NEW ZEALAND DATA SHEET

1 PRODUCT NAME

ILOMEDIN® 50 microgram/0.5 mL Solution for Infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

ILOMEDIN 0.5 mL aqueous solution contains iloprost trometamol 67 micrograms (equivalent to iloprost 50 micrograms)

3 PHARMACEUTICAL FORM

Clear, colourless, sterile pyrogen-free solution for infusion.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of patients with severe peripheral arterial occlusive disease (PAOD), particularly those at risk of amputation and in whom surgery or angioplasty is not possible.

Treatment of advanced thromboangiitis obliterans (Buerger's disease) with critical limb ischaemia in cases where revascularisation is not indicated.

Treatment of patients with severe disabling Raynaud's phenomenon unresponsive to other therapies.

Treatment of moderate or severe primary and secondary pulmonary hypertension such as New York Heart Association functional classes III and IV.

4.2 Dose and method of administration

ILOMEDIN should be used only under strict monitoring in hospitals or out-patient clinics with adequate facilities.

Pregnancy must be excluded before the start of treatment in women.

ILOMEDIN is administered after dilution as an intravenous infusion over 6 hours daily via a peripheral vein or a central venous catheter. The dose is adjusted according to individual tolerability within the range of 0.5 to 2.0 ng iloprost/kg body weight/min.

The infusion solution should be made up freshly each day to ensure sterility.

The contents of the ampoule and the diluent should be mixed thoroughly.

The blood pressure and heart rate must be measured at the start of the infusion and after every increase of the dose.

During the first 2 - 3 days, the individually tolerated dose is established. For this purpose, treatment should be started at an infusion rate to deliver 0.5 ng/kg/min. for 30 minutes. The dose should then be increased at intervals of about 30 minutes in steps of 0.5 ng/kg/min. up to 2.0 ng/kg/min. The exact infusion rate should be calculated on the basis of body weight to effect an infusion within the range of 0.5 to 2.0 ng/kg/min. (see tables below for use with infusion pump or for use with syringe driver).

Depending on the occurrence of side effects such as headache and nausea or an undesired drop of blood pressure, the infusion rate should be reduced until the tolerable dose is found. If the side effects are severe, the infusion should be interrupted. The treatment should then be continued - usually for 4 weeks - with the dose found to be tolerated in the first 2 to 3 days.

Depending on the infusion technique there are two different dilutions of one ampoule. One of those two dilutions is 10-fold less concentrated than the other (0.2 microgram/mL) and may only be applied with an infusion pump (e.g. Infusomat®). On the contrary, the more concentrated solution is applied via a syringe driver (e.g. the Perfusor®), see 6.6 Special precautions for disposal and other handling

- Infusion rates (mL/hour) for different doses for use with infusion pump

In general, the ready-to-use infusion solution is infused intravenously by means of an infusion pump (e.g. Infusomat®). For instructions for dilution for use with infusion pump, see 6.6 Special precautions for disposal and other handling. In the case of an ILOMEDIN concentration of 0.2 microgram/mL, the required infusion rate should be determined according to the above described scheme to effect a dose within the range of 0.5 to 2.0 ng/kg/min.

The following table can be used to calculate the weight of the patient and the dose to be infused. (Please interpolate to match the patient's actual body weight, then set the infusion rate to the target dose in ng/kg/min.)

Body weight (kg)		Dose (ng/kg/min) 0.5 1.0 1.5 2.0 Infusion rate (mL/h)			
	40	6.0	12	18.0	24
	50	7.5	15	22.5	30
	60	9.0	18	27.0	36
	70	10.5	21	31.5	42
	80	12.0	24	36.0	48
	90	13.5	27	40.5	54
	100	15.0	30	45.0	60
	110	16.5	33	49.5	66

- Infusion rates (mL/hour) for different doses for use with syringe driver

A syringe driver with a 50mL injection syringe (e.g. the Perfusor®) may also be used. For instructions for dilution for use with syringe driver, see 6.6 Special precautions for disposal and other handling.

In the case of an ILOMEDIN concentration of 2 microgram/mL, the required infusion rate should be determined according to the above described scheme to effect a dose within the range of 0.5 to 2.0 ng/kg/min.

The following table can be used to calculate the infusion rate corresponding to the individual weight of the patient and the dose to be infused. (Please interpolate to match the patient's actual body weight, then set the infusion rate to the target dose in ng/kg/min.)

Body weight (kg)		Dose (ng/kg/min) 0.5 1.0 1.5 2.0 Infusion rate (mL/h)			
	40	0.6	1.2	1.80	2.4
	50	0.75	1.5	2.25	3.0
	60	0.90	1.8	2.70	3.6
	70	1.05	2.1	3.15	4.2
	80	1.20	2.4	3.60	4.8
	90	1.35	2.7	4.05	5.4
	100	1.50	3.0	4.50	6.0
	110	1.65	3.3	4.95	6.6

The duration of treatment is up to 4 weeks. Shorter treatment periods (3 to 5 days) are often sufficient in Raynaud's phenomenon to achieve improvement over several weeks.

The treatment of primary and secondary pulmonary hypertension (PHT) should be initiated and supervised by a physician experienced in the treatment of this condition. In each individual patient careful titration of the dose should be carried out under close haemodynamic monitoring.

In PHT, the dosage of iloprost should be titrated up to the maximum tolerated dose of 1 - 8 ng/kg/min.

Continuous infusion over several days is not recommended. This is because of the possible development of tachyphylaxis of platelet effects and the possibility of rebound platelet hyperaggregability at the end of treatment, although no clinical complications associated with these phenomena have been reported.

- Patients with renal or hepatic impairment

It should be borne in mind that, in patients with renal failure requiring dialysis and in patients with liver cirrhosis, iloprost elimination is reduced. In these patients a dose reduction (e.g. half the recommended dose) is necessary.

4.3 Contraindications

Hypersensitivity to iloprost or to any of the excipients.

Pregnancy, lactation.

Conditions where the effects of ILOMEDIN on platelets might increase the risk of haemorrhage (e.g. active peptic ulcers, trauma, intracranial haemorrhage).

Severe coronary heart disease or unstable angina; myocardial infarction within the last six months; decompensated cardiac failure if not under close medical supervision; severe arrhythmias; suspected pulmonary congestion; cerebrovascular events (e.g. transient ischaemic attack, stroke) within the last 3 months.

Acute or chronic congestive heart failure (NYHA II-IV)

Pulmonary hypertension due to venous occlusive disease.

Congenital or acquired valvular defects with clinically relevant myocardial function disorders not related to pulmonary hypertension.

4.4 Special warnings and precautions for use

Surgery should not be delayed in patients requiring urgent amputation (e.g. in infected gangrene).

Patients should be strongly advised to stop smoking.

Iloprost elimination is reduced in patients with hepatic dysfunction and in patients with renal failure requiring dialysis (see Dose and method of administration and Pharmacokinetic properties).

In patients with low blood pressure care should be taken to avoid further hypotension and patients with significant heart disease should be closely monitored. ILOMEDIN should not be initiated in patients with systolic arterial hypotension less than 85 mmHg.

In patients with PHT with low systemic blood pressure or at high risk of cardiac output failure, careful initiation of the therapy, under close haemodynamic monitoring, must be taken. This is necessary to avoid further hypotension or other undesirable effects such as a decrease in mean systemic arterial pressure and vascular resistance leading to a worsening of cardiac output.

The possibility of orthostatic hypotension should be borne in mind in patients getting up from the lying to an upright position after the end of administration.

Patients with acute pulmonary infections, chronic obstructive pulmonary disease, and severe asthma should be carefully monitored.

ILOMEDIN should not be used as the first treatment option in thromboembolic pulmonary hypertension if surgery is feasible.

In the long-term administration of intravenous iloprost for PHT, particularly in a community setting, care should be taken to avoid any infection or sepsis arising from the procedures necessary for the administration of ILOMEDIN.

Currently only sporadic reports of use in children and adolescents are available. ILOMEDIN should be used only after dilution. Because of the possibility of interactions, no other medicine should be added to the ready-to-use infusion solution.

The paravascular infusion of undiluted ILOMEDIN can lead to local changes at the injection site.

Oral ingestion and contact with mucous membranes must be avoided. On contact with the skin, iloprost may provoke long-lasting but painless erythema. Suitable precautions should therefore be taken to avoid iloprost contact with the skin. In the event of such contact, the affected area should be washed immediately with copious amounts of water or saline.

4.5 Interaction with other medicines and other forms of interaction

Iloprost may increase the antihypertensive activity of β-receptor blockers, calcium antagonists, vasodilators and ACE inhibitors. Should significant hypotension occur this can be corrected by dose reduction of iloprost.

Because iloprost inhibits platelet function, its use with anticoagulants (such as heparin coumarin-type anticoagulants), or other inhibitors of platelet aggregation (such as acetylsalicylic acid, non-steroidal anti-inflammatory medicines, phosphodiesterase inhibitors and nitro vasodilators e.g. molsidomine) may increase the risk of bleeding. If this occurs, iloprost administration should be stopped.

Oral premedication with acetylsalicylic acid up to 300 mg per day over a period of 8 days had no impact on the pharmacokinetics of iloprost. In an animal study, it was found that iloprost may result in a reduction in t-PA steady-state plasma concentration. The results of human studies show that iloprost infusions do not affect the pharmacokinetics of multiple oral doses of digoxin in patients and iloprost has no impact on the pharmacokinetics of co-administered t-PA.

In animal experiments, the vasodilatory effect of iloprost is attenuated when the animals are pre-treated with glucocorticoids, while the inhibitory effect on platelet aggregation remains unaffected. The significance of this finding for use in man is not known.

Although, clinical studies have not been conducted, in vitro studies investigating the inhibitory potential of iloprost on the activity of cytochrome P450 enzymes revealed that no relevant inhibition of medicine metabolism via these enzymes by iloprost have to be expected.

4.6 Fertility, pregnancy and lactation

ILOMEDIN must not be administered to pregnant or lactating women.

Use in Pregnancy

There are no adequate data from the use of iloprost in pregnant women. Preclinical studies have shown evidence of foetotoxicity in rats, but not rabbits and monkeys (see Preclinical safety data).

As the potential risk of the therapeutic use of iloprost during pregnancy is unknown, women of child-bearing potential should use effective contraceptive measures during treatment.

Use in Lactation

It is not known whether iloprost enters human breast milk. As extremely low levels of iloprost pass into the milk of rats, iloprost should not be administered to nursing women.

4.7 Effects on ability to drive and use machines

It is unlikely that ILOMEDIN will have any deleterious effects (e.g. sedation), but care should be exercised during initiation of therapy until any effects on the individual have been determined. In

patients experiencing hypotensive symptoms such as dizziness, ability to drive or operate machinery may be seriously affected.

4.8 Undesirable effects

The most frequently observed adverse drug reactions (≥ 10%) in patient receiving iloprost in clinical trials are headache, flushing, nausea, vomiting and hyperhidrosis. These are likely to occur while the dose is titrated at the start of treatment to identify the best tolerable dose for the individual patient. However, all these side effects usually disappear quickly with dose reduction.

Overall, the most serious adverse drug reactions in patients receiving iloprost are cerebrovascular accident, myocardial infarction, pulmonary embolism, cardiac failure, convulsion, hypotension, tachycardia, asthma, angina pectoris, dyspnoea and pulmonary oedema.

Another group of side effects is related to the local infusion site reactions. For example, infusion site redness and infusion site pain may occur or a cutaneous vasodilation may give rise to a streaky erythema above the infusion vein.

The adverse drug reactions observed with ILOMEDIN are represented in the table below. They are classified according to System Organ Class (MedDRA version 14.1). The most appropriate MedDRA term is used to describe a certain reaction and its synonyms and related conditions.

Adverse drug reactions from clinical trials are classified according to their frequencies. Frequency groupings are defined below:

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
Very rare:		< 1/10,000		

The overall safety profile of ILOMEDIN is based on data from post-marketing surveillance and on pooled clinical trial data. The crude incidences were based on the cumulative database of 3325 patients having received iloprost either in controlled or uncontrolled clinical trials or in a compassionate use program from generally elderly and multimorbid patients with peripheral arterial occlusive disease (PAOD) in its advanced stages III and IV and patients with thromboangiitis obliterans (TAO), for details see Table 1

Table 1: Adverse drug reactions reported in clinical trials or during post-marketing surveillance in patients treated with ILOMEDIN

System Organ Class (MedDRA)	Very Common	Common	Uncommon	Rare
Blood and lymphatic system disorders			Thrombocytopaenia	
Immune system disorders			Hypersensitivity	
Metabolism and nutrition disorders		Decreased appetite		
Psychiatric disorders		Apathy, Confusional state	Anxiety, Depression, Hallucination	

System Organ Class (MedDRA)	Very Common	Common	Uncommon	Rare
Nervous system disorders	Headache	Dizziness/ Vertigo, Paraesthesia/ Throbbing sensation/ Hyper-aesthesia/ Burning sensation, Restlessness, Agitation Sedation, Drowsiness	Convulsion*, Syncope, Tremor, Migraine	
Eye disorders			Vision blurred, Eye irritation, Eye pain	
Ear and labyrinth disorders				Vestibular disorder
Cardiac disorders		Tachycardia*, Bradycardia, Angina pectoris*	Myocardial infarction*, Cardiac failure*, Arrhythmia/ Extrasystoles	
Vascular disorders	Flushing	Hypotension*, Blood pressure increased	Cerebrovascular accident*/Cerebral ischaemia, Pulmonary embolism*, Deep vein thrombosis	
Respiratory, thoracic and mediastinal disorders		Dyspnoea*	Asthma*, Pulmonary oedema*	Cough
Gastrointestinal disorders	Nausea, Vomiting	Diarrhoea, Abdominal discomfort/ Abdominal pain	Diarrhoea haemorrhagic, Rectal haemorrhage Dyspepsia, Rectal tenesmus, Constipation, Eructation, Dysphagia, Dry mouth/Dysgeusia	Proctitis
Hepato-biliary disorders			Jaundice	
Skin and subcutaneous tissue disorders	Hyperhidrosis		Pruritus	

System Organ Class (MedDRA)	Very Common	Common	Uncommon	Rare
Musculoskeletal and connective tissue disorders		Pain in jaw/Trismus, Myalgia/Arthralgia	Tetany/Muscle spasms, Hypertonia	
Renal and urinary disorders			Kidney pain, Vesical tenesmus, Urine abnormality, Dysuria, Urinary tract disorder	
General disorders and administration site conditions		Pain, Pyrexia/Body temperature increased, Feeling hot, Asthenia/Malaise, Chills Fatigue/Tiredness, Thirst, Infusion site reactions (infusion site erythema, infusion site pain, infusion site phlebitis)		

* life threatening and/or fatal cases have been reported

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. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/

Iloprost may provoke angina pectoris, especially in patients with coronary artery disease.
The risk of bleeding is increased in patients when inhibitors of platelet aggregation, heparin or anticoagulants of the coumarin-type are given concomitantly.

4.9 Overdose

Symptoms of Overdose
Hypotensive reaction might be anticipated as well as headache, flushing, nausea, vomiting and diarrhoea. An increase of blood pressure, bradycardia or tachycardia and limb or back pain might be possible.
Treatment of Overdose
A specific antidote is not known. In the event of myocardial ischaemia provoked by iloprost, the administration of 125 mg aminophylline i.v. has been shown to be an effective countermeasure. Interruption of iloprost administration, monitoring and symptomatic measures are recommended. For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Iloprost is a synthetic prostacyclin analogue. The following pharmacological effects have been observed:

- Inhibition of aggregation, platelet adhesion and release reaction;
- Dilatation of arterioles and venules,
- Increase of capillary density and reduction of increased vascular permeability caused by mediators such as serotonin or histamine in the microcirculation;
- Stimulation of endogenous fibrinolytic potential
- Anti-inflammatory effects such as inhibition of leukocyte adhesion after an endothelial lesion and of leukocyte accumulation in injured tissue, and reduced release of tumour necrosis factor

Iloprost, due to its anti-aggregatory effects and potent pulmonary vasodilatory effect, has demonstrated beneficial haemodynamic effects and an improvement in exercise tolerance in patients suffering from severe pulmonary hypertension (PHT). In addition, recent studies have reported that this action on the pulmonary circulation can be augmented by the inhalative delivery of iloprost. Treatment with iloprost results in a reduction in pulmonary vascular resistance and pulmonary artery pressure, an increase in cardiac output and an improvement in oxygenation.

5.2 Pharmacokinetic properties

- Distribution

Steady-state plasma levels are achieved as early as 10 - 20 minutes after the start of an intravenous infusion. The steady-state plasma levels are linearly related to the infusion rate. Plasma levels of about 135 ± 24 pg/mL are obtained at an infusion rate of 3 ng/kg/min. The plasma concentration of iloprost falls very quickly after the end of the infusion because of the high rate of metabolism. The metabolic clearance of the substance from plasma is about 20 ± 5 mL/kg/min. The half-life of the terminal disposition phase from plasma is 0.5 hours, as a result of which the substance level falls to less than 10% of the equilibrium concentration just two hours after the end of infusion.

Interactions with other medicines at the level of plasma protein binding are improbable because the greater portion of iloprost is bound to the albumin of blood plasma (protein binding: 60%) and only very low iloprost concentrations are achieved. An effect of iloprost therapy on the biotransformation of other medicines is likewise extremely unlikely because of the metabolic pathways and the low absolute dose.

Following intravenous infusion, the apparent steady-state volume of distribution was 0.6 to 0.8 L/kg in healthy subjects. Total plasma protein binding of iloprost is concentration independent in the range of 30 to 3000 pg/mL and amounts to approximately 60%, of which 75% is due to albumin binding.

- Metabolism

Iloprost is extensively metabolised principally via ß-oxidation of the carboxyl side chain. No unchanged substance is eliminated. The main metabolite is tetranor-iloprost, which is found in the

urine in free and conjugated form in 4 diastereoisomers. Tetranor-iloprost is pharmacologically inactive as shown in animal experiments. In vivo studies suggest that metabolism of iloprost in the lungs is similar after intravenous administration or inhalation.

- Elimination

In subjects with normal renal and hepatic function, the disposition of iloprost following intravenous infusion is characterised in most cases by a two-phase profile with mean half-lives of 3 to 5 minutes and 15 to 30 minutes. The total clearance of iloprost is about 20 mL/kg/min, which indicates extrahepatic contribution to the metabolism of iloprost.

A mass-balance study was done using 3H-iloprost in healthy subjects. Following intravenous infusion, the recovery of total radioactivity is 81%, and the respective recoveries in urine and faeces are 68% and 12%. The metabolites are eliminated from plasma and with urine in 2 phases for which half-lives of about 2 and 5 hours (plasma) and 2 and 18 hours (urine) have been calculated.

- Characteristics in patients

Renal dysfunction:

In a study with intravenous infusion of iloprost, patients with end stage renal failure undergoing intermittent dialysis treatment are shown to have a significantly lower clearance (mean CL= 5 ± 2 mL/min/kg) than that observed in patients with renal failure not undergoing intermittent dialysis treatment (mean CL= 18 ± 2 mL/min/kg).

Hepatic dysfunction:

Because iloprost is extensively metabolised by the liver, the plasma levels of the medicine are influenced by changes in hepatic function. In an intravenous study, results were obtained involving 8 patients suffering from liver cirrhosis. The mean clearance of iloprost is estimated to be 10 mL/min/kg.

Age and gender:

Age and gender are not of clinical relevance to the pharmacokinetics of iloprost.

5.3 Preclinical safety data

Preclinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential. Preclinical effects were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use.

- Systemic toxicity

In acute toxicity studies, single intravenous and oral doses of iloprost caused severe symptoms of intoxication or death (i.v.) at dosages about two orders of magnitude above the intravenous therapeutic dose. Considering the high pharmacological potency of iloprost and the absolute doses required for therapeutic purposes the results obtained in acute toxicity studies do not indicate a risk of acute adverse effects in humans. As expected for a prostacyclin, iloprost produced haemodynamic effects (vasodilatation, reddening of skin, hypotension, inhibition of platelet function, respiratory distress) and general signs of intoxication such as apathy, gait disturbances, and postural changes.

In systemic toxicity studies with repeated (continuous) i.v. infusion, a slight reduction of the blood pressure occurred at doses above 14 ng/kg/min. and severe undesired effects (hypotension, disturbance of respiratory function) appeared only after extremely high dosages.

Continuous i.v./s.c.infusion of iloprost up to 26 weeks in rodents and non-rodents at dose levels which exceeded the human therapeutic systemic exposure between 14 and 47 times (based on plasma levels) did not cause any organ toxicity. Only expected pharmacological effects like hypotension, reddening of skin, dyspnoea and increased intestinal motility were observed.

- Genotoxic potential

In vitro and in vivo studies for genotoxic effects have not produced any evidence for a mutagenic potential.

No tumourigenic potential of iloprost could be demonstrated in tumourigenicity studies in rats and mice.

- Reproductive toxicology

In embryo- and foetotoxicity studies in rats continuous intravenous administration if iloprost led to anomalies of single phalanges of the forepaws in a few foetuses/pups without dose-dependence.

These alterations are not considered as true teratogenic effects, but are most likely related to iloprost induced growth retardation in late organogensis due to haemodynamic alterations in the foetoplacental unit. It can be assumed that this growth retardation is widely reversible during the postnatal development. In comparable embryotoxicity studies in rabbits and monkeys no such digit anomalies or other gross-structurally abnormalities were observed even after considerably higher dose levels which exceeded the human dose multiple times.

In rats a passage of extremely low levels of iloprost into the milk were observed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Trometamol; ethanol, 96 % (v/v); sodium chloride; hydrochloric acid, 1N; water for injections

6.2 Incompatibilities

No data available for other than those medicinal products described under 6.6 Special precautions for disposal and other handling.

6.3 Shelf life

48 months

6.4 Special precautions for storage

Store all medicines properly and keep them out of reach of children
Store below 30ºC

6.5 Nature and contents of container

Pack of 5 ampoules each containing 0.5 mL concentrate for solution for infusion.

6.6 Special precautions for disposal and other handling

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

ILOMEDIN should be used only after dilution. Because of the possibility of interactions, no other medicine should be added to the ready-to-use infusion solution.
The ready-to-use infusion solution must be freshly prepared each day in order to guarantee sterility.

- Instructions for dilution

The contents of the ampoule and the diluent should be mixed thoroughly.

Dilution of ILOMEDIN for use with an infusion pump:
For this purpose, the contents of an ampoule of 1 mL ILOMEDIN (i.e. 100 micrograms) are diluted with 500 mL of a sterile physiological saline solution or a 5% glucose solution. Or the contents of an ampoule of 0.5 mL ILOMEDIN (i.e. 50 micrograms) are diluted with 250 mL of a sterile physiological saline solution or a 5% glucose solution.

Dilution of ILOMEDIN for use with a syringe driver:
In this case, the contents of one ampoule ILOMEDIN of 1 mL (i.e. 100 micrograms) are diluted with 50 mL of sterile physiological saline solution or 5% glucose solution. Or the contents of one ampoule ILOMEDIN of 0.5 mL (i.e. 50 micrograms) are diluted with 25 mL of sterile physiological saline solution or 5% glucose solution.

7 MEDICINE SCHEDULE

Prescription Medicine

8 SPONSOR

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3 Argus Place
Hillcrest
North Shore
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9 DATE OF FIRST APPROVAL

19th March 2012

10 DATE OF REVISION OF THE TEXT

5 December 2019

SUMMARY TABLE OF CHANGES

Section Changed	Summary of New Information
Whole document	Data sheet reformatted with minor editorial changes- update to the SPC-style format only.
4.2, 6.2	Cross-references updated
1, 2, 4.2, 4.5, 6.1, 6.4, 6.5, 6.6	Minor editorial changes
6.5, 7.0	Re-introduction of information accidentally omitted during Data sheet reformat
8.0	Sponsor's contact number updated

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