SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Calcium Folinate 10 mg/ml Injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial of 10 ml solution contains 10 mg/ml of folinic acid provided as calcium folinate.
Excipients with known effect:

Calcium folinate 50 mg/5 ml solution for injection contains 16.74 mg of sodium in each 5 ml of vial.

Calcium folinate 100 mg/10 ml solution for injection contains 33.5 mg of sodium in each 10 ml vial.

Calcium folinate 300 mg/30 ml solution for injection contains 100.5 mg of sodium in each 30 ml vial.

For excipients, see 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

Calcium folinate is indicated in:

1) Neutralising the immediate toxic effects of folic acid antagonists, e.g. Methotrexate.

2) Calcium Folinate Rescue - a treatment technique using calcium folinate in conjunction with folic acid antagonists, e.g. methotrexate, to minimise systemic toxicity.

3) The treatment of megaloblastic anaemias due to sprue, nutritional deficiency, pregnancy, infancy, liver disease and malabsorption syndrome when oral therapy is not possible.

4.2. Posology and Method of Administration

Calcium folinate may be given parenterally by intramuscular injection, intravenous injection or intravenous infusion.

When required for intravenous infusion, it may be diluted with 5% Glucose Injection or 0.9% Sodium Chloride Injection. Diluted solutions should be used immediately, but if this is not possible the diluted solution may be stored for a maximum of 24 hours at 2-

8°C, protected from light.

Calcium Folinate Rescue (Adults and Children)
Calcium folinate may be used in conjunction with folic acid antagonists, e.g. Methotrexate, to reduce their systemic toxicity. It is given 12 to 24 hours after the antineoplastic drug. Doses of up to 120 mg maybe given over 12 to 24 hours by intramuscular injection or intravenous injection or infusion followed by 12 to 15 mg intramuscularly or 15 mg orally, every 6 hours for the next 48 hours. With lower doses of methotrexate, leucovorin 15 mg orally every 6 hours for 48 to 72 hours may be sufficient.

Treatment of Megaloblastic Anaemia
The dose should not exceed 1 mg daily given intramuscularly. When given orally, the recommended dosage is one Calcium Leucovorin Tablet (15 mg) daily. Children up to 12 years: 0.25 mg/kg/day. Normal adult dosage: 10-20 mg daily.

Treatment of Overdosage of Folic Acid Antagonists
In cases of overdosage of folic acid antagonists, calcium folinate may be administered by intravenous infusion in doses of up to 75 mg within 12 hours, followed by 12 mg intramuscularly every 6 hours for 4 doses.

In general, where overdosage is suspected, the dose of calcium folinate should be equal to or greater than the offending dose of the folic acid antagonist administered, and should be given as soon as possible; preferably within the first hour and certainly within 4 hours after which it may not be effective.

4.3. Contraindications

- Known hypersensitivity to calcium folinate, or to any of the excipients.
- Pernicious anaemia or other anaemias due to vitamin B_{12} deficiency.

Regarding the use of calcium folinate with methotrexate or 5-fluorouracil during pregnancy and lactation, see section 4.6, “Pregnancy and Lactation” and the summaries of product characteristics for methotrexate- and 5-fluorouracil- containing medicinal products.

4.4. Special Warnings and Precautions for Use

Calcium folinate should only be given by intramuscular or intravenous injection and must not be administered intrathecally. When folinic acid has been administered intrathecally following intrathecal overdose of methotrexate, death has been reported.

General

Calcium folinate should be used with methotrexate or 5-fluorouracil only, under the direct supervision of a clinician experienced in the use of cancer chemotherapeutic agents.

Calcium folinate treatment may mask pernicious anaemia and other anaemias resulting from vitamin B_{12} deficiency.

Many cytotoxic medicinal products- direct or indirect DNA synthesis inhibitors – lead to macrocytosis (hydroxycarbamide, cytarabine, mercaptopurine, thioguanine). Such

macrocytosis should not be treated with folinic acid.

In epileptic patients treated with phenobarbital, phenytoin, primidone, and succinimides there is a risk to increase the frequency of seizures due to a decrease of plasma concentrations of anti-epileptic drugs. Clinical monitoring, possibly monitoring of the plasma concentrations and, if necessary, dose adaptation of the anti-epileptic drug during calcium folinate administration and after discontinuation is recommended (see also section 4.5 Interactions).

Calcium folinate/5-fluorouracil

Calcium folinate may enhance the toxicity risk of 5-fluorouracil, particularly in elderly or debilitated patients. The most common manifestations are leucopenia, mucositis, stomatitis and/or diarrhoea, which may be dose limiting. When calcium folinate and 5-fluorouracil are used in combination, the 5- fluorouracil dosage has to be reduced more in cases of toxicity than when 5-fluorouracil is used alone.

Combined 5-fluorouracil/calcium folinate treatment should neither be initiated nor maintained in patients with symptoms of gastrointestinal toxicity, regardless of the severity, until all of these symptoms have completely disappeared.

Because diarrhoea may be a sign of gastrointestinal toxicity, patients presenting with diarrhoea must be carefully monitored until the symptoms have disappeared completely, since a rapid clinical deterioration leading to death can occur. If diarrhoea and/or stomatitis occur, it is advisable to reduce the dose of 5-fluorouracil until symptoms have fully disappeared. Especially the elderly and patients with a low physical performance due to their illness are prone to these toxicities. Therefore, particular care should be taken when treating these patients.

In elderly patients and patients who have undergone preliminary radiotherapy, it is recommended to begin with a reduced dosage of 5-fluorouracil.

Calcium folinate must not be mixed with 5-fluorouracil in the same IV injection or infusion.

Calcium levels should be monitored in patients receiving combined 5-fluorouracil/calcium folinate treatment and calcium supplementation should be provided if calcium levels are low.

Calcium folinate/methotrexate

Calcium folinate has no effect on non-haematological toxicities of methotrexate such as the nephrotoxicity resulting from methotrexate and/or metabolite precipitation in the kidney. Patients who experience delayed early methotrexate elimination are likely to develop reversible renal failure and all toxicities associated with methotrexate (please refer to the SPC for methotrexate). The presence of preexisting- or methotrexate-induced renal insufficiency is potentially associated with delayed excretion of methotrexate and may increase the need for higher doses or more prolonged use of calcium folinate.

Excessive calcium folinate doses must be avoided since this might impair the antitumour activity of methotrexate, especially in CNS tumours where calcium folinate accumulates after repeated courses.

Resistance to methotrexate as a result of decreased membrane transport implies also resistance to folinic acid rescue as both medicinal products share the same transport system.

An accidental overdose with a folate antagonist, such as methotrexate, should be treated as a medical emergency. As the time interval between methotrexate administration and calcium folinate rescue increases, calcium folinate effectiveness in counteracting toxicity decreases.

The possibility that the patient is taking other medications that interact with methotrexate (e.g., medications which may interfere with methotrexate elimination or binding to serum albumin) should always be considered when laboratory abnormalities or clinical toxicities are observed.

Excipient information

Calcium folinate 50 mg/5 ml solution for injection contains 16.74 mg of sodium per 5 ml vial, equivalent to 0.8% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

Calcium folinate 100 mg/10 ml solution for injection contains 33.5 mg of sodium in each 10 ml vial, equivalent to 1.7% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

Calcium folinate 300 mg/30 ml solution for injection contains 100.5 mg sodium in each 30 ml vial, equivalent to 5% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

4.5. Interactions with other Medicaments and other forms of Interaction

When calcium folinate is given in conjunction with a folic acid antagonist (e.g. cotrimoxazole, pyrimethamine) the efficacy of the folic acid antagonist may either be reduced or completely neutralised.

Calcium folinate may diminish the effect of anti-epileptic substances: phenobarbital, primidone, phenytoin and succinimides, and may increase the frequency of seizures (a decrease of plasma levels of enzymatic inductor anticonvulsant drugs may be observed because the hepatic metabolism is increased as folates are one of the cofactors) (see also sections 4.4 and 4.8).

Concomitant administration of calcium folinate with 5-fluorouracil has been shown to enhance the efficacy and toxicity of 5-fluorouracil (see sections 4.2, 4.4 and 4.8).

4.6. Pregnancy and Lactation

Use in Pregnancy
There are no adequate and well-controlled clinical studies conducted in pregnant or breast- feeding women. No formal animal reproductive toxicity studies have been conducted with calcium folinate. Calcium Folinate is the calcium salt of 5-formyl tetrahydrofolic acid, which is an active metabolite of folic acid. There are no indications that folic acid induces harmful effects if administered during pregnancy and it is not known whether calcium folinate can cause foetal harm, when administered to pregnant women.

Calcium folinate should be used during pregnancy only when clearly needed. During pregnancy, methotrexate should only be administered on strict indications, where the benefits of the drug to the mother should be weighed against possible hazards to the foetus. Should treatment with methotrexate or other folate antagonists take place despite pregnancy or lactation, there are no limitations as to the use of calcium folinate to diminish toxicity or counteract the effects.

The use of 5-fluorouracil is contraindicated during pregnancy and breastfeeding; this applies also to the combined use of calcium folinate with 5-fluorouracil.

Use in Lactation
It is not known whether calcium folinate is excreted into human breast milk. Calcium folinate can be used during breast feeding when considered necessary according to the therapeutic indications.

4.7. Effects on Ability to Drive and Use Machines

There is no evidence that calcium folinate has an effect on the ability to drive or use machines.

4.8. Undesirable Effects

Frequencies are 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);

very rare (<1/10,000);

not known (cannot be estimated from the available data).

Immune system disorders

Very rare (<0.01%): allergic reactions, including anaphylactoid/ anaphylactic reactions and urticaria.

Psychiatric disorders

Rare (0.01-0.1%): insomnia, agitation and depression after high doses.

Gastrointestinal disorders

Rare (0.01-0.1%): gastrointestinal disorders after high doses.

Neurological disorders

Rare (0.01-0.1%): increase in the frequency of attacks in epileptics (see also section 4.5Interactions).

General disorders and administration site conditions

Uncommon (0.1-1%): fever has been observed after administration of calcium folinate as solution for injection.

Combination therapy with 5-fluorouracil only:

Generally, the safety profile depends on the applied regimen of 5-fluorouracil due to enhancement of the 5-fluorouracil induced toxicities:

Metabolism and nutritional disorder

Not known: hyperammonaemia

Blood and lymphatic system disorders

Very common: bone marrow failure, including fatal cases

General disorders and administration site conditions

Very common (>10%): mucositis, including stomatitis and cheilitis. Fatalities have occurred as a result of mucositis

Skin and subcutaneous tissue disorders

Common: Palmar-Plantar Erythrodysaesthesia

Monthly regimen

Gastrointestinal disorders

Very common (>10%): vomiting and nausea

No enhancement of other 5-fluorouracil induced toxicities (e.g. neurotoxicity).

Weekly regimen

Gastrointestinal disorders

Very common (>10%): diarrhoea with higher grades of toxicity, and dehydration, resulting in hospital admission for treatment and even death.

4.9. Overdose

There have been no reported sequelae in patients who have received significantly more calcium folinate than the recommended dosage. However, excessive amounts of calcium folinate may nullify the chemotherapeutic effect of folic acid antagonists.

Should overdosage of the combination of 5-fluorouracil and calcium folinate occur, the overdosage instructions for 5-FU should be followed.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties

Pharmacotherapeutic group: Detoxifying agents for antineoplastic treatment; ATC code: V03AF03

Calcium folinate is a derivative of tetrahydrofolic acid, the reduced form of folic acid, which is involved as a cofactor for 1-carbon transfer reactions in the biosynthesis of purine and pyrimidines of nucleic acids in cytotoxic therapy.

Calcium folinate is frequently used to diminish the toxicity and counteract the action of folate antagonists, such as methotrexate. Calcium folinate and folate antagonists share the same membrane transport carrier and compete for transport into cells, stimulating folate antagonist efflux. It also protects cells from the effects of folate antagonist by repletion of the reduce folate pool. Calcium folinate serves as a pre-reduced source of H4 folate; it can therefore bypass folate antagonist blockage and provide a source for the various coenzyme forms of folic acid.

Calcium folinate is also frequently used in the biochemical modulation of fluoropyridine (5-FU) to enhance its cytotoxic activity. 5-FU inhibits thymidylate synthase (TS), a key enzyme involved in pyrimidine biosynthesis, and calcium folinate enhances TS inhibition by increasing the intracellular folate pool, thus stabilising the 5FU-TS complex and increasing activity.

Finally intravenous calcium folinate can be administered for the prevention and treatment of folate deficiency when it cannot be prevented or corrected by the administration of folic acid by the oral route. This may be the case during total parenteral nutrition and severe malabsorption disorders. It is also indicated for the treatment of megaloblastic anaemia due to folic acid deficiency, when oral administration is not feasible.

Impairment of thymidylate synthesis in patients with folic acid deficiency is thought to account for the defective DNA synthesis that leads to megaloblast formation and megaloblastic and macrocytic anemias. Because of its ready conversion to other tetrahydrofolic acid derivatives, calcium folinate is a potent antidote for both hematopoietic and reticuloendothelial toxic effects of folic acid antagonists, (e.g. Methotrexate, Pyrimethamine, Trimethoprim). It is postulated that in some cancers, calcium folinate enters and “rescues" normal cells from the toxic effects of folic acid antagonists, in preference to tumour cells, because of a difference in membrane transport mechanisms; this principle is the basis of high- dose Methotrexate therapy with “calcium folinate rescue".

5.2. Pharmacokinetic Properties

Absorption
Following intramuscular administration of the aqueous solution, systemic availability is comparable to an intravenous administration. However, lower peak serum levels (C_{max}) are achieved.

Metabolism

Calcium folinate is a racemate where the L-form (L-5-formyl-tetrahydrofolate, L-5-formyl-THF), is the active enantiomer. The major metabolic product of folinic acid is 5-methyl-tetrahydrofolic acid (5-methyl-THF) which is predominantly produced in the liver and intestinal mucosa.

Distribution
In general, serum folate concentrations less than 0.005 µg/ml indicate folate deficiency and concentrations less than 0.002 µg/ml usually result in megaloblastic anemia. Peak serum levels of the parent substance (D/L-5-formyl-tetrahydrofolic acid, folinic acid) are reached 10 minutes after i.v. administration. Following IM administration of a 15 mg (7.5 mg/m^2) dose in healthy men, mean peak serum folate concentrations of 0.241 µg/ml occur within about 40 minutes. Following oral administration of a 15 mg (7.5 mg/m^2) dose in healthy men, mean peak serum folate concentrations of 0.268 µg/ml occur within about 1.72 hours. Areas under the serum folate concentration-time curves (AUCs) are reported to be about 8% less following IM injection in the gluteal region than in the deltoid region and about 12% less following IM injection in the gluteal region than following IV or oral administration. AUC for L-5-formyl-THF and 5-methyl-THF were 28.4±3.5 mg.min/l and 129±112 mg.min/l after a dose of 25 mg. The inactive D-isomer is present in higher concentration than L-5-formyltetrahydrofolate.

Elimination
The elimination half-life is 32 - 35 minutes for the active L-form and 352 - 485 minutes for the inactive D-form, respectively.

The total terminal half-life of the active metabolites is about 6 hours (after intravenous and intramuscular administration).

Excretion
Calcium folinate is excreted 80-90% in urine, mainly as 5-and 10-formyl tetrahydrofolate inactive metabolites and 5,10-methenyl tetrahydrofolate, 5-8% with faeces.

5.3. Preclinical Safety Data

There is no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

Sodium Chloride, Water for Injections, Hydrochloric acid, Sodium hydroxide.

6.2. Incompatibilities

Incompatibilities have been reported between injectable forms of calcium folinate and injectable forms of droperidol, fluorouracil, foscarnet and methotrexate.

Droperidol
1. Droperidol 1.25 mg/0.5 ml with calcium folinate 5 mg/0.5 ml, immediate precipitation in direct admixture in syringe for 5 minutes at 25°C followed by 8 minutes of

centrifugation.

2. Droperidol 2.5 mg/0.5 ml with calcium folinate 10 mg/0.5 ml, immediate precipitation when the drugs were injected sequentially into a Y-site without flushing the Y-side arm between injections.

Fluorouracil
Calcium folinate must not be mixed in the same infusion as 5-fluorouracil because a precipitate may form. Fluorouracil 50 mg/ml with calcium folinate 20 mg/ml, with or without dextrose 5% in water, has been shown to be incompatible when mixed in different amounts and stored at 4°C, 23°C, or 32°C in polyvinyl chloride containers.

Foscarnet
Foscarnet 24 mg/ml with calcium folinate 20 mg/ml formation of a cloudy yellow solution reported.

6.3. Shelf Life

Refer to outer carton for expiry date.

In use: From a microbial point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2°C to 8°C.

6.4. Special Precautions for Storage

Store at 2°C -8°C. Protect from light.

6.5. Nature and Contents of Container

Clear Type I Glass Vials of 5 ml, 10 ml and 30 ml in single packs.

Not all presentations may be available locally.

6.6. Instruction for Use and Handling and disposal

Prior to administration, calcium folinate should be inspected visually. The solution for injection or infusion should be a clear and yellowish solution. If cloudy in appearance or particles are observed, the solution should be discarded. Calcium folinate solution for injection or infusion is intended only for single use. Any unused portion of the solution should be disposed of in accordance with the local requirements.

7. NAME AND ADDRESS OF MANUFACTURER

Hospira Australia Pty Ltd
1 – 5, 7 – 23 and 25 – 39 Lexia Place
Mulgrave, Victoria, 3170
Australia

PACKAGE LEAFLET: INFORMATION FOR THE USER
Calcium Folinate 10 mg/ml Injection

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

1. WHAT CALCIUM FOLINATE INJECTION IS AND WHAT IT IS USED FOR

Calcium folinate is one of the B group of vitamins.

Calcium Folinate Injection is used to reduce the side effects of other medicines (a group of medicines called folic acid antagonists). Examples of folic acid antagonists are:

- Methotrexate (a medicine often used to treat cancer)
- Trimetrexate (an antibiotic and anti-cancer medicine)
- Trimethoprim (an antibiotic)
- Pyrimethamine (a medicine often used to treat malaria)

It may also be used to treat an overdose of these medicines.

The treatment of megaloblastic anaemias due to sprue, nutritional deficiency, pregnancy, infancy, liver disease and malabsorption syndrome when oral therapy is not possible.

2. BEFORE YOU USE CALCIUM FOLINATE INJECTION

Calcium Folinate Injection must not be injected intrathecally (into the spine).

Do not use Calcium Folinate Injection

- If you have shown signs of hypersensitivity (severe allergy) to calcium folinate in the past.
- If you have a type of anaemia caused by too little vitamin B12

Tell your doctor if either of the above applies to you before this medicine is used.

Take special care with Calcium Folinate Injection

If you are to receive calcium folinate and fluorouracil treatment at the same time take special care if:

- You have had radiotherapy
- You have stomach or bowel trouble

Tell your doctor if the above applies to you before this medicine is used.

Special care is also needed if you are elderly and you are to receive calcium folinate and fluorouracil treatment at the same time.

Taking/using other medicines

Special care is needed if you are taking/using other medicines as some could interact with Calcium Folinate Injection, for example:

- Folic acid antagonists (see section ‘ What is Calcium Folinate is and what it is used for? ‘ for examples of these medicines) – the effectiveness of these medicines will be reduced by calcium folinate
- Fluorouracil (anti-cancer medicine) – the effectiveness and side effects of this medicine will be increased by calcium folinate
- Medicines used to treat epilepsy (phenobarbitone, phenytoin, primidone or succinimides) – the effectiveness of these medicines may be reduced by calcium folinate. Your doctor may check blood levels of these medicines and change your dose to prevent increased convulsions (fits)

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant, trying to become pregnant or breast-feeding.

It is unlikely that your doctor will ask you to take/use a folic acid antagonist or fluorouracil whilst you are pregnant or breast-feeding. However, if you have taken/used a folic acid antagonist whilst pregnant or breast-feeding, this medicine (calcium folinate) may be used to reduce its side effects.

Ask your doctor or pharmacist for advice before taking any medicine.

Calcium Folinate Injection contains sodium

Calcium folinate 50 mg/5 ml solution for injection contains 16.74 mg of sodium (main component of cooking/table salt) in each 5 ml vial. This is equivalent to 0.8% of the recommended maximum daily dietary intake of sodium for an adult.

Calcium folinate 100 mg/10 ml solution for injection contains 33.5 mg of sodium (main component of cooking/table salt) in each 10 ml vial. This is equivalent to 1.7% of the recommended maximum daily dietary intake of sodium for an adult.

Calcium folinate 300 mg/30 ml solution for injection contains 100.5 mg sodium (main component of cooking/table salt) in each 30 ml vial. This is equivalent to 5% of the recommended maximum daily dietary intake of sodium for an adult.

3. HOW TO USE CALCIUM FOLINATE INJECTION

This medicine may be given by injection (using a syringe) into muscle. Alternatively it may be given by injection or infusion (drip) into a vein. If it is given by infusion Calcium Folinate Injection will be diluted first.

Dose
Your doctor will work out the correct dose of Calcium Folinate Injection for you and how often it must be given. It will depend upon the medical condition which is being treated.

If you are given too much or too little Calcium Folinate Injection
This medicine will be given to you in a hospital, under the supervision of a doctor. It is unlikely that you will be given too much or too little, however, tell your doctor or nurse if you have any concerns.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Calcium Folinate Injection can cause side effects, although not everybody gets them.

Very rare: may affect up to 1 in 10,000 people:

- severe allergic reaction – you may experience a sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), and you may feel you are going to faint. This is a serious side effect. You may need urgent medical attention.

Uncommon: may affect up to 1 in 100 people
- fever

Rare: may affect up to 1 in 1,000 people
- an increase in convulsions (fits) in patients with epilepsy
- depression
- agitation
- problem with the digestive system
- difficulty sleeping (insomnia)

Combination therapy with 5-fluorouracil only:
If you receive calcium folinate in combination with an anticancer medicine containing fluoropyrimidines, it is more likely that you experience the following side effects of this other medicine:

Very common: may affect more than 1 in 10 people
- nausea
- vomiting
- severe diarrhoea
- drying out which may be due to diarrhoea
- inflammation of the lining of the intestine and mouth (life-threatening conditions have occurred)
- reduction in the number of blood cells (including life-threatening conditions)

Common: may affect up to 1 in 10 people
- redness and swelling of the palms of the hands or the soles of the feet which may cause the skin to peel (hand-foot syndrome)

Not known: frequency cannot be estimated from the available data
- elevated ammonia level in the blood

Your doctor may do tests to check for low levels of calcium in your blood.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE CALCIUM FOLINATE INJECTION

Keep out of the reach and sight of children

Expiry
This medicine must not be used after the expiry date which is stated on the vial and carton after 'EXP'. Where only a month and year is stated, the expiry date refers to the last day of that month.

Storage
The vials should be stored in the outer carton, in order to protect from light, in a refrigerator.

Visible signs of deterioration
Only clear, pale yellow solutions should be used. If cloudy in appearance or particles can be seen, the solution should be discarded.

6. FURTHER INFORMATION

What Calcium Folinate Injection contains
The active substance is folinic acid. Each millilitre (ml) of solution contains 10 milligrams (mg) of folinic acid in the form of calcium folinate.

The other ingredients are sodium chloride and Water for Injections. See section 2 ‘Important information about one of the ingredients of Calcium Folinate Injection’ for further information about the sodium content.

What Calcium Folinate Injection looks like and contents of the pack
Calcium Folinate Injection is a clear, pale yellow solution for injection which comes in glass containers called vials.

It is supplied in packs containing:
- 1 x 50 mg/5 ml vial
- 1 x 100 mg/10 ml vial
- 1 x 300 mg/30 ml vial

Not all presentations may be available locally.

CFH-SIN-0521/0
Date of last revision: 17 May 2021