NEW ZEALAND DATA SHEET

1. FOSCAVIR 24 mg/mL solution for infusion.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Foscarnet trisodium hexahydrate 24 mg/mL

3. PHARMACEUTICAL FORM

Solution for infusion.

A clear, colourless, particle-free, sterile, isotonic solution (pH 7.4) containing 24 mg/mL (80 µmol/mL) foscarnet trisodium hexahydrate, hydrochloric acid q.s. and water q.s.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

- Treatment of cytomegalovirus (CMV) retinitis in patients with acquired immunodeficiency syndrome (AIDS).
- Treatment of aciclovir resistant HSV infections in immunocompromised patients. The safety and efficacy of FOSCAVIR for the treatment of other HSV infections (e.g. retinitis, encephalitis); congenital or neonatal disease; or HSV in immunocompetent individuals has not been established.

4.2. Dose and method of administration

Contact with the skin and eyes may cause local irritation and a burning sensation. If accidental contact occurs, the exposed area should be rinsed immediately with cold water.

Method of administration

FOSCAVIR must be given by the intravenous route only, either via a central venous line or directly into peripheral veins.

When peripheral veins are used, FOSCAVIR 24 mg/mL must be diluted with glucose (dextrose) 5% or normal saline to a concentration of 12 mg/mL immediately prior to administration. (See **Section 4.4 Special warnings and precautions for use** regarding total daily sodium intake).

FOSCAVIR 24 mg/mL solution may be given without dilution via a central vein.

CAUTION - Do not administer foscarnet by rapid intravenous injection.

Adults
CMV retinitis

Induction therapy

Foscarnet can be administered over 2-3 weeks, depending on clinical response, as intermittent infusions every 8 hours at a dose of 60 mg/kg in patients with normal renal function (see dosing chart below). The infusion time should not be shorter than one hour for the 60 mg/kg dose.

The dose of foscarnet should be adjusted to the renal function as assessed by estimated creatinine clearance.

Maintenance therapy

For maintenance therapy, following induction therapy of CMV retinitis, foscarnet is administered seven days a week as a once daily infusion over 2 hours at a dose determined by renal function as assessed by estimated creatinine clearance. In patients with normal renal function the dose range is 90-120 mg/kg/day. Dosage must be individualised for patients renal function (see dosing chart below). It is recommended to initiate therapy at 90 mg/kg and increase up to 120 mg/kg in patients in whom retinitis is progressing and who show good tolerance to the lower dose.

The dosage used can be calculated from the following dosage charts or from experience obtained with the patient during the induction phase by correlating their renal function with plasma levels.

These dosage recommendations are approximate and actual dosing should always be based on the clinical situation.

HSV infections

Induction therapy

Foscarnet should be administered at a dose of 40 mg/kg, over one hour, every 8 hours, in patients with normal renal function (see dosing chart below). The infusion time should not be shorter than 1 hour. The time taken for healing depends on the size of the initial lesion and foscarnet therapy should continue until complete re-epithelialization occurs, usually 2-3 weeks. A clinical response to foscarnet therapy should be evident after one week's treatment; therapy in patients showing no response at this time should be re-assessed.

Maintenance therapy

The efficacy of FOSCAVIR maintenance therapy in the treatment of aciclovir resistant HSV infections has not been established.

FOSCAVIR dosing charts.

Induction therapy

Creatinine clearance mL/min/kg	CMV every 8 hrs (mg/kg)	HSV every 8 hrs (mg/kg)	Continuous infusion mg/kg/24hrs
> 1.6	60	40	200
1.6-1.4	55	37	175
1.4-1.2	49	33	133
1.2-1.0	42	28	110
1.0-0.8	35	24	85
0.8-0.6	28	10	40
0.6-0.4	21	14	20
< 0.4	treatment not recommended		

Maintenance therapy

Creatinine clearance mL/min/kg	One infusion mg/kg/day over 2 hours
>1.4	90-120
1.4-1.2	78-104
1.2-1.0	75-100
1.0-0.8	71-94
0.8-0.6	63-84
0.6-0.4	57-76
<0.4	treatment not recommended

Foscarnet is not recommended for use in patients undergoing haemodialysis as dosage guidelines have not been established.

Hydration

Renal toxicity can be reduced by adequate hydration of the patient. Prior to the first foscarnet infusion it is recommended that diuresis be established by hydration with 0.5 - 1.0 litre normal saline. Subsequently add 0.5 - 1.0 litre normal saline to each infusion. In compliant patients, oral hydration with similar hydration regimens has been used. Clinically dehydrated patients should have their condition corrected before initiating foscarnet therapy.

Duration of Treatment

An initial induction treatment period of 2-3 weeks is recommended, depending on the clinical response, followed by maintenance therapy for as long as considered appropriate.

Elderly

As for adults.

Paediatric population
The safety and efficacy of foscarnet in children have not been established. Please refer to **Section 4.4 Special warnings and precautions for use, Section 5.3. Preclinical safety data** and **Section 5.2 Pharmacokinetic properties.**

Renal or hepatic insufficiency
The dose must be reduced in patients with renal insufficiency according to the creatinine clearance level as described in the table above. Dose adjustment is not required in patients with hepatic insufficiency.

4.3 Contraindications
Hypersensitivity to foscarnet.

4.4 Special warnings and precautions for use
Renal impairment
Foscarnet should be used with caution in patients with reduced renal function. Since renal function impairment may occur at any time during foscarnet administration, serum creatinine should be monitored every second day during induction therapy and once weekly during maintenance therapy. Appropriate dose adjustments should be made if renal function is affected. (See **Section 4.2 Dose and method of administration**). To minimise the potential of renal function impairment, adequate hydration should be maintained in all patients. The renal function of patients with renal disease or receiving concomitant treatment with other nephrotoxic medicinal products must be closely monitored (see **Section 4.5 Interaction with other medicines and other forms of interaction**).

Due to the sodium content of FOSCAVIR (240 micromoles (5.5 mg) of sodium per mL), its use should be avoided when a saline load cannot be tolerated (e.g. in cardiomyopathy). This should also be taken into consideration by patients on a controlled sodium diet.

Due to the propensity of foscarnet to chelate bivalent metal ions, such as calcium, foscarnet administration may be associated with an acute decrease of ionised serum calcium proportional to the rate of foscarnet infusion, which may not be reflected in total serum calcium levels. Particular caution is advised in patients with decreased calcium levels before treatment and in those receiving other medicines known to influence serum calcium levels. Electrolytes, especially calcium and magnesium, should be assessed prior to and during foscarnet therapy and deficiencies corrected.

QT prolongation
Foscarnet has been associated with prolongation of the QT interval on the electrocardiogram. During post-marketing surveillance, there have been very rare cases of QT prolongation and Torsade de pointes in patients taking foscarnet. These reports included patients with confounding risk factors, electrolyte abnormalities and concomitant treatment which may have been contributing factors.

Patients with known existing prolongation of cardiac conduction intervals, particularly QTc, in patients with significant electrolyte disturbances (hypokalaemia, hyperkalaemia, hypomagnesaemia), or bradycardia, as well as patients with

underlying cardiac diseases such as congestive heart failure should be carefully monitored due to increased risk of ventricular arrhythmia. Electrolyte disturbances (hypokalaemia, hyperkalaemia, hypomagnesaemia) or bradycardia are known to be conditions increasing the proarrhythmic risk.

Patients should be advised to promptly report any cardiac symptoms.

Foscarnet is deposited in teeth, bone and cartilage. Animal data show that deposition is greater in young animals. The safety of foscarnet and its effect on skeletal development have not been investigated in children. Please refer to **Section 5.3. Preclinical safety data**.

Seizures, related to alterations in plasma minerals and electrolytes, have been associated with FOSCAVIR treatment. Cases of status epilepticus have been reported. Therefore, patients must be carefully monitored for such changes and their potential sequelae. Mineral and electrolyte supplementation may be required.

FOSCAVIR is excreted in high concentrations in the urine and may be associated with significant genital irritation and/or ulceration. To prevent irritation and ulceration, close attention to personal hygiene is recommended and cleaning of the genital area after each micturition is recommended.

Should patients experience extremity paraesthesia or nausea, it is recommended to reduce the speed of infusion.

When diuretics are indicated, thiazides are recommended.

Development of resistance: If the administration of FOSCAVIR does not lead to a therapeutic response or leads to a worsened condition after an initial response, this may result from a reduced sensitivity of viruses towards foscarnet. In this case, termination of FOSCAVIR therapy and a change to an appropriate other medicinal product should be considered.

Paediatric population
There are insufficient data available either *in vivo* or *in vitro* to establish any possible effect in growing bone. See **Section 4.4 Special warnings and precautions for use** and **Section 5.3. Preclinical safety data** .

4.5 Interaction with other medicines and other forms of interaction

Since foscarnet can impair renal function, additive toxicity may occur when used in combination with other nephrotoxic medicines such as aminoglycosides, amphotericin B, ciclosporin A, aciclovir, methotrexate and tacrolimus. Moreover, since foscarnet can reduce serum levels of ionised calcium, extreme caution is advised when used concurrently with other medicines known to influence serum calcium levels, like IV pentamidine. Renal impairment and symptomatic hypocalcaemia (Trousseau's and Chvostek's signs) have been observed during concurrent treatment with foscarnet and IV pentamidine. Abnormal renal function has been reported in connection with the use of foscarnet in combination with ritonavir and / or saquinavir.

There is no pharmacokinetic interaction with zidovudine (AZT), ganciclovir, didanosine (ddI), zalcitabine (ddC) or probenecid.

Pharmaceutical interactions (incompatibilities for infusion) are described in **Section 6.2 Incompatibilities**.

4.6 Fertility, pregnancy and lactation

Pregnancy

Since there is no clinical experience or investigational data available, FOSCAVIR should not be given to pregnant women.

Breast-feeding

Since there is no clinical experience or investigational data available, FOSCAVIR should not be given during lactation.

Fertility

There are no data available regarding the influence of FOSCAVIR on fertility. No effects on fertility were observed in animal studies (see **Section 5.3. Preclinical safety data**).

Women capable of childbearing should use effective contraception methods during FOSCAVIR therapy. Men treated with FOSCAVIR should not father a child during or up to 6 months after therapy.

4.7 Effects on ability to drive and use machines

Adverse effects such as dizziness and convulsions may occur during foscarnet therapy. The physician is advised to discuss this issue with the patient, and based upon the condition of the disease and the tolerance of medication, give his/her recommendation in the individual case.

4.8 Undesirable effects

The majority of patients who receive FOSCAVIR are severely immuno-compromised and suffering from serious viral infections. Patients' physical status, the severity of the underlying disease, other infections and concurrent therapies contribute to adverse events observed during the use of FOSCAVIR.

The undesirable effects reported with FOSCAVIR during clinical trials and post-marketing surveillance are shown in the table below. They are listed by System-Organ Class (SOC) and in order of frequency, 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); very rare (<1/10,000); not known (cannot be estimated from the available data).

Please note that in these clinical trials, hydration and attention to electrolyte balance was not consistently given; the frequency of some adverse events will be lower when current recommendations are followed (see **Section 4.2 Dose and method of administration**, **Section 4.4 Special warnings and precautions for use**).

Tabulated list of adverse reactions

SOC	Frequency	Event
Blood and lymphatic system disorders	Very common	Granulocytopenia, anaemia
	Common	Leukopenia, thrombocytopenia, neutropenia
	Uncommon	Pancytopenia
Immune system disorders	Common	Sepsis
	Not known	Hypersensitivity (including anaphylactic reactions), anaphylactoid reactions
Endocrine disorders	Not known	Diabetes insipidus
Metabolism and nutrition disorders	Very common	Decreased appetite, hypokalaemia, hypomagnesaemia, hypocalcaemia
	Common	Hyperphosphataemia, hyponatraemia, hypophosphataemia, blood alkaline phosphatase increased, blood lactate dehydrogenase increased, hypercalcaemia, dehydration
	Uncommon	Acidosis
	Not known	Hypernatraemia
Psychiatric disorders	Common	Aggression, agitation, anxiety, confusional state, depression, nervousness
	Not known	Mental status changes
Nervous system disorders	Very common	Dizziness, headache, paraesthesia
	Common	Coordination abnormal, convulsion, hypoaesthesia, muscle contractions involuntary, neuropathy peripheral, tremor
	Not known	Encephalopathy, status epilepticus
Cardiac disorders	Common	Palpitations, tachycardia
	Not known	Electrocardiogram QT prolonged, ventricular arrhythmia, Torsade de pointes
Vascular disorders	Common	Hypertension, hypotension, thrombophlebitis[a]
Gastrointestinal disorders	Very common	Diarrhoea, nausea, vomiting
	Common	Abdominal pain, constipation, dyspepsia, pancreatitis, gastrointestinal haemorrhage
	Not known	Oesophageal ulceration
Hepatobiliary disorders	Common	Hepatic function abnormal

SOC	Frequency	Event
Skin and subcutaneous disorders	Very common	Rash
	Common	Pruritus
	Uncommon	Urticaria, angioedema
	Not known	Erythema multiforme, toxic epidermal necrolysis, Stevens Johnson syndrome[b]
Musculoskeletal and connective tissue disorders	Common	Myalgia
	Not known	Muscular weakness, myopathy, myositis, rhabdomyolysis
Renal and urinary disorders	Common	Renal impairment, renal failure acute, dysuria, polyuria, proteinuria
	Uncommon	Renal tubular disorder, glomerulonephritis, nephrotic syndrome
	Not known	Renal pain, renal tubular acidosis, renal tubular necrosis, acute tubular necrosis, crystal nephropathy, Fanconi syndrome acquired, haematuria
Reproductive system and breast disorders	Common	Genital discomfort and ulceration[c]
General disorders and administration site conditions	Very common	Asthenia, chills, fatigue, pyrexia
	Common	Malaise, oedema, chest pain[d], injection site pain, injection site inflammation
	Uncommon	Localised oedema
	Not known	Extravasation
Investigations	Very common	Blood creatinine increased, haemoglobin decreased
	Common	Creatinine renal clearance decreased, electrocardiogram abnormal, gamma-glutamyltransferase increased, alanine aminotransferase increased, aspartate aminotransferase increased, lipase increased
	Uncommon	Amylase increased, blood creatine phosphokinase increased

[a] Thrombophlebitis in peripheral veins following infusion of undiluted foscarnet solution has been observed.
[b] Cases of vesiculobullous eruptions including erythema multiforme, toxic epidermal necrolysis, and Stevens Johnson syndrome have been reported. In most cases, patients were taking other medications that have been associated with toxic epidermal necrolysis or Stevens Johnson syndrome.
[c] Foscarnet is excreted in high concentrations in the urine and may be associated with significant irritation and ulceration in the genital area, particularly after prolonged therapy.
[d] Transient chest pain has been reported as part of infusion reactions to foscarnet.

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/.

4.9 Overdose

Overdose has been reported during the use of FOSCAVIR, the highest being some 20 times the recommended dose. Some of the cases were relative overdoses, in that the dose of the drug used had not been promptly adjusted for a patient experiencing reduced renal function.

There are cases where it has been reported that no clinical sequalae were consequent on the overdose.

The pattern of adverse events reported in association with an overdose of FOSCAVIR is in accordance with the known adverse event profile of the drug.

Haemodialysis increases FOSCAVIR elimination and may be of benefit in relevant cases.

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

Pharmacotherapeutic group: Antivirals for systemic use; direct acting antivirals; phosphonic acid derivatives, ATC code: J05AD01

Foscarnet is an antiviral agent with a broad spectrum, inhibiting human viruses of the herpes group including herpes simplex virus type 1 and 2, human herpes virus 6, varicella zoster virus, Epstein-Barr virus and cytomegalovirus (CMV) and some retroviruses including human immunodeficiency virus (HIV) at concentrations not affecting normal cell growth. Foscarnet also inhibits the viral DNA polymerase from hepatitis B virus. Foscarnet exerts its antiviral activity by a direct inhibition of viral specific DNA polymerase and reverse transcriptase at concentrations that do not affect cellular DNA polymerases. Foscarnet does not require activation (phosphorylation) by thymidine kinase or other kinases, and therefore is active *in vitro* against HSV mutants deficient in thymidine kinase (TK). CMV strains resistant to ganciclovir may be sensitive to foscarnet. Sensitivity test results, expressed as concentration of the drug required to inhibit growth of virus by 50% in cell culture (IC_{50}), vary greatly depending on the assay method used and cell type employed.

A number of sensitive viruses and their IC_{50} are listed below.

FOSCARNET Inhibition of virus multiplication cell culture	
Virus	**IC_{50} (µM)**
CMV	50 – 800*
HSV-1, HSV-2	10 – 130
VZV	48 – 90
EBV	<500 **
HHV-6	49
Ganciclovir resistant CMV	190
HSV – TK Minus Mutant	67
HSV – DNA Polymerase Mutant	5 – 443
HIV-1	11 – 32
Zidovudine resistant HIV-1	10 – 32
* Mean = 269 µM ** 97% of viral antigen synthesis inhibited at 500 µM	

Following treatment with foscarnet, clinical unresponsiveness can appear which may be due to appearance of virus strains with decreased sensitivity towards foscarnet. Termination of treatment with foscarnet should then be considered.

The mean foscarnet 50% inhibition value (IC_{50}) for more than one hundred clinical CMV isolates was approximately 270 µmol/L, while a reversible inhibition of normal cell growth was observed at about 1,000 µmol/L.

Therapeutic Properties

CMV retinitis in patients with AIDS

Following induction therapy over 2-3 weeks, foscarnet produced stabilization of retinal lesions in approximately 90% of cases treated. However, since CMV causes latent infections and since foscarnet exerts a virustatic activity, relapses are likely in the majority of patients with persistent immunodeficiency once treatment is discontinued. Institution of a once daily maintenance regimen at doses ranging from 90-120 mg/kg, following completion of induction therapy, has produced a delay in time to retinitis progression. In patients experiencing progression of retinitis while receiving maintenance therapy or off therapy, reinstitution of induction therapy has shown equal efficacy to the initial course.

Aciclovir unresponsive HSV infections in the immunocompromised host

For treatment of aciclovir unresponsive mucocutaneous infections, foscarnet was administered at 40 mg/kg every 8 hours over 2-3 weeks or until healing occurred. In a prospective randomised study in patients with AIDS, foscarnet treated patients healed within 11-25 days, had a complete relief of pain within 9 days and stopped shedding HSV virus within 7 days.

There is no evidence of an increased myelotoxicity when foscarnet is used in combination with zidovudine (AZT).

5.2 Pharmacokinetic properties

Following IV administration in man foscarnet plasma concentrations follow a multi-exponential decay pattern with several half-lives. The initial decline has a half-life of approximately 2-4 hours if renal function is normal. An apparent terminal half-life of approximately 1 to 8 days has been recorded, probably reflecting the slow release of foscarnet from bone.

The plasma clearance of foscarnet after intravenous administration to man varies between 130-160 mL/min. The mean volume of distribution of foscarnet at steady state varies between 0.4-0.6 L/kg.

Foscarnet is eliminated by the kidney mainly through glomerular filtration. Renal clearance is approximately 130 mL/min.

There is no metabolic conversion of foscarnet, and the binding to human plasma proteins is less than 20%. Foscarnet is distributed to the cerebrospinal fluid and concentrations ranging from 10 to 70% of the concurrent plasma concentrations have been observed in HIV infected patients.

In man, up to 20% of the cumulative intravenous dose has not been excreted in the urine 7 days after cessation of infusion, and can be assumed to have been deposited in bone. The molecular similarity to phosphate and pyrophosphate, and the ability to form metal and calcium ion complexes may explain the rapid interchange of foscarnet with the calcium pools, including the inorganic matrix of bone. The binding of foscarnet to the inorganic matrix of bone has no known effect on bone marrow. At present there are no studies available on the effects of foscarnet binding in growing bone. Also see **Section 4.4 Special warnings and precautions** for use and **Section 5.3 Preclinical safety data**.

The table below shows pharmacokinetic properties of foscarnet in AIDS patients treated for CMV infections (mainly retinitis) using TID dosage regimens.

Parameter	**TID (60 mg/kg Q8h)***
C_{max} at steady-state (µM)	589 ± 192 (24)
C_{trough} at steady-state (µM)	114 ± 91 (24)
Volume of distribution (L/kg)	0.41 ± 0.13 (12)
Plasma half-life (h)	4.0 ± 2.0 (24)
Systemic clearance (L/h)	6.2 ± 2.1 (24)
Renal clearance (L/h)	5.6 ± 1.9 (5)
CSF/plasma ratio	0.69 ± 0.19 (9)**

* Mean ± SD (number of subjects studied) for each parameter
** 50 mg/kg Q8h for 28 days, samples taken 3h after end of 1h infusion

5.3. Preclinical safety data

The most pronounced effects noted during general toxicity studies performed with foscarnet are perturbation of some serum electrolytes, and kidney and bone changes.

An observed reduction of serum electrolytes such as calcium and magnesium can be explained by the property of foscarnet to chelate with divalent metal ions. The

reduction of ionised calcium and magnesium is, most probably, the explanation for seizures/convulsions seen during and shortly after the infusion of high doses of foscarnet. This reduction may also have a bearing on heart function (e.g. ECG) although the toxicological studies performed did not disclose any such effects. The rate of infusion of foscarnet is critical to disturbances in the homeostatsis of some serum divalent cations.

The mechanism behind the kidney changes, e.g. tubular atrophy, mainly confined to juxtamedullary nephrons, is less clear. The changes were noted in all species investigated. It is known that other complex binders of divalent cations (EDTA and biphosphonates) can cause changes of the kidney similar to those of foscarnet. It has been shown that hydration, to induce diuresis, significantly reduces kidney changes during foscarnet treatment.

The bone changes were characterised as increased osteoclast activity and bone resorption. Roughly 20% of the administered drug is taken up into bone and cartilage and deposition is greater in young and growing animals. This effect has only been seen in the dog. The reason for these changes may be that foscarnet, due to the structural similarity to phosphate, is incorporated into the hydroxyapatite. Autoradiographic studies showed that foscarnet has a pronounced affinity to bone tissue. Recovery studies revealed that the bone changes were reversible. Foscarnet sodium has been demonstrated to adversely affect development of tooth enamel in mice and rats. The effects of this deposition on skeletal development have not been studied.

Mutagenicity studies showed that foscarnet has a genotoxic potential. The possible explanation for the observed effect in the mutagenicity studies is an inhibition of the DNA polymerase in the cell line used. Foscarnet therapeutically acts by inhibition of the herpes virus specific DNA polymerase. The human cellular polymerase α is about 100 times less sensitive to foscarnet. The carcinogenicity studies performed did not disclose any oncogenic potential. The information gained from teratogenicity and fertility studies did not reveal any adverse events on the reproductive process. However, the results are of limited value since the dose levels used in these studies are below or at most similar (75-150 mg/kg sc) to those used in man for treatment of CMV retinitis.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

- Water for injection
- Hydrochloric acid

6.2. Incompatibilities

FOSCAVIR is not compatible with glucose 30% solution, amphotericin B, aciclovir sodium, ganciclovir, pentamidine isethionate, trimethoprim-sulphamethoxazole, vancomycin hydrochloride, or with solutions containing calcium.

It is recommended that other agents should not be infused concomitantly in the same line.

6.3. Shelf life

36 months.

FOSCAVIR contains no preservative and once the sterility seal of a bottle has been broken the solution should be discarded within 24 hours.

Individually dispensed doses of foscarnet can be aseptically transferred to plastic infusion bags by the hospital pharmacy. The physico-chemical stability of foscarnet and dilutions thereof in equal parts with sodium chloride 9 mg/mL or dextrose 50 mg/mL in PVC bags is 7 days.

Depending on local/domestic regulations the storage time after such hospital pharmacy preparations can be restricted.

6.4. Special precautions for storage

Store at room temperature (15-30°C). Do not refrigerate. If refrigerated or exposed to temperatures below freezing point precipitation may occur. By keeping the bottle at room temperature with repeated shaking, the precipitate can be brought back into solution again.

6.5. Nature and contents of container

250 mL glass infusion bottle.

6.6. Special precautions for disposal and other handling

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

Accidental skin and eye contact with the FOSCAVIR solution may cause local irritation and burning sensation. If accidental contact occurs the exposed area should be rinsed with water.

7. MEDICINE SCHEDULE

Prescription Medicine.

8. SPONSOR

Link Pharmaceuticals Ltd
Level 31
Vero Centre
48 Shortland Street
AUCKLAND 1140

9 DATE OF FIRST APPROVAL

16 April 1992

10 DATE OF REVISION OF THE TEXT

5 February 2019

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
N/A	DS reformatted to align with new requirement.