 4.6).
- A QTc duration of > 450 msec (e.g., congenital QT prolongation).
- Concomitant use with medicines known to prolong the QT time e.g., class I (e.g., procainamide, quinidine) or class III (amiodarone, sotalol) antidysrhythmic medicines (see section 4.4 and 4.5).

4.4 Special warnings and precautions for use

Effect on QT/QTc interval

Long-term androgen deprivation therapy may prolong the QT interval (see section 5.1). In the confirmatory study where monthly ECGs were performed, FIRMAGON® showed QT/QTc intervals exceeding 450 msec in approximately 20 % of the patients, and 500 msec in 1 % of the patients. Degarelix has not been studied in patients with a history of a corrected QT interval over 450 msec, in patients with a history of or risk factors for torsades de pointes and in patients receiving concomitant medicines that might prolong the QT interval (see section 4.3 and 4.5).

A thorough QT study in healthy men showed that there was no intrinsic effect of degarelix QT/QTc interval (see section 4.8).

Hepatic impairment

Patients with known or suspected hepatic disorder have not been included in long-term clinical trials with FIRMAGON®. Mild, transient increases in Alanine Aminotransferase (ALT) and Aspartate Aminotransferase (AST) have been seen, these were not accompanied by a rise in bilirubin or clinical symptoms. Monitoring of liver function in patients with known or suspected hepatic disorder is advised during treatment. The pharmacokinetics of FIRMAGON® has been investigated after single intravenous administration in subjects with mild to moderate

hepatic impairment (see section 5.2).

Renal impairment

FIRMAGON® has not been studied in patients with severe renal impairment and caution is therefore warranted.

Hypersensitivity

FIRMAGON® has not been studied in patients with a history of severe untreated asthma, anaphylactic reactions or severe urticaria or angioedema.

Changes in bone mineral density

Decreased bone mineral density has been reported in the medical literature in men who have had orchiectomy or who have been treated with a GnRH agonist. It can be anticipated that long term treatment with FIRMAGON® will have effects on bone mineral density (see section 5.1).

Glucose tolerance

A reduction in glucose tolerance has been observed in men who have had orchiectomy or who have been treated with a GnRH agonist. Development or aggravation of diabetes may occur; therefore, diabetic patients may require more frequent monitoring of blood glucose when receiving androgen deprivation therapy. The effect of FIRMAGON® on insulin and glucose levels has not been studied.

Cardiovascular disease

Cardiovascular disease such as stroke and myocardial infarction has been reported in the medical literature in patients with androgen deprivation therapy. Therefore, all cardiovascular risk factors should be taken into account.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies have been performed.

Since androgen deprivation treatment may prolong the QTc interval, the concomitant use of degarelix, such as contained in FIRMAGON®, with medicine known to prolong the QTc interval or medicine able to induce torsades de pointes such as class IA (e.g. quinidine, disopyramide) or class III (e.g. amiodarone, sotalol, dofetilide, ibutilide) antidysrhythmic medicine, methadone, moxifloxacin, antipsychotics, etc., is contraindicated (see section 4.3 and 4.4).

Degarelix is not a substrate for the human CYP450 system and has not been shown to induce or inhibit CYP1A2, CYP2B6, CYP2C8, CYP2C9, CYP2C19, CYP2D6, CYP2E1, or CYP3A4/5 to any great extent *in vitro*. Further, degarelix did not interact with any of the relevant efflux and uptake drug transporters tested. Therefore, clinically significant pharmacokinetic interactions are unlikely.

4.6 Fertility, pregnancy and lactation

Pregnancy

FIRMAGON® must not be used in pregnant women. See section 4.3.

Lactation

There is no relevant indication for use of FIRMAGON® in women.

Fertility

FIRMAGON® may inhibit male fertility as long as the testosterone is suppressed.

4.7 Effect on ability to drive and use machines

FIRMAGON® has no or negligible influence on the ability to drive and use machines. Fatigue and dizziness are common adverse reactions that might influence the ability to drive and use machines (see section 4.8).

4.8 Undesirable effects

a. Summary of the safety profile

The most commonly observed adverse reactions during FIRMAGON® therapy in the confirmatory Phase 3 study were due to the expected physiological effects of testosterone suppression, including hot flushes and weight increase (reported in 25 % and 7 %, respectively, of patients receiving treatment for one year) or injection site adverse events. Transient chills, fever or influenza like illness were reported to occur hours after dosing (in 3 %, 2 % and 1 % of patients, respectively).

The injection site adverse events reported were mainly pain and erythema, reported in 28 % and 17 % of patients, respectively, less frequently reported were swelling (6 %), induration (4 %) and nodule (3 %). These events occurred primarily with the starting dose whereas during maintenance therapy the incidence of these events per 100 injections was: 3 for pain and < 1 for erythema, swelling, nodule and induration. The reported events were mostly transient, of mild to moderate intensity and led to very few discontinuations (< 1 %). Serious injection site reactions were very rarely reported such as injection site infection, injection site abscess or injection site necrosis that could require surgical treatment/drainage.

b. Tabulated list of adverse reactions

Information is presented by system organ class and frequency. The frequency of undesirable effects listed below is defined using the following convention: very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1 000 to < 1/100); rare (≥ 1/10 000 to < 1/1 000) and very rare (< 1/10 000). Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

MedDRA System Organ Class (SOC)	**Very common**	**Common**	**Uncommon**	**Rare**

Blood and lymphatic system disorders		Anaemia*		Neutropenic fever
Immune system disorders			Hypersensitivity	Anaphylactic reactions
Metabolism and nutrition disorders		Weight increase*	Hyperglycaemia/ diabetes mellitus, increase in cholesterol, weight decrease, changes in blood calcium, appetite decrease	
Psychiatric disorders		Insomnia	Libido decreased*, depression	
Nervous system disorders		Dizziness, headache	Hypoaesthesia, mental impairment	
Eye disorders			Blurred vision	
Cardiac disorders			Cardiac dysrhythmias (incl. atrial fibrillation), palpitations, QT prolongation *(see sections 4.4 and 4.5)	Myocardial infarction, cardiac failure

Vascular disorders	Hot flush *		Hypertension, vasovagal reaction (incl. hypotension)	
Respiratory, thoracic and mediastinal disorders			Dyspnoea	
Gastrointestinal disorders		Nausea, diarrhoea	Dry mouth, abdominal pain, constipation, vomiting, abdominal discomfort	
Hepato-biliary disorders		Liver transaminases increased	Bilirubin increased, alkaline phosphatase increased	
Skin and subcutaneous tissue disorders		Hyperhidrosis (including night sweats)*, rash	Urticaria, skin hyperpigmentation (skin nodule), alopecia, pruritus, erythema	
Musculoskeletal and connective tissue disorders		Musculoskeletal pain and discomfort	Osteoporosis/ osteopenia, decreased bone mineral density, arthralgia muscular	Rhabdomyo-lysis

			weakness, muscle spasms, joint swelling/ stiffness	
Renal and urinary disorders			Pollakiuria, micturition urgency, dysuria, nocturia, renal impairment, incontinence	
Reproductive system and breast disorders		Erectile dysfunction*, testicular atrophy*, gynaecomastia*	Testicular pain, breast pain, pelvic pain, genital irritation, ejaculation failure	
General disorders and administration site conditions	Injection site adverse events (pain, erythema, swelling, induration nodule)	Chills, pyrexia, asthenia, fatigue*, influenza-like illness	Peripheral oedema, malaise	

*Known physiological consequence of testosterone suppression

c. Description of selected adverse reactions

Hypersensitivity

Hypersensitivity reactions, including anaphylaxis, urticaria and angioedema, have been rarely reported post-marketing with FIRMAGON® (see section 4.3 and 4.4).

Changes in bone density

Decreased bone density has been reported in the medical literature in men who have had orchiectomy or who have been treated with a GnRH agonist. It can be anticipated that long periods of testosterone suppression in men will have effects on bone density (see section 4.4).

Changes in laboratory parameters

Changes in laboratory values as shown in the confirmatory Phase 3 study were in the same range for degarelix, such as contained in FIRMAGON® and a GnRH-agonist (leuprorelin) used as comparator. Markedly abnormal (>3 *ULN) liver transaminase values (ALT, AST and GGT) were seen in 2 - 6 % of patients with normal values prior to treatment, following treatment with both medicines. Marked decrease in haematological values, hematocrit (≤ 0,37 and hemoglobin (≤ 115 g/l) were seen in 40 % and 13 - 15, respectively, of patients with normal values prior to treatment, following treatment with both medicines. It is unknown to what extent this decrease in haematological values was caused by the underlying prostate cancer and to what extent it was a consequence of androgen deprivation therapy. Markedly abnormal values of potassium (≥ 5,8 mmol/l), creatinine (≥ 177 µmol/l) and BUN (≥ 10,7 mmol/l) in patients with normal values prior to treatment, were seen in 6 %, 2 % and 15 % of degarelix, such as contained in FIRMAGON®, treated patients and 3 %, 2 % and 14 % of leuprorelin treated patients, respectively.

Changes in ECG measurements

Changes in ECG measurements seen in the confirmatory Phase 3 study were in the same range for degarelix, such as contained in FIRMAGON®, and a GnRH-agonist (leuprorelin) used as comparator. Three (< 1 %) out of 409 patients in the degarelix group and four (2 %) out of 201 patients in the leuprorelin 7,5 mg group, had a QTcF ≥ 500 msec. From baseline to end of study the median change in QTcF for degarelix was 12,0 msec and for

leuprorelin was 16,7 msec.

The lack of intrinsic effect of degarelix on cardiac repolarisation (QTcF), heart rate, AV conduction, cardiac depolarisation, or T or U wave morphology was confirmed in a thorough QT study in healthy subjects receiving an i.v. infusion of degarelix over 60 min, reaching a mean C_{max} of 222 ng/mL, approx. 3-4-fold the C_{max} obtained during prostate cancer treatment.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/ risk balance of the medicine. Health care providers are requested to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

4.9 Overdose

There is no clinical experience with the effects of an acute overdose with FIRMAGON®. In the event of an overdose, treatment is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

FIRMAGON® 80 mg & 120 mg: A. 21.12 Hormone inhibitors

Pharmacotherapeutic group: Endocrine therapy, other hormone antagonists and related agents, ATC code: L02BX02.

FIRMAGON® SOLVENT: A. 32.4 Water for injection

Mechanism of action

Degarelix is a selective GnRH receptor antagonist (blocker) that competitively and reversibly binds to the pituitary

GnRH receptors, thereby reducing the release of gonadotrophins and consequently testosterone (T).

Prostatic cancer is known to be androgen sensitive and responds to treatment that removes the source of androgen. Unlike GnRH agonists, GnRH antagonists do not induce a luteinizing hormone (LH) surge with subsequent testosterone surge/tumour stimulation and potential symptomatic flare after the initiation of treatment.

A single dose of 240 mg degarelix, followed by a monthly maintenance dose of 80 mg, rapidly causes a decrease in the concentrations of LH, follicle stimulating hormone (FSH) and subsequently testosterone. The serum concentration of dihydrotestosterone (DHT) decreases in a similar manner to testosterone.

Anti-degarelix antibodies

Anti-degarelix antibody development has been observed in 10 % of patients after treatment with degarelix for 1 year and 29 % of patients after treatment with degarelix for up to 5.5 years. There is no indication that the efficacy or safety of degarelix treatment is affected by antibody formation after up to 5.5 years of treatment.

5.2 Pharmacokinetic properties

Absorption

FIRMAGON® forms a depot upon subcutaneous administration, from which degarelix is released to the circulation. The relevant pharmacokinetic results of degarelix evaluated in prostate cancer patients are as follows: C_{max} 53,4 ng/ml; T_{max} 1,4 days; $T_{½}$ 43 days; and AUC 1240 day.ng/ml. Median degarelix trough concentration in the maintenance phase with 80 mg at a concentration of 20 mg/ml was 10,9 ng/ml.

Following subcutaneous administration of 240 mg at a concentration of 40 mg/ml to prostate cancer patients, degarelix is eliminated in a biphasic fashion, with a median terminal half-life of approximately 43 days. The long half-life after subcutaneous administration is a consequence of a very slow release of degarelix from the FIRMAGON® depot formed at the injection site(s). The pharmacokinetic behaviour of the medicine is strongly

influenced by its concentration in the injection solution.

Distribution

The distribution volume in healthy elderly men is approximately 1 l/kg. Plasma protein binding is estimated to be approximately 90 %.

Metabolism

Degarelix is subject to common peptidic degradation during the passage of the hepato-biliary system and is mainly excreted as peptide fragments in the faeces. No significant metabolites were detected in plasma samples after subcutaneous administration. *In vitro* studies have shown that degarelix is not a substrate for the human CYP450 system.

Excretion

In healthy men, approximately 20-30 % of a given dose of degarelix was renally excreted, suggesting that approximately 70-80 % is excreted via the hepato-biliary system in humans. The clearance in healthy elderly men is 35-50 ml/h/kg.

Special populations

Patients with renal impairment

No pharmacokinetic studies in renally impaired patients have been conducted. Only about 20-30 % of a given dose of degarelix is excreted unchanged by the kidneys. A population pharmacokinetics analysis of the data from the confirmatory Phase 3 study has demonstrated that the clearance of degarelix in patients with mild to moderate renal impairment is reduced by 23 %; therefore dose adjustment in patients with mild or moderate renal impairment is not recommended.

Safety and efficacy of degarelix have not been established in patients with severe impairment of renal function.

Patients with hepatic impairment

Degarelix has been studied in a pharmacokinetic study in patients with mild to moderate hepatic impairment. No signs of increased exposure in the hepatically impaired were observed compared to healthy subjects. No shifts in liver function tests were observed 24 hours post-dose compared to baseline in patients with hepatic impairment. Dose adjustment is not necessary in patients with mild or moderate hepatic impairment. Safety and efficacy of degarelix have not been established in patients with severe impairment of hepatic function.

Elderly

The patient population tested in the clinical program was typical of the intended target population of patients with prostate cancer. The mean age was 74 years (range 47 to 98 years).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Powder

Mannitol.

Solvent

Water for injection.

6.2 Incompatibilities

In the absence of compatibility studies, this medicine must not be mixed with other medicine.

6.3 Shelf life

3 years.

After reconstitution

Chemical and physical in-use stability has been demonstrated for 2 hours at 25 °C. From a microbiological point of view, unless the method of reconstitution precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

6.4 Special precautions for storage

Store at or below 25 °C. Do not freeze.

For storage conditions of the reconstituted medicine, see section 6.3.

6.5 Nature of contents of the container

FIRMAGON® 120 mg:

Starting dose (240 mg, 40 mg/ml) – 1 pack contains:

Vials with 120 mg powder for solution for injection. The vials are clear, colourless [Ŧ]type I glass vials (10R) sealed with 20 mm bromobutyl rubber-type stopper and 20 mm aluminium flip-off white seal.

Clear, colourless pre-filled glass (type I) syringes with elastomer plunger stopper, tip cap and line-marking at 3 ml containing 3 ml solvent.

- Plunger rods
- Vial adapters
- Injections needles (25G 0,5 x 25 mm)

Pack size:

1 pack containing 2 powder vials, 2 solvent pre-filled syringes, 2 plunger rods, 2 vial adapters and 2 needles.

FIRMAGON® 80 mg:

Maintenance dose (80 mg, 20 mg/ml) – 1 pack contains:

Vial with 80 mg powder for solution for injection. The vial is a clear, colourless [Ŧ]type I glass vials (10R) sealed

with 20 mm bromobutyl rubber-type stopper and 20 mm aluminium flip-off dark blue seal.

Clear, colourless pre-filled glass (type I) syringe with elastomer plunger stopper, tip cap and line-marking at 4 ml containing 4,2 ml solvent

- Plunger rod
- Vial adapter
- Injection needle (25 G 0,5 x 25 mm)

Pack sizes:

1 pack containing 1 powder vial, 1 solvent pre-filled syringe, 1 plunger rod, 1 vial adapter and 1 needle.

Multipack containing 3 x 1 (1 powder vial, 1 solvent pre-filled syringe, 1 plunger rod, 1 vial adapter and 1 needle).

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

The following information is intended for healthcare provider only.

The instructions for reconstitution must be followed carefully.

Administration of other concentrations is not recommended because the gel depot formation is influenced by the concentration. The reconstituted solution should be a clear liquid, free of undissolved matter.

NOTE:

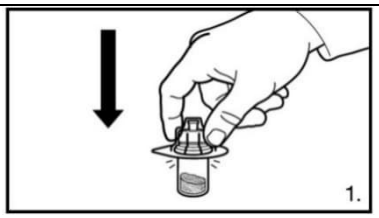
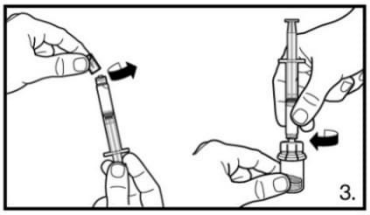
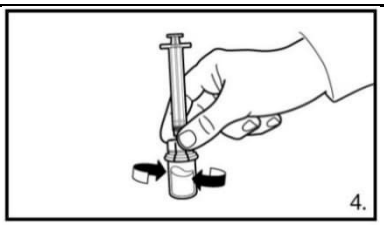
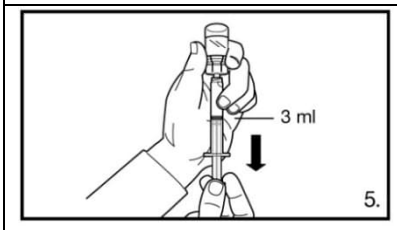
GLOVES SHOULD BE WORN DURING PREPARATION AND ADMINISTRATION

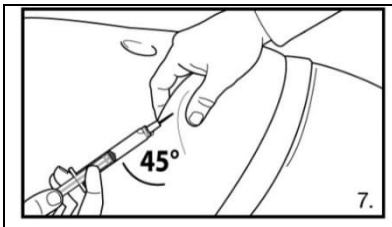
DO NOT SHAKE THE VIALS

FOLLOW ASEPTIC TECHNIQUE

FIRMAGON® 120 mg

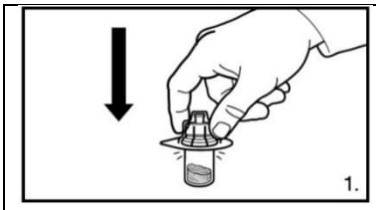
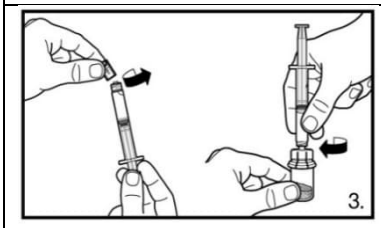
The pack contains two vials of powder and two pre-filled syringes with solvent that must be prepared for subcutaneous injection (s.c.). Hence, the procedure described below need to be repeated a second time.

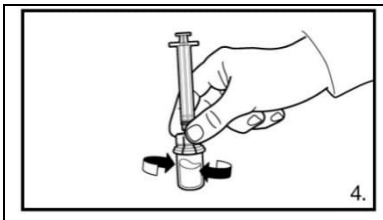
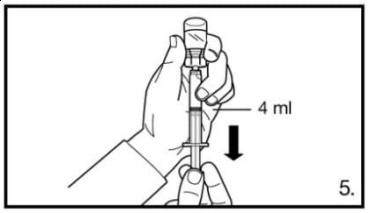
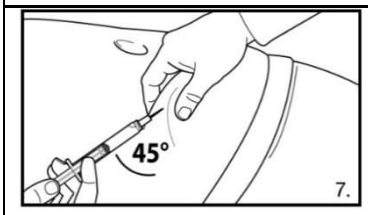
	1. Remove the cover from the vial adapter pack. Attach the adapters to the powder vial by pressing the adapter down until the spike pushes through the rubber stopper and the adapter snaps in place.
2. Prepare the pre-filled syringe by attaching the plunger rod.	
	3. Remove the cap of the pre-filled syringe. Attach the syringe to the powder vial by screwing it on to the adapter. **Transfer all solvent to the powder vial.**
	4 With the syringe still attached to the adapter, swirl gently until the liquid looks clear and without undissolved powder or particles. If the powder adheres to the side of the vial above the liquid surface, the vial can be tilted slightly. **Avoid shaking to prevent foam formation.** A ring of small air bubbles on the surface of the liquid is acceptable. The reconstitution procedure usually takes a few minutes, but may take up to 15 minutes in some cases.
	5. Turn the vial upside down and draw up to the line mark on the syringe for injection. **Always make sure to withdraw the precise volume** and adjust for any air bubbles. **Withdraw until the line marking at 3 ml.**
6. Detach the syringe from the vial adapter and attach the needle for deep s.c. injection to the syringe.	

	7. Perform a deep subcutaneous injection. To do so: grasp the skin of the abdomen, elevate the subcutaneous tissue and insert the needle deeply at an angle of **not less than 45 degrees**. Inject **3 ml of FIRMAGON® 120 mg** slowly, immediately after reconstitution.
8. No injections should be given in areas where the patient will be exposed to pressure, e.g., around the belt or waistband or close to the ribs. Do not inject directly into a vein. Gently pull back the plunger to check if blood is aspirated. If blood appears in the syringe, the product can no longer be used. Discontinue the procedure and discard the syringe and the needle (Reconstitute a new dose for the patient).	
9. Repeat reconstitution procedure for the second dose. Choose a different injection site **and inject 3 ml**.	

FIRMAGON® 80 mg

The pack contains one vial of powder and one pre-filled syringe with solvent that must be prepared for subcutaneous injection (s.c.).

	1. Remove the cover from the vial adapter pack. Attach the adapter to the powder vial by pressing the adapter down until the spike pushes through the rubber stopper and the adapter snaps in place.
2. Prepare the pre-filled syringe by attaching the plunger rod.	
	3. Remove the cap of the pre-filled syringe. Attach the syringe to the powder vial by screwing it on to the adapter. **Transfer all solvent to the powder vial**.

	4. With the syringe still attached to the adapter, swirl gently until the liquid looks clear and without undissolved powder or particles. If the powder adheres to the side of the vial above the liquid surface, the vial can be tilted slightly. **Avoid shaking to prevent foam formation.** A ring of small air bubbles on the surface of the liquid is acceptable. The reconstitution procedure usually takes a few minutes, but may take up to 15 minutes in some cases.
	5. Turn the vial upside down and draw up to the line mark on the syringe for injection. **Always make sure to withdraw the precise volume** and adjust for any air bubbles. **Withdraw until the line marking at 4 ml.**
6. Detach the syringe from the vial adapter and attach the needle for deep s.c. injection to the syringe.	
	7. Perform a deep subcutaneous injection. To do so: grasp the skin of the abdomen, elevate the subcutaneous tissue and insert the needle deeply at an angle of **not less than 45 degrees**. Inject 4 **ml of FIRMAGON® 80 mg** slowly, immediately after reconstitution.
8. No injections should be given in areas where the patient will be exposed to pressure e.g. around the belt or waistband or close to the ribs. Do not inject directly into a vein. Gently pull back the plunger to check if blood is aspirated. If blood appears in the syringe, the product can no longer be used. Discontinue the procedure and discard the syringe and the needle (reconstitute a new dose for the patient).	

Any unused medicine or waste material should be disposed of in accordance with local requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

Ferring (Pty) Ltd.

Route 21 Corporate Offices

6 Regency Drive

Irene Ext. 30

South Africa

8 REGISTRATION NUMBER(S)

FIRMAGON® 120 mg: A43/21.12/0920

FIRMAGON® 80 mg: A43/21.12/0918

FIRMAGON® SOLVENT: A43/32.4/0919

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20 June 2013

10 DATE OF REVISION OF TEXT

03 March 2025

NAME AND BUSINESS ADDRESS OF THE MANUFACTURER

Ferring GmbH

Wittland 11, D-24109 Kiel,

Germany

Namibia

NS2	FIRMAGON® 80 mg powder for solution for injection	16/21.12/0076
NS2	FIRMAGON® 120 mg powder for solution for injection	16/21.12/0077
NS2	FIRMAGON® SOLVENT for solution for injection	16/34/0078