ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

TESLASCAN 0.01 mmol/ml solution for infusion.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains 7.57 mg of anhydrous mangafodipir trisodium, 0.01 mmol (10 µmol), equivalent to 6.91 mg of mangafodipir.
50 ml contains 378.5 mg of anhydrous mangafodipir trisodium, 0.50 mmol (500 µmol), equivalent to 345.5 mg of mangafodipir.

Excipient: Sodium 0.16 mmol (3.6 mg)/ml equivalent to 126 mg per normal dose of 35 ml.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for infusion

A clear bright to dark yellow solution,

TESLASCAN has the following physicochemical properties:

pH: 7.0-8.0.

Osmolality (mosmol/kg H_2O) at 37 °C	290
Viscosity (mPa.s) at 20 °C	1.0
Viscosity (mPa.s) at 37 °C	0.7
Density (g/ml) at 20 °C	1.01

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

This medicinal product is for diagnostic use only.
Contrast medium for diagnostic Magnetic Resonance Imaging (MRI) for the detection of lesions of the liver suspected to be due to metastatic disease or hepatocellular carcinomas. As an adjunct to MRI to aid in the investigation of focal pancreatic lesions.

4.2 Posology and method of administration

The medicinal product is for single intravenous use only as repeated dosing has not been studied. It should be administered as an intravenous infusion at the rate of 2-3 ml/min for liver imaging and at a rate of 4-6 ml/min for imaging of the pancreas.

Near maximal enhancement of the normal liver and pancreas parenchyma is generally observed 15-20 minutes from the start of administration and lasts for approximately 4 hours.

At the clinical dose the contrast agent has no T_2-effect, and pre- and post- T_2-weighted images are equivalent. The clinical use of TESLASCAN has been investigated at field strengths from 0.5 to 2.0 Tesla.

Dosage for adults
The recommended dose is 0.5 ml/kg bodyweight (5 µmol/kg bodyweight). This corresponds to a dose of 35 ml for a 70 kg person. Above 100 kg body weight, 50 ml is usually sufficient to provide a diagnostically adequate contrast effect.

Dosage for elderly
Pharmacokinetics in the elderly has not been investigated. However, clinical studies to date do not suggest that a dose adjustment is required.

Use in children
There are limited data available on the use of Teslascan in children. The available data do not support safety and efficacy in the paediatric population and therefore such use is not recommended.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients.
Pregnancy and lactation.
Phaeochromocytoma.
Severely reduced liver function (Child - Pugh class C), especially severe obstructive hepatobiliary disease.
Severely reduced renal function.

4.4 Special warnings and precautions for use

Rarely, hypersensitivity reactions (urticaria and other possible allergic phenomena) or anaphylactoid reactions may occur. Familiarity with the practice and technique of resuscitation and treatment of anaphylaxis is essential. Appropriate medicinal products and instruments should be readily available.

Care should be exercised in patients with severe cardiac disease and in patients with injuries of the blood brain barrier and severe cerebral disease.

The fact that long term parenteral nutrition with manganese supplementation can cause manganese accumulation in the basal ganglia should be considered when administering TESLASCAN to patients on such treatment.

This medicinal product contains 5.5 mmol (126 mg) sodium per normal dose of 35 ml. To be taken into consideration by patients on a controlled sodium diet.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Pregnancy and lactation

Pregnancy
The safety of TESLASCAN in human pregnancy has not been established. TESLASCAN must not be used during pregnancy (see section 4.3).
Prior to administration of TESLASCAN to women of child bearing potential, pregnancy should be excluded.

Pre-clinical studies in rats have established teratogenic effects when TESLASCAN was given repeatedly during major organogenesis. TESLASCAN causes foetotoxicity and embryotoxicity in rabbits. TESLASCAN is not teratogenic in rabbits. TESLASCAN has no effect on male or female fertility in rats.

Lactation
The degree of excretion into human breast milk is not known. Breast-feeding should be discontinued from the time of administration and should not be recommenced until 14 days after administration of TESLASCAN.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects

Most of the adverse reactions reported were transient and of mild intensity. Those most commonly reported were: feeling of warmth/flushing, headache and nausea.
In clinical trials with Teslascan, adverse reactions have been reported with the following frequencies given in the table 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, not known (cannot be estimated from the available data). Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

System Organ Class	Adverse Reactions	Frequency
Immune system disorders	Hypersensitivity reactions (such as skin reactions, rhinitis, pharyngitis)	Uncommon
	Anaphylactic/anaphylactoid reactions	Not known
Nervous system disorders	Headache	Common
	Dizziness, paraesthesia, transient perverted sensation of taste	Uncommon
Eye disorders	Visual disturbance	Very rare
Cardiac disorders	Palpitation	Uncommon
Vascular disorders	Hypertension	Rare
Gastrointestinal disorders	Nausea	Common
	Abdominal pain, diarrhoea, vomiting	Uncommon
	Flatulence	Very rare
General disorders and administration site conditions	Flushing, feeling hot	Common
	Fever, injection site pain	Uncommon
	Chest pain	Very rare

Mangafodipir can cause transient increases of bilirubin and liver transaminases and transient decreases in plasma zinc.

The frequency of mild and moderate, non-serious adverse reactions, mainly transient warmth and flushing, is likely to increase when TESLASCAN is administered at the faster rate advised (4–6 ml/min).

4.9 Overdose

Serious adverse events have not been reported in healthy subjects with dosages up to 5 times the normal clinical dose (maximum dose investigated).

High doses of manganese can have negative inotropic and vasodilatory effects as well as effects on heart rhythm and conduction because of calcium antagonism.

Treatment of an overdose should be symptomatic and directed towards the support of vital functions. There is no antidote to this contrast medium.

Mangafodipir and its metabolites are dialysable whereas manganese is not dialysable because of protein binding (see also section 5.2).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Paramagnetic MRI contrast medium, ATC Code: V08C A05

Mangafodipir is a chelate containing the metal manganese - which has paramagnetic properties and is responsible for the contrast enhancement effect in MRI - and the ligand fodipir (dipyridoxyl diphosphate). Manganese is preferentially taken up by normal liver parenchyma and also in the pancreas so that contrast enhancement between abnormal and normal tissue can be expected.

The effect of mangafodipir is to shorten the longitudinal relaxation time (T_1) of targeted tissues during MRI, leading to an increase in signal intensity (brightness) of, for example, pancreas and liver parenchyma. Enhancement in both organs is near maximal for up to approx. 4 hours after the end of administration. Lesion-related enhancement of certain types of lesions, such as liver metastases and hepatocellular carcinomas, may be detectable for up to 24 hours. Clinical studies have demonstrated that mangafodipir facilitates the detection of liver lesions in patients with such lesions.

TESLASCAN is isotonic with blood and normal body fluids.

Paediatric use

An uncontrolled observational study assessed the use of mangafodipir in the radiological assessment of infant patients with suspected bilary atresia. 23 consecutive patients aged 24-139 days (mean 69 days) with prolonged jaundice and lightened stool colour in whom bilary atresia had not been ruled out underwent MR cholangiography with contrast. The dose of mangafodipir used was 5 µmol/kg. No safety concerns arose from this study, although the numbers were too small to be useful in this regard.

5.2 Pharmacokinetic properties

Mangafodipir trisodium is metabolised (dephosphorylated) and manganese ions are released from the mangafodipir by exchange with plasma zinc (mainly) after intravenous administration. Manganese and the ligand (fodipir), which have different pharmacokinetics, are eliminated by different routes.

The mean initial plasma half-life of manganese is 20 minutes or less, with significant uptake into the liver, pancreas, kidneys and spleen. The initial plasma half-life of ligand is about 50 minutes. The volume of distribution for manganese is between 0.5 and 1.5 l/kg, and for fodipir 0.17 to 0.45 l/kg. Following its metabolism, nearly all of the ligand (fodipir) is excreted in urine within 24 hours, with negligible amounts being eliminated via the faeces. About 15-20 % of the manganese is eliminated in the urine within the first 24 hours, most of the remainder is excreted in the faeces over the following 4 days.

In whole human blood *in vitro*, the protein binding of manganese is approximately 27 % but binding of fodipir to protein is negligible.

5.3 Preclinical safety data

Non-clinical studies reveal no special hazard for humans based on conventional studies of genotoxicity, safety pharmacology and validating kinetics and metabolism. Relevant adverse effects from repeated dose toxicity studies were liver toxicity (cholangiohepatitis) observed at relatively low dosages in dogs, while sufficient margins of safety were determined in rats and monkeys.

Mangafodipir is teratogenic in rats; it causes increased foetal skeletal abnormalities when given daily by intravenous injection to female rats at dosages slightly greater than clinical dosages**.** Embryo- and foetotoxicity has been observed in rabbits.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ascorbic acid
Sodium chloride
Sodium hydroxide and/or hydrochloric acid (pH adjustment)
Water for injections.

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products.

A separate cannula should be used.

6.3 Shelf life

Unopened: 2 years.
Once opened the product should be used immediately.

6.4 Special precautions for storage

Keep the vial in the outer carton in order to protect from light.
The product should be used immediately after first opening (see section 6.3).

6.5 Nature and contents of container

50 ml clear, colourless vials (type 1 glass). The containers are closed with rubber stoppers and sealed with aluminium caps with polypropylene lids.
TESLASCAN is supplied in packs of 1 x 50 ml and 10 x 50 ml vials.

Not all pack sizes may be marketed

6.6 Special precautions for disposal and other handling

TESLASCAN vials should be visually inspected for particulate matter and for the integrity of the container prior to use. Vials are intended for single use only; any unused portions must be discarded.

The required volume to be given to the patient should be determined and any excess volume should be withdrawn from the vial before infusion.

Connective tubing may be flushed with physiological saline (sodium chloride 9 mg/ml (0.9%)), to ensure complete administration of the contrast medium.

7. MARKETING AUTHORISATION HOLDER

GE Healthcare AS
Nycoveien 1-2
P.O. Box 4220 Nydalen
NO-0401 OSLO, Norway

8. MARKETING AUTHORISATION NUMBERS

EU/1/97/040/001
EU/1/97/040/002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22.05.1997
Date of latest renewal: 22.05.2007

10. DATE OF REVISION OF THE TEXT

ANNEX II

A. MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OF THE MARKETING AUTHORISATION

A. MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

GE Healthcare AS
Nycoveien 1-2
P.O. Box 4220 Nydalen
NO-0401 Oslo
Norway

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

- **CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT**

Not applicable.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

1 x 50 ml, 10 x 50 ml

1. NAME OF THE MEDICINAL PRODUCT

TESLASCAN 0.01 mmol/ml solution for infusion
mangafodipir trisodium

2. STATEMENT OF ACTIVE SUBSTANCE(S)

1 ml contains:
7.57 mg of anhydrous mangafodipir trisodium, 0.01 mmol (10 µmol), equivalent to 6.91 mg of mangafodipir

3. LIST OF EXCIPIENTS

Ascorbic acid
Sodium chloride
Sodium hydroxide or
hydrochloric acid
Water for injections
Also contains Sodium: 0.16 mmol (3.6 mg) per ml. See the package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for infusion.
1 x 50 ml
10 x 50 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

MRI contrast medium
Intravenous infusion
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

Each vial for one patient only.
Discard unused portion.

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton in order to protect from light.

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

GE Healthcare AS
Nycoveien 1-2
NO-0401 Oslo, Norway

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/97/040/001
EU/1/97/040/002

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. BRAILLE

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

50 ml

1. NAME OF THE MEDICINAL PRODUCT

TESLASCAN 0.01 mmol/ml solution for infusion
mangafodipir trisodium

2. STATEMENT OF ACTIVE SUBSTANCE(S)

1 ml contains:
7.57 mg of anhydrous mangafodipir trisodium, 0.01 mmol (10 µmol), equivalent to 6.91 mg of mangafodipir

3. LIST OF EXCIPIENTS

Ascorbic acid
Sodium chloride
Sodium hydroxide or
hydrochloric acid
Water for injections
Also contains Sodium: 0.16 mmol (3.6 mg) per ml. See the package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Infusion
50 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

MRI contrast medium
Intravenous infusion
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

Each vial for one patient only.
Discard unused portion.

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton in order to protect from light.

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

GE Healthcare AS
NO-0401 Oslo

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. BRAILLE

The labels will be designed as triple-labels in the same way as for our other contrast media.
The tear-off labels are intended to be stuck to the patient records and to the syringe if this is used.

Text on the two tear-off labels:

TESLASCAN
50 ml
Batch

B. PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

TESLASCAN 0.01 mmol/ml solution for infusion.
Mangafodipir trisodium

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 or pharmacist.

In this leaflet:

1. WHAT TESLASCAN IS AND WHAT IT IS USED FOR

TESLASCAN is a paramagnetic contrast medium used in connection with Magnetic Resonance Imaging (MRI), to improve the diagnostic information.

This medicine is for diagnostic use only.
TESLASCAN is used in magnetic resonance imaging (MRI) to detect certain lesions in the liver and pancreas.

2. BEFORE YOU USE TESLASCAN

Do not use TESLASCAN if one of the following conditions exists:

- Pregnancy
- Allergy (hypersensitivity) to the active substance or any of the other ingredients of TESLASCAN
- Pheochromocytoma
- Breast-feeding
- Severe kidney disease
- Severe liver disease

Take special care with TESLASCAN if one of the following conditions exists:

- Severe heart disease - in particular heart failure or when there is a risk of disorders of heart rhythm
- in patients with injuries of the blood brain barrier and severe cerebral disease

Rarely, hypersensitivity reactions (urticaria and other possible allergic phenomena) may occur.

Using other medicines:

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

TESLASCAN must not be used if you are pregnant.

The amount of TESLASCAN in breast milk is not known. As a precaution, to prevent exposing infants to the medicine, breast-feeding should be stopped from the time of dosing and all milk should be discarded for the first 14 days afterwards.

Driving and using machines:

No effects are known. There is no reason why you cannot drive after the investigation, unless you feel dizzy or are unsure of yourself.

Important information about some of the ingredients of Teslascan

This medicine contains 5.5 mmol (126 mg) sodium per normal dose of 35 ml. To be taken into consideration by patients on a controlled sodium diet.

3. HOW TO USE TESLASCAN

TESLASCAN is for use in patients over the age of 18 years.

Dosage:
The amount given will depend on the weight of the patient: 0.5 ml/kg body weight is the recommended dosage for adults and elderly.

TESLASCAN is for intravenous use and will be infused before the MRI examination. TESLASCAN may be infused into a vein, normally an arm vein, via a thin plastic tube. The administration may last for up to 15-20 minutes.

TESLASCAN should be visually inspected for particulate matter and for the integrity of the container prior to use. Vials are intended for single use only. The medicinal product should not be mixed with other medicinal products. Any unused portions must be discarded.

Overdose

There is no known antidote to this contrast medium. Treatment of any overdose will be performed at the hospital. Treatment will be supportive to relieve the symptoms.

High doses of manganese can make the heart pump less efficiently, dilate the blood vessels, as well as induce disturbances of heart rhythm.

4. POSSIBLE SIDE EFFECTS

Like all medicines, TESLASCAN can cause side effects, although not everybody gets them.

The reported side effects are usually mild and of short duration:

Common (1 in 100 to 1 in 10 patients experiences the side effect):

- Headache
- Nausea
- Feeling of warmth/flushing

Uncommon (1 in 1,000 to 1 in 100 patients experiences the side effect):

- Hypersensitivity reactions (e.g., skin reactions, rhinitis (nasal catarrh) pharyngitis (throat inflammation))
- Fever
- Diarrhoea
- Vomiting
- Dizziness
- Palpitation
- Paraesthesia (sensation of tingling)
- Abdominal pain
- Injection site pain
- Taste sensations

Rare (1 in 10,000 to 1 in 1,000 patients experiences the side effect):

- Hypertension

Very rare (less than 1 in 10,000 patients experiences the side effect):

- Visual disturbances
- Chest pain
- Flatulence

Anaphylactoid reactions (wheeziness, difficulty in breathing or tightness or pain in the chest) may occur.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell the radiologist/radiographer or your doctor or pharmacist.

5. HOW TO STORE TESLASCAN

Keep out of the reach and sight of children.

Expiry date

Do not use TESLASCAN after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Storage precautions

Keep the vial in the outer carton in order to protect from light.

Once opened the product should be used immediately. For single use only. Any unused portion should be discarded.
Do not use Teslascan if the colour changes from dark yellow to brown.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What TESLASCAN contains

- The active substance is mangafodipir trisodium.
1 ml of solution contains 7.57 mg mangafodipir trisodium anhydrous (corresponding to 0.01 mmol per ml)

- The other ingredients are ascorbic acid, sodium chloride, sodium hydroxide and/or hydrochloric acid (for pH adjustment) and water for injections.

What TESLASCAN looks like and contents of the pack

Solution for infusion.The solution is clear and bright to dark yellow in colour.

The medicine is supplied in pack of:
1 vial of 50 ml
10 vials of 50 ml

Not all pack sizes may be marketed

Marketing Authorization Holder and Manufacturer:

GE Healthcare AS
Nycoveien 1-2
P.O. Box 4220 Nydalen
NO-0401 OSLO, Norway

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

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This leaflet was last approved in