

NEW ZEALAND DATA SHEET

PUREGON SOLUTION FOR INJECTION

Follicle stimulating hormone (follitropin beta)

Presentation

- 150iu cartridge: a clear, colourless, aqueous solution containing 833iu FSH (follitropin beta) per ml.
Total volume = 0.270ml
- 300iu cartridge: a clear, colourless, aqueous solution containing 833iu FSH (follitropin beta) per ml.
Total volume 0.480ml (= 437iu)
- 600iu cartridge: a clear, colourless aqueous solution containing 833iu FSH (follitropin beta) per ml.
Total volume 0.840ml (= 737iu)
- 900iu cartridge: a clear, colourless, aqueous solution containing 833iu FSH (follitropin beta) per ml.
Total volume = 1.230ml

Uses

Actions

Pharmacotherapeutic group: gonadotrophins; ATC code: G03G A06.

PUREGON contains a recombinant FSH. This is produced by recombinant DNA technology, using a Chinese hamster ovary cell line transfected with the human FSH subunit genes. The primary amino acid sequence is identical to that of natural human FSH. Small differences in the carbohydrate chain structure are known to exist.

FSH is indispensable in normal follicular growth and maturation, and gonadal steroid production. In the female the level of FSH is critical for the onset and duration of follicular development, and consequently for the timing and number of follicles reaching maturity. PUREGON can thus be used to stimulate follicular development and steroid production in selected cases of disturbed gonadal function. Furthermore, PUREGON can be used to promote multiple follicular development in medically assisted reproduction programmes [e.g. *in vitro* fertilisation/embryo transfer (IVF/ET), gamete intra-fallopian transfer (GIFT) and intracytoplasmic sperm injection (ICSI)]. Treatment with PUREGON is generally followed by administration of hCG to induce the final phase of follicle maturation, resumption of meiosis and rupture of the follicle.

In men deficient in FSH, PUREGON should be used concomitantly with hCG for at least four months to promote spermatogenesis.

Pharmacokinetics

After subcutaneous administration of PUREGON, high concentrations of FSH are reached within about 12 hours. Due to the sustained release from the injection site and the elimination half-life of about 40 hours (ranging from 12 to 70 hours), FSH levels remain high for 24-48 hours. Due to the relatively long elimination half-life, after repeated administration, plasma concentrations of FSH are approximately 1.5-2.5 times higher than after single administration. This increase contributes to reach therapeutic FSH concentrations.

Since follitropin beta (recombinant FSH) is very similar to endogenous FSH, it is expected that it would be distributed, metabolised, and excreted in the same way.

A bioequivalence study was performed to compare the pharmacokinetics of FSH after subcutaneous single-dose injection of PUREGON with a conventional syringe as dissolved freeze-dried cake (2 x 75 IU) versus administration of PUREGON Solution (150 IU) with pen-injector.

Due to the precision of the device, it can be assumed that exactly 150 IU was injected with the Pen-injector. The dose injected with the syringe was actually lower than the anticipated 150 IU, which is due to losses while filling the syringe and/or removing excess air and to the void volume of the syringe. After correction of the dose by a factor of 1.18, bioequivalence was demonstrated for all relevant pharmacokinetic parameters (see Table below). Since the daily dose of PUREGON is determined by the patient's individual ovarian response, the slightly higher dose delivered by the Pen is unlikely to affect clinical outcome. The following table shows the main pharmacokinetic results of the study:

Parameter	Pen injector (n=20)	Syringe (n=20)	Point estimate	90% CI	Outcome
AUC _{0-∞} (IU/L.h)	215.1	220.3	1.01	0.93-1.10	bioequivalent
Cmax (IU/L)	3.36	3.43	1.00	0.91-1.11	bioequivalent
Cl app (L/h/kg)	0.0117	0.0122	0.99	0.91-1.08	bioequivalent

Indications

In the female

- Anovulatory infertility
- Controlled ovarian hyperstimulation to induce the development of multiple follicles in medically assisted reproduction programmes [e.g. *in vitro* fertilisation and related procedures].

In the male

- Deficient spermatogenesis due to hypogonadotropic hypogonadism.

Dosage and Administration

Treatment with Puregon should be initiated under the supervision of a physician experienced in the treatment of fertility problems

Dosage in the female

Anovulation/defective follicle ripening and/or corpus luteum insufficiency

There are great inter- and intra-individual variations in the response of the ovaries to exogenous gonadotropins. This makes it impossible to set a uniform dosage scheme. The dosage should, therefore, be adjusted individually depending on the ovarian response. This requires ultrasonography and monitoring of oestradiol levels and clinical evaluation of oestrogen activity.

In general, a sequential treatment scheme is recommended. This starts with daily administration of 75-150 IU FSH. This dose is maintained for 5-7 days. If there is no apparent ovarian response, the daily dose is gradually increased until oestrogen levels start to rise.

A daily ascent rate of 40-100% is considered to be optimal. The daily effective dose is then maintained until pre-ovulatory conditions are reached. If oestrogen levels rise too rapidly, i.e. more than a daily doubling for 2 or 3 consecutive days, the daily dose should be decreased.

Pre-ovulatory conditions are reached when plasma oestradiol levels of 300-900 picogram/mL (1000-3000 pmol/L), or a total urinary oestrogen excretion of 75-200 microgram (250-650 nmol)/24 hours are attained, and/or when there is ultrasonographic evidence of a dominant follicle of at least 18mm in diameter. The administration of PUREGON is then discontinued and ovulation can be induced by administering human chorionic gonadotropin (hCG) in a dose of 5000-10,000 IU. Two to three injections of 1000-3000 IU hCG each may be given within the following 9 days to prevent insufficiency of the corpus luteum.

Since follicles of over 15mm may produce pregnancies, a maximum of two additional follicles exceeding 15mm is acceptable. If this limit is exceeded, hCG should be withheld and pregnancy should be avoided in order to prevent large multiple gestations.

In women with polycystic ovarian disease, induction of a hypogonadotropic state by a GnRH agonist before and during treatment with PUREGON may result in better pregnancy rates than without the use of an agonist.

Controlled ovarian hyperstimulation in medically assisted reproduction programmes

Various stimulation protocols are applied. Stimulation of follicular growth is generally achieved by daily administration of 75-300 IU FSH. PUREGON can be given either alone, or in combination with clomiphene citrate to stimulate the endogenous production of gonadotropins, or in combination with a GnRH agonist, in particular to prevent premature luteinization.

Maturation of follicles is monitored by ultrasonography and measurement of plasma oestrogen levels. When ultrasonic evaluation indicates the presence of at least three follicles of 16-20mm, and there is evidence of a good oestradiol response (plasma levels of about 300-400 picogram/mL (1000-1300

pmol/L) for each follicle with a diameter greater than 18mm), the final phase of maturation of the follicles is induced 30-40 hours after the last administration of PUREGON by administration of hCG in a dose of 5000-10,000 IU oocyte retrieval is performed 34-35 hours later.

After embryo transfer, up to three repeat injections of 1000 to 3000 IU hCG each may be given within the following 9 days to provide luteal phase support.

Dosage in the male

75 IU FSH injections are given daily or 2-3 times a week. These injections should be combined with a simultaneous dose of 1000-2000 IU hCG, 2-3 times a week to make up the necessary LH activity. This treatment should be continued for at least three months before any improvement in spermatogenesis can be expected. During this treatment testosterone replacement therapy should be suspended. Once achieved, the improvement may in some cases be maintained by hCG alone.

Method of administration

PUREGON Solution for Injection in cartridges has been developed for use in the PUREGON Pen and should be administered **subcutaneously**. The injection site should be alternated to prevent lipoatrophy.

Using the pen, injection of PUREGON can be carried out by the patient herself, provided that proper instructions are given by the physician.

Contraindications

- Hypersensitivity to the active substance or any of the excipients
- Tumours of ovarium, breasts, uterus, testes, hypothalamus and pituitary gland.
- Pregnancy and during lactation
- Unexplained vaginal bleeding
- Ovarian enlargement or cyst not due to polycystic ovarian disease, ovarian, uterine or mammary carcinoma.
- PUREGON is contraindicated when an effective response cannot be obtained, such as:
 - primary ovarian failure such as indicated by high levels of FSH
 - organic disorders of the reproductive organs incompatible with pregnancy such as congenital malformations of the uterus and fibroids
- Any condition in which a pregnancy (including multiple pregnancy) would be particularly hazardous (e.g. extremes of weight disorders and uterine abnormalities).
- Primary testicular failure.
- PUREGON should not be used in the elderly or in children.

Warnings and Precautions

- The presence of uncontrolled non-gonadal endocrinopathies (e.g. thyroid, adrenal or pituitary disorders) should be ruled out.
- Prior to treating patients for inadequate gonadal function, the following should be assessed:
 - (i) Careful clinical examination to determine general, pelvic or genital pathology
 - (ii) Serum gonadotrophin levels concentrations to exclude gonadal failure
 - (iii) Thyroid function, serum prolactin to exclude endocrinopathies that may be responsible
 - (iv) A semen analysis of the partner
- Ovarian torsion has been reported after treatment with follitropin beta and after intervention with other gonadotrophins. This may be associated with other risk factors such as Ovarian Hyperstimulation Syndrome (OHSS), pregnancy, previous abdominal surgery, past history of ovarian torsion, previous or current cyst and polycystic ovaries. Damage to the ovary due to reduced blood supply can be limited by early diagnosis and immediate detorsion.
- In pregnancies occurring after induction of ovulation with gonadotropic preparations, there is an increased risk of multiples. Appropriate FSH dose adjustment(s) should prevent multiple follicle development. Multiple gestations, especially high order, carry an increased risk of adverse maternal and perinatal outcomes. The parents should be advised of the potential risks of multiple births before starting treatment.
- The first injection of PUREGON should be performed under direct medical supervision.

- Since infertile women undergoing assisted reproduction, and particularly IVF, often have tubal abnormalities the incidence of ectopic pregnancies might be increased. Early ultrasound confirmation that a pregnancy is intrauterine is therefore important.
- Rates of pregnancy loss in women undergoing ART are higher than in the normal population.
- The incidence of congenital malformations after Assisted Reproductive Technologies (ART) may be slightly higher than after spontaneous conceptions. This slightly higher incidence is thought to be related to differences in parental characteristics (e.g. maternal age, sperm characteristics) and to the higher incidence of multiple gestations after ART. Analysis of pooled data does not indicate that the use of gonadotrophins in ovulation induction and medically assisted reproduction programmes carries an increased risk of congenital malformations.
- There have been reports of ovarian and other reproductive system neoplasms, both benign and malignant, in women who have undergone multiple drug regimens for infertility treatment. It is not yet established whether or not treatment with gonadotrophins increases the baseline risk of these tumours in infertile women,
- PUREGON would not be expected to be effective in the absence of endogenous luteinising hormone (LH). The presence of spontaneous or progestogen withdrawal menstruation is suggestive of adequate endogenous LH.
- Women with generally recognised risk factors for thrombosis, such as a personal or family history, severe obesity (Body Mass Index > 30kg/m²) or thrombophilia, may have an increased risk of venous or arterial thromboembolic events, during or following treatment with gonadotrophins. In these women the benefits of IVF treatment need to be weighed against the risks. It should be noted, however, that pregnancy itself also carries an increased risk of thrombosis.
- PUREGON may contain traces of streptomycin and/or neomycin. These antibiotics may cause hypersensitivity reactions in susceptible persons.
- Elevated endogenous FSH levels in men are indicative of primary testicular failure. Such patients are unresponsive to PUREGON/hCG therapy.
- In men, semen analysis is recommended 4 to 6 months after the beginning of treatment in assessing the response.

Unwanted Hyperstimulation

Female patients undergoing superovulation are at an increased risk of developing hyperstimulation in view of the excessive oestrogen response and multiple follicular development. Ultrasonic assessment of follicular development, and determination of oestrogen levels should be performed prior to and at regular intervals during stimulation therapy, especially in patients with Polycystic Ovarian Disease (PCOD). Oestrogen levels may rise very rapidly, e.g. more than a daily doubling for 2 or 3 consecutive days, and possibly reaching excessively high values.

Aspiration of all follicles, prior to ovulation may reduce the incidence of hyperstimulation. Refer to **Overstimulation of the Ovary During Puregon Therapy** below for further information on Ovarian Hyperstimulation Syndrome (OHSS).

Overstimulation of the Ovary During Puregon Therapy

Ovarian enlargement

Mild to moderate uncomplicated ovarian enlargement which may be accompanied by abdominal distension and/or abdominal pain occurs in approximately 20% of those treated with PUREGON and hCG and generally regresses without treatment within two or three weeks.

In order to minimise the hazard associated with the occasional abnormal ovarian enlargement which may occur with PUREGON-hCG therapy, the lowest dose consistent with expectation of good results should be used. Careful monitoring of ovarian response can further minimise the risk of overstimulation.

If the ovaries are abnormally enlarged on the last day of PUREGON therapy, hCG should not be administered in this course of therapy; this will reduce the chances of development of the Ovarian Hyperstimulation Syndrome.

The Ovarian Hyperstimulation Syndrome (OHSS)

OHSS is a medical event distinct from uncomplicated ovarian enlargement. The diagnosis of ovarian hyperstimulation may be confirmed by ultrasound examination. OHSS may progress rapidly to become a serious medical event. It is characterised by an apparent dramatic increase in vascular

permeability which can result in a rapid accumulation of fluid in the peritoneal cavity, thorax and potentially, the pericardium. The early warning signs of development of OHSS are severe pelvic pain, nausea, vomiting and weight gain. The following symptomatology has been seen with cases of OHSS: abdominal pain, abdominal distension, gastrointestinal symptoms including nausea, vomiting and diarrhoea, severe ovarian enlargement, weight gain, dyspnoea and oliguria. Transient liver function test abnormalities suggestive of hepatic dysfunction which may be accompanied by morphologic changes on liver biopsy, have been reported in association with OHSS. Clinical evaluation may reveal hypovolaemia haemoconcentration, electrolyte imbalances, ascites, haemoperitoneum, pleural effusions, hydrothorax, acute pulmonary distress and thromboembolic events (see **Pulmonary and Vascular Complications**).

OHSS occurs uncommonly in patients when the recommended dose is administered and is more common in patients when higher than recommended doses are administered. Cases of OHSS are more common, more severe and more protracted if pregnancy occurs. OHSS develops rapidly; therefore patients should be followed for at least two weeks after hCG administration. Most often, OHSS occurs after treatment has been discontinued and reaches its maximum at about seven to ten days following treatment. Usually, OHSS resolves spontaneously with the onset of menses. If there is evidence that OHSS may be developing prior to hCG administration, the hCG should be withheld.

If OHSS occurs, treatment should be stopped and the patient hospitalised. Treatment is primarily symptomatic, consisting of bed rest, fluid and electrolyte management and analgesics if needed. The phenomenon of haemoconcentration associated with fluid loss into the peritoneal cavity, pleural cavity and the pericardial cavity has been seen to occur and should be thoroughly assessed in the following manner: (1) fluid intake and output, (2) weight, (3) haematocrit, (4) serum and urinary electrolytes, (5) urine specific gravity, (6) BUN and creatinine, and (7) abdominal girth. These determinations are to be performed daily or more often if the need arises.

With OHSS there is an increased risk of injury to the ovary. The ascetic, pleural and pericardial fluid should not be removed unless absolutely necessary to relieve symptoms such as pulmonary distress or cardiac tamponade. Pelvic examination may cause rupture of an ovarian cyst, which may result in haemoperitoneum, and should therefore be avoided. If this does occur, and if bleeding becomes such that surgery is required, the surgical treatment should be designed to control bleeding and to retain as much ovarian tissue as possible. Intercourse should be prohibited in those patients in whom significant ovarian enlargement occurs after ovulation because of the danger of haemoperitoneum resulting from ruptured ovarian cysts.

The management of OHSS may be divided into three phases: an acute, a chronic, and a resolution phase. Because the use of diuretics can accentuate the diminished intravascular volume, diuretics should be avoided except in the late phase of resolution as described below.

Acute Phase: Management during the acute phase should be designed to prevent haemoconcentration due to loss of intravascular volume to the third space and to minimise the risk of thromboembolic phenomena and kidney damage. Treatment is designed to normalise electrolytes while maintaining an acceptable but somewhat reduced intravascular volume. Full correction of the intravascular volume deficit may lead to an unacceptable increase in the amount of third space fluid accumulation. Management includes administration of limited intravenous fluids, electrolytes, and human serum albumin. Monitoring for the development of hyperkalaemia is recommended.

Chronic Phase: After stabilising the patient during the acute phase, excessive fluid accumulation in the third space should be limited by instituting severe potassium, sodium and fluid restriction.

Resolution Phase: A fall in haematocrit and an increasing urinary output without an increased intake are observed due to the return of third space fluid to the intravascular compartment. Peripheral and/or pulmonary oedema may result if the kidneys are unable to excrete third space fluid as rapidly as it is mobilised. Diuretics may be indicated during the resolution phase if necessary to combat pulmonary oedema.

Pulmonary and Vascular Complication

Serious pulmonary conditions (e.g. atelectasis, acute respiratory distress syndrome) have been reported. In addition, thromboembolic events both in association with, and separate from the Ovarian

Hyperstimulation Syndrome are possible following PUREGON therapy. Intravascular thrombosis, which may originate in venous or arterial vessels, can result in reduced blood flow to vital organs or the extremities. Sequelae of such event have included venous thrombophlebitis, pulmonary embolism, pulmonary infarction, cerebral vascular occlusion (Stroke) and arterial occlusion resulting in loss of limb. In rare cases, pulmonary complications and/or thromboembolic events could result in death.

Multiple Births

In the majority of patients, the pregnancies following treatment with PUREGON resulted in single births. For patients undergoing IVF treatment the risk of multiple pregnancy following assisted reproductive technologies is related to the number of oocytes/embryos replaced, in other patients the incidence of multiple pregnancies is increased by PUREGON, as with other agents used to stimulate ovulation. However, the majority of multiple conceptions are twins.

Pregnancy loss is higher than that in the normal population, but comparable with the rates found in women with other fertility problems.

Carcinogenicity and Mutagenicity

Long-term studies in animals have not been performed to evaluate the carcinogenic potential of follitropin beta. Follitropin beta showed no genotoxic activity in a series of assays performed to evaluate its potential to cause gene mutations (*Salmonella typhimurium* and *E coli*) and chromosomal damage (human lymphocytes *in vitro*).

Pregnancy and Lactation

Category B2: Follitropin beta is not intended for use during pregnancy (see **Contraindications**). There are no available data from studies in which PUREGON was administered to pregnant animals. In case of inadvertent exposure during pregnancy, clinical data are not sufficient to exclude a teratogenic effect of recombinant FSH.

It is not known whether follitropin beta is excreted in human milk. Because many medicines are excreted in human milk and because of the potential for serious adverse reactions in the nursing infant from PUREGON, a decision should be made whether to discontinue nursing or to discontinue the medicine, taking into account the importance of the medicine to the mother.

Effects on Ability to Drive and Use Machines

No effects on ability to drive and use machines have been observed.

Adverse Effects

Unwanted ovarian hyperstimulation, ovarian hyperstimulation syndrome. Signs and symptoms of ovarian hyperstimulation syndrome were reported in 3% of women treated with PUREGON in clinical trials. Multiple pregnancy (including higher order multiplets than twins).

Body System Disorders

Percentages of patients with at least one adverse experience classified by body system and reported as related to study medicine pre-marketing in clinical trials (1)		
Body system (WHO system-organ class)	Puregon n = 1074	Metrodin (Urinary FSH) n = 498
	%	%
Gastrointestinal system disorders		
Nausea	0.5	0.8
Abdominal Pain	0.1	0
Other	3.0	3.4
Reproductive disorders, female (2)		
Hyperstimulation Syndrome	5.2	4.0
Ectopic Pregnancy	2.2	3.4
Abdominal Pain	3.0	3.2
Vaginal Haemorrhage	1.1	0.3
Foetal disorders		
Miscarriage	3.1	4.2
Body as a whole-general disorders		
Pain	0.5	0.2

Influenza-like symptoms	0.2	0.2
Swollen Abdomen	0.2	0
Other	0.3	0.6
Application site disorders		
Injection Site Pain	1.0	0.6

(1) a subject can have adverse experiences in more than one body system.

(2) for this category the number of female patients is used.

Application Site Disorders

Bruising*, pain, redness, swelling, itching.

* In one study of 195 women undergoing superovulation for IVF, comparing intramuscular and subcutaneous routes of administration, no differences between the two routes of administration were significant apart from bruising which was more common in the subcutaneous group.

Generalised hypersensitivity reactions which may include erythema, urticaria, rash and pruritus have been observed uncommonly

In the Female

Headache (in up to 1.0% of the women treated with Puregon).

Ovarian torsion has been reported (see PRECAUTIONS).

In rare instances thromboembolism has been associated with Puregon/hCG treatment as with other gonadotrophins.

Characteristic symptoms of ovarian hyperstimulation and the ovarian hyperstimulation syndrome are included under **Precautions**.

In the Male

Gynaecomastia and acne may occur occasionally during PUREGON/hCG therapy. These are known effects of hCG treatment.

Interactions

Concomitant use of PUREGON and clomiphene citrate may enhance the follicular response. After pituitary desensitization induced by a GnRH agonist, a higher dose of PUREGON may be necessary to elicit an adequate follicular response.

Overdosage

The acute toxicity of gonadotrophin preparations has been shown to be very low. However, too high a dosage for more than one day may lead to hyperstimulation of the ovaries (see Unwanted ovarian hyperstimulation).

Pharmaceutical Precautions

Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

Shelf-Life

The shelf-life of PUREGON solution for injection is three years under the conditions specified under Special Precautions for Storage. PUREGON may be used until the expiration date indicated on the package.

Special Precautions For Handling and Disposal

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

PUREGON 150iu, 300iu, 600iu or 900iu Solution for Injection is designed to be used in conjunction with the PUREGON Pen. The instructions for using the pen must be followed carefully.

Air bubbles must be removed from the cartridge before injection (see instructions for using the pen).

Empty cartridges must not be refilled.

PUREGON cartridges are not designed to allow any other medicine to be mixed in the cartridges.

Discard used needles immediately after injection.

Discard used cartridges (including the remaining volume) after the last injection of the treatment cycle.

Special Precautions for Storage

Keep the cartridge in the outer carton.

Keep PUREGON out of reach of children.

Storage by the Pharmacist

Store at 2-8°C. Do not freeze. Protect from light.

Storage by the Patient

There are 2 options:

Either, Store at 2-8°C. Do not freeze.

or Store below 25°C for a maximum of 3 months.

Once the rubber inlay of a cartridge is pierced by a needle, the product may be stored for a maximum of 28 days below 25°C. Protect from light.

Medicine Classification

Prescription Medicine.

Package Quantities

Boxes of PUREGON Solution for Injection contain 1 cartridge of follitropin beta and either 3 (150iu cartridge), 6 (300iu and 600iu cartridges) or 9 (900iu cartridges) needles to be used with the PUREGON Pen. The cartridges are of colourless hydrolytic (class 1) glass, with a rubber piston and an aluminium crimp-cap with a rubber inlay.

Cartridges contain 833iu of FSH activity per ml aqueous solution. Cartridges with a net dose of 150iu contain a minimum of 225iu in 0.270ml; those of 300iu contain a minimum of 400iu in 0.480ml; those of 600iu contain a minimum of 700iu in 0.840ml; those of 900iu contain a minimum of 1025iu in 1.230ml.

Further Information

Qualitative and Quantitative Composition

PUREGON cartridges contain the active substance follitropin beta (recombinant follicle-stimulating hormone, FSH produced by genetic engineering of a Chinese hamster ovary (CHO) cell line, in a concentration of 833iu/ml aqueous solution. This strength corresponds to 83.3mcg of protein/ml (specific *in vivo* bioactivity equal to approximately 10,000iu FSH/mg protein). One cartridge contains a net total dose of 150iu, 300iu, 600iu or 900iu. Total dosings are limited to 3 (150iu cartridge), 6 (300 or 600iu cartridges), or 9 (900iu cartridge).

PUREGON cartridges also contain as excipients sucrose, sodium citrate, methionine, polysorbate 20 and benzyl alcohol in water for injections. The pH may have been adjusted with sodium hydroxide and/or hydrochloric acid.

Pre-Clinical Safety Data

Single-dose administration of PUREGON to rats induced no toxicologically significant effects. In repeated-dose studies in rats (two weeks) and dogs (13 weeks) up to 100-fold the maximal human dose, PUREGON induced no toxicologically significant effects. PUREGON showed no mutagenic potential in the Ames test or in the *in vitro* chromosome aberration test with human lymphocytes.

Name and Address

Merck Sharp & Dohme (NZ) Ltd
P O Box 99 851
Newmarket
Auckland 1149

Tel: 0800 500 673

Date of Preparation

20 January 2011