ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Forcaltonin 100 IU solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ampoule of Forcaltonin 100 IU contains 100 International Units (IU) corresponding to approximately 15 micrograms recombinant salmon calcitonin (produced by recombinant DNA technology in *Escherichia coli)* in 1 ml of an acetate buffer.

For excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection

Clear colourless solution

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Calcitonin is indicated for:

- Prevention of acute bone loss due to sudden immobilisation such as in patients with recent osteoporotic fractures
- Paget's disease
- Hypercalcaemia of malignancy

4.2 Posology and method of administration

For subcutaneous, intramuscular or intravenous infusion (product specific) use in individuals aged 18 years or more.

Salmon calcitonin may be administered at bedtime to reduce the incidence of nausea or vomiting which may occur, especially at the initiation of therapy.

Prevention of acute bone loss:
The recommended dosage is 100 I.U. daily or 50 I.U. twice daily for 2 to 4 weeks, administered subcutaneously or intramuscularly. The dose may be reduced to 50 I.U. daily at the start of remobilisation. The treatment should be maintained until patients are fully mobilized.

Paget's disease:
The recommended dosage is 100 IU per day administered subcutaneously or intramuscularly, however, a minimum dosage regimen of 50 IU three times a week has achieved clinical and biochemical improvement. Dosage is to be adjusted to the individual patient's needs. The duration of treatment depends on the indication for treatment and the patient´s response. The effect of calcitonin may be monitored by measurement of suitable markers of bone remodeling, such as serum alkaline

phosphatase or urinary hydroxyproline or deoxypyridinoline. The dose may be reduced after the condition of the patient has improved.

Hypercalcemia of malignancy:
The recommended starting dose is 100 IU every 6 to 8 hours by subcutaneous or intramuscular injection. In addition, salmon calcitonin could be administered by intravenous injection after previous rehydration.
If the response is not satisfactory after one or two days, the dose may be increased to a maximum of 400 IU every 6 to 8 hours. In severe or emergency cases, intravenous infusion with up to 10 IU/kg body weight in 500ml 0.9% w/v sodium chloride solution may be administered over a period of at least 6 hours.

Use in elderly, hepatic and renal impairment patients
Experience with the use of calcitonin in the elderly has shown no evidence of reduced tolerability or altered dosage requirements. The same applies to patients with altered hepatic function. The metabolic clearance is much lower in patients with end-stage renal failure than in healthy subjects. However, the clinical relevance of this finding is not known (see section 5.2)

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients.

Calcitonin is also contraindicated in patients with hypocalcaemia.

4.4 Special warnings and special precautions for use

Because calcitonin is a peptide, the possibility of systemic allergic reactions exists and allergic-type reactions including isolated cases of anaphylactic shock have been reported in patients receiving calcitonin. Such reactions should be differentiated from generalised or local flushing, which are common non-allergic effects of calcitonin (see 4.8). Skin testing should be conducted in patients with suspected sensitivity to calcitonin prior to their treatment with calcitonin.

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. it is essentially sodium free.

4.5 Interaction with other medicinal products and other forms of interaction

Serum calcium levels may be transiently decreased to below normal levels following administration of calcitonin, notably upon initiation of therapy in patients with abnormally high rates of bone turnover. This effect is diminished as osteoclastic activity is reduced. However, care should be exercised in patients receiving concurrent treatment with cardiac glycosides or calcium channel blocking agents. Dosages of these drugs may require adjustment in view of the fact that their effects may be modified by changes in cellular electrolyte concentrations.

The use of calcitonin in combination with bisphosphonates may result in an additive calcium-lowering effect.

4.6 Pregnancy and lactation

Calcitonin has not been studied in pregnant women. Calcitonin should be used during pregnancy only if treatment is considered absolutely essential by the physician.

It is not known if the substance is excreted in human milk. In animals, salmon calcitonin has been shown to decrease lactation and to be excreted in milk (see 5.3). Therefore, breast-feeding is not recommended during treatment.

4.7 Effects on ability to drive and use machines

No data exist on the effects of injectable calcitonin on the ability to drive and use machines. Injectable calcitonin may cause transient dizziness (see 4.8. Undesirable effects) which may impair the reaction of the patient. Patients must therefore be warned that transient dizziness may occur, in which case they should not drive or use machines.

4.8 Undesirable effects

Frequency categories:
Very common (>1/10); common (>1/100, <1/10); uncommon (>1/1,000, < 1/100); rare (>1/10,000, < 1/1,000); very rare (<1/10,000), including isolated reports.

Gastrointestinal disorder:
Very common: Nausea with or without vomiting is noted in approximately 10% of patients treated with calcitonin. The effect is more evident on initiation of therapy and tends to decrease or disappear with continued administration or a reduction in dose. An antiemetic may be administered, if required. Nausea/vomiting are less frequent when the injection is done in the evening and after meals.
Uncommon: diarrhea

Vascular disorders:
Very common:
Skin flushes (facial or upper body). These are not allergic reactions but are due to a pharmacological effect, and are usually observed 10 to 20 minutes after administration.

General disorders and administration site conditions
Uncommon: local inflammatory reactions at the site of subcutaneous or intramuscular injection

Skin and subcutaneous tissue disorders
Uncommon: skin rash

Nervous system disorders:
Uncommon: metallic taste in the mouth; dizziness

Renal and urinary disorders:
Uncommon: diuresis

Metabolic and nutrition disorders:
Rare: In case of patients with high bone remodelling (Paget's disease and young patients) a transient decrease of calcaemia may occur between the 4th and the 6th hour after administration, usually asymptomatic

Investigations:
***Rare*:** Neutralising antibodies to calcitonin rarely develop. The development of these antibodies is not usually related to loss of clinical efficacy, although their presence in a small percentage of patients following long-term therapy with calcitonin may result in a reduced response to the product. The presence of antibodies appears to bear no relationship to allergic reactions, which are rare. Calcitonin receptor down-regulation may also result in a reduced clinical response in a small percentage of patients following long-term therapy.

Immune system disorders:
Very rare: serious allergic-type reactions, such as bronchospasm, swelling of the tongue and throat, and in isolated cases, anaphylaxis.

4.9 Overdose

Nausea, vomiting, flushing and dizziness are known to be dose dependent when calcitonin is administered parenterally. Single doses (up to 10,000 I.U.) of injectable salmon calcitonin have been administered without adverse reactions, other than nausea and vomiting, and exacerbation of pharmacological effects.

Should symptoms of overdose appear, treatment should be symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: antiparathyroid hormone, ATC code: H05BA01 (calcitonin, salmon).

The pharmacological properties of the synthetic and recombinant peptides have been demonstrated to be qualitatively and quantitatively equivalent.
Calcitonin is a calciotropic hormone, which inhibits bone resorption by a direct action on osteoclasts. By inhibiting osteoclast activity via its specific receptors, salmon calcitonin decreases bone resorption. In pharmacological studies, calcitonin has been shown to have analgesic activity in animal models.

Calcitonin markedly reduces bone turnover in conditions with an increased rate of bone resorption such as Paget ‘s disease and acute bone loss due to sudden immobilisation.
The absence of mineralisation defect with calcitonin has been demonstrated by bone histomorphometric studies both in man and in animals.
Decreases in bone resorption as judged by a reduction in urinary hydroxyproline and deoxypyridinoline are observed following calcitonin treatment in both normal volunteers and patients with bone-related disorders, including Paget’s disease and osteoporosis.

The calcium-lowering effect of calcitonin is caused both by a decrease in the efflux of calcium from the bone to the ECF and inhibition of renal tubular reabsorption of calcium.

5.2 Pharmacokinetic properties

General characteristics of the active substance
Salmon calcitonin is rapidly absorbed and eliminated.
Peak plasma concentrations are attained within the first hour of administration.
Animal studies have shown that calcitonin is primarily metabolised via proteolysis in the kidney following parenteral administration. The metabolites lack the specific biological activity of calcitonin.
Bioavailability following subcutaneous and intramuscular injection in humans is high and similar for the two routes of administration (71% and 66%, respectively).
Calcitonin has short absorption and elimination half-lives of 10-15 minutes and 50-80 minutes, respectively. Salmon calcitonin is primarily and almost exclusively degraded in the kidneys, forming pharmacologically inactive fragments of the molecule. Therefore, the metabolic clearance is much lower in patients with end-stage renal failure than in healthy subjects. However, the clinical relevance of this finding is not known.
Plasma protein binding is 30 to 40%.

Characteristics in patients
There is a relationship between the subcutaneous dose of calcitonin and peak plasma concentrations. Following parenteral administration of 100 I.U. calcitonin, peak plasma concentration lies between about 200 and 400 pg/ml. Higher blood levels may be associated with increased incidence of nausea and vomiting.

5.3 Preclinical safety data

Conventional long-term toxicity, reproduction, mutagenicity, and carcinogenicity studies have been performed in laboratory animals. Salmon calcitonin is devoid of embryotoxic, teratogenic and mutagenic potential.
An increased incidence of pituitary adenomas has been reported in rats given synthetic salmon calcitonin for 1 year. This is considered a species-specific effect and of no clinical relevance.
Salmon calcitonin does not cross the placental barrier.

In lactating animals given calcitonin, suppression of milk production has been observed. Calcitonin is secreted into the milk.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Acetic acid, glacial, sodium acetate trihydrate, sodium chloride and water for injections.

6.2 Incompatibilities

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

6.3 Shelf life

3 years.

Forcaltonin should be used immediately after the single-use ampoule is opened.

6.4 Special precautions for storage

Store in a refrigerator (2°C - 8°C) . Do not freeze.

6.5 Nature and contents of container

Forcaltonin is contained in Type I, glass ampoules, designed to accommodate up to 1 ml of solution. Each pack contains 10 ampoules.

6.6 Instructions for use and handling <and disposal>

For subcutaneous, intramuscular or intravenous use.

The product should be inspected visually for particulate matter and discoloration prior to administration. Any product where such defects are observed should be discarded. Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Unigene UK Limited, 191 Sparrows Herne, Bushey Heath, Hertfordshire WD23 1AJ, UK

8. MARKETING AUTHORISATION NUMBER(S)

EU/1/98/093/002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: 11-01-1999
Date of last renewal:

10. DATE OF REVISION OF THE TEXT

ANNEX II

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OF THE MARKETING AUTHORISATION

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substance

Unigene Laboratories, Inc.
83 Fulton Street
Boonton, New Jersey 07005 USA

Name and address of the manufacturer responsible for batch release

FAMAR S.A.
7, P. Marinopoulou Str.
174 56 Alimos, Athens, Greece.

B. CONDITIONS OF THE MARKETING AUTHORISATION

- **CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IMPOSED ON THE MARKETING AUTHORISATION HOLDER**

Medicinal product subject to medical prescription.

- **OTHER CONDITIONS**

The holder of this marketing authorisation must inform the European Commission about the marketing plans for the medicinal product authorised by this decision.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

{NATURE/TYPE}

1. NAME OF THE MEDICINAL PRODUCT

FORCALTONIN 100 IU solution for injection
Recombinant salmon calcitonin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each ampoule contains 100 IU (15 micrograms in 1.0 ml) of recombinant salmon calcitonin.

3. LIST OF EXCIPIENTS

Excipients: Acetic acid, glacial, sodium acetate trihydrate, sodium chloride and water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection - Pack of 10 doses:

Each ampoule contains 100 IU (15 micrograms in 1.0 ml) of recombinant salmon calcitonin.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For subcutaneous (SC), intramuscular (IM) or intravenous (IV) injection. Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP {MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

Store in refrigerator. Do not freeze.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Unigene UK Limited
191 Sparrows Herne
Bushey Heath
Hertfordshire WD23 1AJ
United Kingdom

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/98/093/002

13. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN>{number}

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

1. NAME OF THE MEDICINAL PRODUCT

FORCALTONIN 100 IU solution for injection
Recombinant salmon calcitonin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Unigene UK Limited
191 Sparrows Herne
Bushey Heath
Hertfordshire WD23 1AJ
United Kingdom

3. EXPIRY DATE

EXP {MM/YYYY}

4. BATCH NUMBER

<Batch> <Lot> <BN> {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{NATURE/TYPE}

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

FORCALTONIN 100 IU solution for injection

2. METHOD OF ADMINISTRATION

Read the package leaflet before use.

3. EXPIRY DATE

EXP {MM/YYYY}

4. BATCH NUMBER

<Batch> <Lot> <BN> {number}

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

B. PACKAGE LEAFLET

PACKAGE LEAFLET

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 further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

FORCALTONIN 100 IU Solution for Injection,
recombinant salmon calcitonin
- The active substance is recombinant salmon calcitonin. Each ampoule contains 100 IU (15 micrograms in 1.0 ml) of recombinant salmon calcitonin. The salmon calcitonin contained in Forcaltonin is not made by a conventional, chemical method but by genetic engineering. However, the structure of the active substance of FORCALTONIN is the same as that of chemically synthesised salmon calcitonin. The effects of recombinant salmon calcitonin on the body have also been shown to be equivalent to those of synthetic salmon calcitonin.
- The other ingredients are acetic acid, glacial, sodium acetate trihydrate, sodium chloride and water for injections.

The Marketing Authorisation Holder for FORCALTONIN is Unigene UK Limited, 191 Sparrows Herne, Bushey Heath, Hertfordshire WD23 1AJ, UK.

The manufacturer is FAMAR S.A., 7 P. Marinopoulou Str., 174 56 Alimos, Athens, Greece.

1. WHAT FORCALTONIN IS AND WHAT IT IS USED FOR

FORCALTONIN is a solution for injection. The solution is clear, colourless and sterile. It is contained in a glass ampoule.

Each ampoule of FORCALTONIN contains 1 ml of solution with 100 International Units (IU) of the active substance. This corresponds to about 15 micrograms of recombinant salmon calcitonin. Each pack contains 10 ampoules.

The active substance of FORCALTONIN is recombinant salmon calcitonin. Salmon calcitonin is a hormone which increases the amount of calcium and phosphate laid down in the bones and lowers the level of calcium circulating in the blood.

FORCALTONIN is used to prevent loss of bone if you are suddenly immobilised, for example, after having a fracture due to osteoporosis. It is also used to treat Paget's disease (a chronic disease of the bones characterised by inflammation and deformation), and hypercalcaemia of malignancy (increased calcium blood levels due to tumours).

2. BEFORE YOU USE FORCALTONIN

Do not use FORCALTONIN:
- if you are hypersensitive (allergic) to salmon calcitonin or any of the other ingredients of FORCALTONIN. Extreme sensitivity to salmon calcitonin may cause difficulties in breathing (bronchospasm), swelling of the tongue or throat, or even an anaphylactic shock (a very severe type of allergic response). Serious allergic reactions will need emergency treatment. If you are unsure whether you are allergic to salmon calcitonin, please discuss the matter with your doctor. He can perform a skin test to find out how sensitive you are to salmon calcitonin. Your doctor may then decide that it is not safe for you to receive this medicine.
- if you have hypocalcaemia.

Pregnancy
If you are pregnant, please tell your doctor. It is not known whether this medicine is safe to use during pregnancy. FORCALTONIN should therefore not be given to pregnant women. Calcitonin should be used during pregnancy only under exceptional circumstances appreciated by the physician.

Breast-feeding
You should not breast-feed your child while you are being treated with FORCALTONIN.

Driving and using machines:
No data exist on the effects of injectable calcitonin on the ability to drive and use machines. Injectable calcitonin may cause transient dizziness which may impair the reaction of the patient. Patients must therefore be warned that transient dizziness may occur, in which case they should not drive or use machines."

Important Information about some of the Ingredients of FORCALTONIN
This medicinal product contains less than 1 mmole (23 mg) sodium per dose, i.e. essentially sodium free.

Using FORCALTONIN with other medicines:
There have been no reports that other drugs influence the effects of FORCALTONIN. However, FORCALTONIN might influence the effects of certain drugs given to treat heart complaints. Please tell your doctor if you are receiving treatment for a heart complaint, because the dose of the heart drug may need to be adjusted.

You should tell your doctor if you are taking other calcium lowering drugs, such as bisphosphonates, as the combination of these drugs with FORCALTONIN might cause the amount of calcium in your blood to become too low.

Use of FORCALTONIN in children:
It is not recommended to use FORCALTONIN in children.

3. HOW TO USE FORCALTONIN

FORCALTONIN is only available from your doctor. It is intended for your use only. Do not pass it on to anyone else.

FORCALTONIN must be given by injection. The injection will be given to you by a doctor or a nurse.

The following instructions for use are recommended to ensure that you obtain the full benefit of treatment with FORCALTONIN. In some cases, however, your doctor may decide to use another dose or another frequency of dosing. Please ask him to explain the reasons for any changes in your treatment schedule.

Prevention of bone loss due to sudden immobilisation. The recommended dose is 100 International Units (15 micrograms of salmon calcitonin) daily, or 50 International Units (7.5 micrograms salmon calcitonin) twice daily, for 2 to 4 weeks, by subcutaneous or intramuscular injection. Your doctor may reduce the dose of FORCALTONIN after your condition has improved.

Paget's disease of bone. The recommended dose is 100 International Units (15 micrograms of salmon calcitonin) once daily by subcutaneous or intramuscular injection. A minimum dose of 50 International Units (7.5 micrograms of salmon calcitonin) three times a week in some patients may be sufficient. Your doctor may reduce the dose of FORCALTONIN you receive after your condition has improved.

Hypercalcaemia of malignancy. The recommended starting dose is 100 International Units (15 micrograms of salmon calcitonin) every 6 to 8 hours by subcutaneous or intramuscular injection. If the response to treatment is not satisfactory after one or two days, the dose may be increased to 400 International Units every 6 to 8 hours. In severe or emergency cases, an intravenous infusion with 10 International Units per kilogram body weight in 500 ml 0.9% w/v sodium chloride solution may be given to you by your doctor or nurse over a period of 6 hours.

If you have any questions about your treatment schedule, ask your doctor or nurse. If you have the impression that the effect of FORCALTONIN is too strong or too weak, talk to your doctor or pharmacist.

Duration of treatment
The length of time over which you will receive FORCALTONIN will depend on the way you respond to the treatment. Your body's response to treatment will be tested at regular intervals and your doctor will decide whether your treatment needs to be continued and which dose should be used.

If you have any questions about the length of your treatment, ask your doctor or nurse. You should also talk to your doctor if you feel that the effect of FORCALTONIN is decreasing or that you are no longer benefiting from treatment. Never change the dose yourself or stop injecting the medicine without consulting your doctor first.

If you use more FORCALTONIN than you should:
If you or your doctor accidentally inject more than the recommended dose of FORCALTONIN, it is extremely unlikely to have any serious effects.

If you forget to take FORCALTONIN:
If you forget to inject your medicine at the correct time, inject it as soon as you remember unless it is almost time for the next dose. In this case, you should wait until it is time to inject the next dose and then continue as before. Never take a double dose to make up for a missed dose.
Tell your doctor as soon as possible if you miss a dose of FORCALTONIN.

4. POSSIBLE SIDE EFFECTS

Like all medicines, FORCALTONIN can have side effects.

You should discuss the possible undesirable effects with your doctor who will be able to advise you on the risks and benefits of your treatment. Some of the undesirable effects will disappear without being treated but others may need medical attention. Tell your doctor or nurse immediately, if you notice any of the effects listed below.

The only serious undesirable effect which has been reported in patients treated with salmon calcitonin is an allergic reaction. Examples of serious allergic reactions to salmon calcitonin are:

- difficulties in breathing (bronchospasm)
- swelling of the tongue or throat
- anaphylactic shock (a very severe type of allergic response)

Such allergic reactions have only been seen in a very few cases and the most extreme form, anaphylactic shock, is very rare. Serious allergic reactions will need emergency treatment. Inform your doctor immediately if any of the above effects occur. He will take the appropriate countermeasures.

Approximately 10% of patients treated with salmon calcitonin suffer from nausea, sometimes with vomiting. This undesirable effect occurs mostly at the beginning of treatment and tends to decrease or even disappear as treatment continues. The effect may also disappear if the dose is reduced.

Irritation at or around the injection site has been reported occasionally in patients treated with salmon calcitonin. The effect disappears without the need for special treatment. It is recommended that you do not inject your medicine at exactly the same site each time you use it in order to avoid discomfort.

Flushing of the face and hands has been noted. Again, this effect disappears with time, usually during the first or second week of treatment.

Other possible but less frequent undesirable effects are:

- skin rash
- diuresis (increase in urination)
- diarrhoea
- metallic taste in the mouth
- dizziness

All of these undesirable effects are mild and occur in isolated cases only. Most of the effects do not last long and disappear of their own accord. The remaining effects can be treated by your doctor if they persist.

Like all medicines, FORCALTONIN may have undesirable effects which are very rare. If you notice any unwanted effects not mentioned in this leaflet or any change in your health while receiving this medicine, or afterwards, please inform your doctor, nurse or pharmacist (chemist).

5. STORING FORCALTONIN

Keep out of the reach and sight of children.

Store in a refrigerator (2°C - 8°C). Do not freeze.
It is recommended to store the ampoule in the lower part or the door of the refrigerator to protect the solution from freezing. Should the solution become frozen, the ampoule must be discarded.

After first opening, the product should be used immediately. Any unused product must be discarded.

Do not use after the expiry date stated on the ampoule and the packaging. Do not use Forcaltonin if you notice the solution is not completely clear and colourless.

This leaflet was last approved on {date}

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