ANNEX I

LIST OF THE NAMES, PHARMACEUTICAL FORM, STRENGTH OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, APPLICANT, MARKETING AUTHORISATION HOLDER IN THE MEMBER STATES

Member State	Marketing Authorisation Holder	Applicant	Invented name	Strength	Pharmaceutical Form	Route of administration
Austria	-	Navamedic ASA Vollsveien 13 C 1327 Lysaker, Norway	Flexove	625 mg	Tablet	Oral use
Belgium	-	Navamedic ASA Vollsveien 13 C 1327 Lysaker, Norway	Flexove	625 mg	Tablet	Oral use
Cyprus	-	Navamedic ASA Vollsveien 13 C 1327 Lysaker, Norway	Glucomed	625 mg	Tablet	Oral use
Czech Republic	-	Navamedic ASA Vollsveien 13 C 1327 Lysaker, Norway	Flexove	625 mg	Tablet	Oral use
Denmark	-	Navamedic ASA Vollsveien 13 C 1327 Lysaker, Norway	Glucomed	625 mg	Tablet	Oral use
Estonia	-	Navamedic ASA Vollsveien 13 C 1327 Lysaker, Norway	Glucomed	625 mg	Tablet	Oral use
Finland	-	Navamedic ASA Vollsveien 13 C 1327 Lysaker, Norway	Glucomed	625 mg	Tablet	Oral use
France	-	Navamedic ASA Vollsveien 13 C 1327 Lysaker, Norway	Glucomed	625 mg	Tablet	Oral use
Germany	-	Navamedic ASA Vollsveien 13 C 1327 Lysaker, Norway	Glucomed	625 mg	Tablet	Oral use
Greece	-	Navamedic ASA Vollsveien 13 C 1327 Lysaker, Norway	Glucomed	625 mg	Tablet	Oral use
Hungary	-	Navamedic ASA Vollsveien 13 C 1327 Lysaker, Norway	Flexove	625 mg	Tablet	Oral use

Ireland	-	Navamedic ASA Vollsveien 13 C 1327 Lysaker, Norway	Flexove	625 mg	Tablet	Oral use
Italy	-	Navamedic ASA Vollsveien 13 C 1327 Lysaker, Norway	Glucomed	625 mg	Tablet	Oral use
Latvia	-	Navamedic ASA Vollsveien 13 C 1327 Lysaker, Norway	Glucomed	625 mg	Tablet	Oral use
Lithuania		Navamedic ASA Vollsveien 13 C 1327 Lysaker, Norway	Glucomed	625 mg	Tablet	Oral use
Luxemburg	-	Navamedic ASA Vollsveien 13 C 1327 Lysaker, Norway	Glucomed	625 mg	Tablet	Oral use
The Netherlands	-	Navamedic ASA Vollsveien 13 C 1327 Lysaker, Norway	Glucomed	625 mg	Tablet	Oral use
Poland	-	Navamedic ASA Vollsveien 13 C 1327 Lysaker, Norway	Glucomed	625 mg	Tablet	Oral use
Portugal	-	Navamedic ASA Vollsveien 13 C 1327 Lysaker, Norway	Glucomed	625 mg	Tablet	Oral use
Slovakia	-	Navamedic ASA Vollsveien 13 C 1327 Lysaker, Norway	Glucomed	625 mg	Tablet	Oral use
Spain	-	Navamedic ASA Vollsveien 13 C 1327 Lysaker, Norway	Glucomed	625 mg	Tablet	Oral use
Sweden	Navamedic ASA Vollsveien 13 C 1327 Lysaker, Norway	-	Glucomed	625 mg	Tablet	Oral use
United Kingdom	-	Navamedic ASA Vollsveien 13 C 1327 Lysaker, Norway	Glucomed	625 mg	Tablet	Oral use

Iceland	-	Navamedic ASA	Glucomed	625 mg	Tablet	Oral use
Norway	-	Navamedic ASA Vollsveien 13 C 1327 Lysaker, Norway	Flexove	625 mg	Tablet	Oral use

ANNEX II

SCIENTIFIC CONCLUSIONS AND GROUNDS FOR AMENDMENT OF THE SUMMARY OF PRODUCT CHARACTERISTICS, LABELLING AND PACKAGE LEAFLET PRESENTED BY THE EMEA

SCIENTIFIC CONCLUSIONS

OVERALL SUMMARY OF THE SCIENTIFIC EVALUATION OF GLUCOMED AND ASSOCIATED NAMES (see Annex I)

Introduction

In patients with mild to moderate osteoarthritis, in addition to physical exercise, paracetamol and NSAIDs are the only existing approved medicinal drug alternatives to obtain symptomatic relief of symptoms such as pain and stiffness. No curative or disease-modifying treatment exists, apart from surgery with arthroplasty.

Glucosamine was mainly introduced on the world-wide market as a food-supplement but with the aim to improve symptoms in patients with osteoarthritis or joint pain or function. Since 1980 many clinical studies of glucosamine have been performed, with varying scientific relevance and quality. Many published reviews, national therapy recommendations and other publications have discussed and evaluated the robustness of efficacy data. Different views on glucosamine, due to different interpretations of regulatory/legal systems have resulted in glucosamine being classified as a medicinal product in many regions of the world, including some Member States.

The applicant was asked to demonstrate efficacy of glucosamine in the intended indication “relief of symptoms in mild to moderate osteoarthritis of the knee”. In addition the applicant was asked to justify the proposed dose and posology, to characterise the safety profile, including a discussion of reported adverse drug reactions (ADRs), to justify the relevance of literature considering that the formulations of glucosamine sulphate (as the sodium chloride complex) used in the cited literature differ from the concerned application formulation and whether the differences in formulation will alter the efficacy and safety of the product, to elucidate the possibility of interactions with other medicinal products, and finally to show a positive risk/benefit profile of glucosamine hydrochloride in the intended indication.

Benefit/risk assessment

The applicant provided bibliographical data from a number of studies.

The applicant nonetheless mainly referred to the two large and long-term studies by Reginster and Pavelka. These two studies use authorised glucosamine-containing medicinal products, are long-term 3-years placebo-controlled studies, include an appropriate number of patients with appropriate inclusion criteria and look at relevant endpoints. For both studies the results are statistically significant for the WOMAC scale (Reginster) and for WOMAC and Lequesne scale (Pavelka) at 3 years. These indicate efficacy even if modest.

Two Cochrane reviews indicate efficacy but in the second review the conclusion are more hesitant. In the most recent meta-analysis from the Cochrane group in 2005, the results are positive when a glucosamine-containing medicinal product was used, positive for placebo-controlled studies in general and negative when the studies with adequate allocation concealment are retained.

The safety in all the performed studies covering thousands of patients is reassuring and was comparable to placebo. Pharmacovigilance reporting, mainly from Sweden and Spain, does not indicate any new safety issues.

The efficacy in symptomatic relief of pain in osteoarthritis, of the existing alternatives, NSAIDs and paracetamol, is of similar magnitude as glucosamine (e.g. ref. review by Bjordal). The safety profiles are, however, inferior to glucosamine. When it comes to relative benefit and risk assessment, the influence of publication bias may be less.

Dose selection in this bibliographical application is made from experience from other related glucosamine products and the dose and posology chosen is the same as used in almost all performed studies. This was considered appropriate.

No formal drug interaction studies have been performed with glucosamine-containing medicinal products. Therefore, a general caution was proposed to be included in the SPC. Pharmacovigilance surveillance has resulted in some reports indicating a potential interaction with warfarin, and hence a warning has been added in the SPC text.

Within this referral procedure, a question was raised, whether Glucomed containing glucosamine hydrochloride, was as effective as glucosamine sulphate. Glucosamine is considered to be an simple substance with a high solubility, and therefore, a comparative bioavailability study was not considered necessary for an approval. The open, comparative study by Qiu 2005 did not identify any efficacy differences between the two formulations.

Although data are not uniformly positive, it was concluded that taken together, glucosamine, both hydrochloride and sulphate, has shown efficacy, for the symptomatic relief in patients with mild to moderate osteoarthritis of the knee. The safety was considered sufficiently shown. Overall the safety profile is favourable with mainly mild gastrointestinal symptoms reported.

Conclusion

- Whereas

- The scope of the referral was to discuss the benefit/risk of glucosamine hydrochloride in the proposed indication
- The Summary of Products Characteristic, labelling and package leaflet proposed by the applicant has been assessed based on the documentation submitted and the scientific discussion within the Committee.

the CHMP has recommended by majority the granting of the Marketing Authorisation of Glucomed and associated names for the following indication: “relief of symptoms in mild to moderate osteoarthritis of the knee”.

The Summary of Product Characteristics, labelling and package leaflet are set out in Annex III of the opinion for Glucomed and associated names (see Annex I).

ANNEX III

SUMMARY OF PRODUCT CHARACTERISTICS, LABELLING AND PACKAGE LEAFLET

Note: This SPC, labelling and package leaflet is the version that was annexed to the Commission Decision on this Article 29 referral for glucosamine hydrochloride containing medicinal products. The text was valid at that time.

After the Commission Decision, the Member State competent authorities will update the product information as required. Therefore, this SPC, labelling and package leaflet may not necessarily represent the current text.

1. NAME OF THE MEDICINAL PRODUCT

Glucomed and associated names (see Annex I) 625 mg tablets

[See Annex I – To be completed nationally]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 625 mg of glucosamine (as glucosamine hydrochloride).

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablet

White to light beige, oval tablet marked with “G” and a score line. The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Relief of symptoms in mild to moderate osteoarthritis of the knee.

4.2 Posology and method of administration

1250 mg glucosamine once daily for relief of symptoms.

Glucosamine is not indicated for the treatment of acute painful symptoms. Relief of symptoms (especially pain relief) may not be experienced until after several weeks of treatment and in some cases even longer. If no relief of symptoms is experienced after 2-3 months, continued treatment with glucosamine should be re-evaluated.

Tablets can be taken with or without food.

Additional information on special populations.

Children and Adolescents
Glucomed is not recommended for use in children and adolescents below the age of 18, due to lack of data on safety and efficacy.

Elderly
No specific studies have been performed in the elderly, but according to clinical experience dosage adjustment is not required when treating otherwise healthy, elderly patients.

Impaired renal and/or liver function
In patients with impaired renal and/or liver function no dose recommendations can be given, since no studies have been performed.

4.3 Contraindications

Known hypersensitivity to glucosamine or to any of the excipients.

Glucomed must not be given to patients who are allergic to shellfish as the active substance is obtained from shellfish.

4.4 Special warnings and precautions for use

A doctor must be consulted to rule out the presence of joint diseases for which other treatment should be considered.

In patients with impaired glucose tolerance, monitoring of the blood glucose levels and, where relevant, insulin requirements is recommended before start of treatment and periodically during treatment.

In patients with a known risk factor for cardiovascular disease, monitoring of the blood lipid levels is recommended, since hypercholesterolemia has been observed in a few cases in patients treated with glucosamine.

A report on exacerbated asthma symptoms triggered after initiation of glucosamine therapy has been described (symptoms resolved after withdrawal of glucosamine). Asthmatic patients starting on glucosamine should therefore be aware of potential worsening of symptoms.

4.5 Interaction with other medicinal products and other forms of interaction

Data on possible drug interactions with glucosamine is limited, but increased INR with coumarin anticoagulants (warfarin and acenocoumarol) has been reported. Patients treated with coumarin anticoagulants should therefore be monitored closely when initiating or ending glucosamine therapy.

Concurrent treatment with glucosamine may increase the absorption and serum concentration of tetracyclines, but the clinical relevance of this interaction is probably limited.

Due to limited documentation on potential drug interactions with glucosamine, one should generally be aware of altered response or concentration of concurrently used medicinal products.

4.6 Pregnancy and lactation

Pregnancy
There is no adequate data from the use of glucosamine in pregnant women. From animal studies only insufficient data are available. Glucosamine should not be used during pregnancy.

Breast Feeding
There is no data available on the excretion of glucosamine in human milk. The use of glucosamine during breastfeeding is therefore not recommended as there is no data on the safety of the newborn.

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.
If dizziness or drowsiness is experienced, car driving and the operating of machinery is not recommended.

4.8 Undesirable effects

The most common adverse reactions associated with treatment with glucosamine are nausea, abdominal pain, indigestion, constipation, and diarrhoea. In addition, headache, tiredness, rash, itching, and flushing have been reported. The reported adverse reactions are usually mild and transitory.

System Organ Class	Common (≥1/100 to <1/10)	Uncommon (≥1/1,000 to <1/100)	Rare (≥ 1/10,000 to < 1/1000)
Nervous system disorders	Headache Tiredness	-	-
Gastrointestinal disorders	Nausea Abdominal pain Indigestion Diarrhoea Constipation	-	-
Skin and subcutaneous tissue disorders	-	Rash Itching Flushing	-

Sporadic, spontaneous cases of hypercholesterolaemia have been reported, but causality has not been established.

4.9 Overdose

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other anti-inflammatory and anti-rheumatic agents, non-steroidal anti-inflammatory drugs.
ATC code: M01AX05

Glucosamine is an endogenous substance, a normal constituent of the polysaccharide chains of cartilage matrix and synovial fluid glucosaminoglycans. *In vitro* and *in vivo* studies have shown glucosamine stimulates the synthesis of physiological glycosaminoglycans and proteoglycans by chondrocytes and of hyaluronic acid by synoviocytes.

The mechanism of action of glucosamine in humans is unknown.
The period to onset of response cannot be assessed.

5.2 Pharmacokinetic properties

Glucosamine is a relatively small molecule (molecular mass 179), which is easily dissolved in water and soluble in hydrophilic organic solvents.

The available information on the pharmacokinetics of glucosamine is limited. The absolute bioavailability is unknown. The distribution volume is approximately 5 litres and the half-life after intravenous administration is approximately 2 hours. Approximately 38% of an intravenous dose is excreted in the urine as unchanged substance.

5.3 Preclinical safety data

D-glucosamine has low acute toxicity.

Animal experimental data relating to toxicity during repeated administration, reproduction toxicity, mutagenicity and carcinogenicity is lacking for glucosamine.

Results from in vitro studies and in vivo studies in animals have shown that glucosamine reduces insulin secretion and induces insulin resistance, probably via glucokinase inhibition in the beta cells. The clinical relevance is unknown.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose
Hydroxypropyl cellulose
Low substituted hydroxypropyl cellulose (L-HPC)
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Do not store above 30^{o}C.

Keep the bottle or blister package tightly closed. Store in the original package in order to protect from moisture.

6.5 Nature and content of container

PVC/PVDC-aluminium blisters packed in paper cartons.
Pack-sizes of 40, 60 or 180 tablets.

HDPE tablet container with a silica gel desiccant in paper bags.
Pack-sizes of 60 or 180 tablets.

Not all pack-sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Navamedic ASA
Vollsvn. 13 C
1327 Lysaker
Norway

8. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[To be completed nationally]

10. DATE OF REVISION OF THE TEXT

[To be completed nationally]

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

Bottle

1. NAME OF THE MEDICINAL PRODUCT

Glucomed and associated names (see Annex I) 625 mg tablets
[See Annex I – To be completed nationally]
glucosamine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

1 tablet contains: 625 mg of glucosamine (as glucosamine hydrochloride).

3. LIST OF EXCIPIENTS

Microcrystalline cellulose
Hydroxypropyl cellulose
Low substituted hydroxypropyl cellulose (L-HPC)
Magnesium stearate

4. PHARMACEUTICAL FORM AND CONTENTS

60 tablets
180 tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
For oral 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: Y

9. SPECIAL STORAGE CONDITIONS

Keep the bottle tightly closed. Store in the original package in order to protect from moisture.
Store below 30˚C

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

Navamedic ASA, Vollsveien 13 C, P. O. box 438, 1327 Lysaker, Norway

12. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

13. BATCH NUMBER

Batch:

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Glucomed

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

Paper cartons for the blister

1. NAME OF THE MEDICINAL PRODUCT

Glucomed and associated names (see Annex I) 625 mg tablets
[See Annex I – To be completed nationally]
glucosamine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

1 tablet contains: 625 mg of glucosamine (as glucosamine hydrochloride).

3. LIST OF EXCIPIENTS

Microcrystalline cellulose
Hydroxypropyl cellulose
Low substituted hydroxypropyl cellulose (L-HPC)
Magnesium stearate

4. PHARMACEUTICAL FORM AND CONTENTS

40 tablets
60 tablets
180 tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
For oral 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: Y

9. SPECIAL STORAGE CONDITIONS

Store in the original package in order to protect from moisture.
Store below 30˚C

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

Navamedic ASA, Vollsveien 13 C, P. O. box 438, 1327 Lysaker, Norway

12. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

13. BATCH NUMBER

Batch:

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Glucomed

MINIMUM PARTICULARS TO APPEAR ON BLISTER OR STRIPS

Blister text

1. NAME OF THE MEDICINAL PRODUCT

Glucomed and associated names (see Annex I) 625 mg tablets
[See Annex I – To be completed nationally]
glucosamine

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Navamedic ASA

3. EXPIRY DATE

EXP:

4. BATCH NUMBER

Batch:

5. OTHER

PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Glucomed and associated names 625 mg tablets
[see Annex I – To be completed nationally]

Glucosamine

Read all of this leaflet carefully before you start taking 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.
- 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 GLUCOMED IS AND WHAT IT IS USED FOR

Glucomed belongs to the group of medicines called other anti-inflammatory and anti-rheumatic agents, non-steroids.
Glucomed is used for the relief of symptoms in mild to moderate osteoarthritis of the knee.

2. BEFORE YOU TAKE GLUCOMED

Do not take Glucomed
- if you are allergic (hypersensitive) to glucosamine or to any of the other ingredients of Glucomed.
- if you are allergic (hypersensitive) to shellfish, since glucosamine is manufactured from shellfish.

Take special care with Glucomed
- if you suffer from impaired glucose tolerance. More frequent controls of your blood glucose levels may be necessary when starting treatment with glucosamine.
- if you have kidney or liver dysfunction, since no studies have been performed in such patients dose recommendations cannot be given.
- If you have a known risk factor for cardiovascular disease, since hypercholesterolemia has been observed in a few cases in patients treated with glucosamine.
- If you suffer from asthma. When starting on glucosamine, you should be aware of potential worsening of symptoms.

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

Caution should be exercised if Glucomed has to be combined with other medicines, especially warfarin and tetracycline. Please contact your doctor for medical advice.

Taking Glucomed with food and drink
You can take the tablets with or without food.

Pregnancy and breast-feeding

Glucomed should not be used during pregnancy.
The use of glucosamine during breastfeeding is not recommended
Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines:
No studies on the effects on the ability to drive and use machines have been performed. If you experience dizziness or drowsiness from the tablets, you should not be driving or operating machinery.

3. HOW TO TAKE GLUCOMED

Always take Glucomed exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual starting dose is 2 tablets (1250 mg glucosamine) once daily.

Glucosamine is not indicated for the treatment of acute painful symptoms. Relief of symptoms (especially pain relief) may not be experienced until after several weeks of treatment and in some cases even longer. If no relief of symptoms is experienced after 2-3 months, continued treatment with glucosamine should be re-evaluated.

For oral use.

The tablets should be swallowed together with some water or other suitable liquid.

If you take more Glucomed than you should
If you have taken large quantities you must consult your doctor or a hospital.

If you forget to take Glucomed
Do not take a double dose to make up for a forgotten dose.

If you stop taking Glucomed
Your symptoms may reoccur.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Glucomed can cause side effects, although not everybody gets them.
The following have been reported:

Common (≥1/100 to <1/10): headache, tiredness, nausea, abdominal pain, indigestion, diarrhoea, constipation.
Uncommon (≥1/1,000 to < 1/100): rash, itching, flushing.

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.

5. HOW TO STORE GLUCOMED

Keep out of the reach and sight of children.

Do not use Glucomed after the expiry date which is stated on the blister/carton or tablet container.

Keep the bottle or blister tightly closed. Store in the original package in order to protect from moisture.
Store below 30˚C.

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 Glucomed contains
- The active substance is glucosamine. Each tablet contains 625 mg of glucosamine (as glucosamine hydrochloride)
- The other ingredients are microcrystalline cellulose, hydroxypropyl cellulose, low substituted hydroxypropyl cellulose (L-HPC) and magnesium stearate.

What Glucomed looks like and content of the pack
Glucomed is a white to light beige, oval tablet marked with “G” and a score line. The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

PVC/PVDC-aluminium blisters packed in paper cartons.
Pack-sizes of 40, 60 or 180 tablets.

HDPE tablet container with a silica gel desiccant in paper bags.
Pack-sizes of 60 or 180 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Navamedic ASA
Vollsveien 13 C, P.O. box 438, 1327 Lysaker, Norway

Manufacturer:

Weifa AS, Hausmannsgate 6, P. O. box 9113, Grønland, 0133 Oslo, Norway

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Flexove
Belgium	Flexove
Cyprus	Glucomed
Czech Republic	Flexove
Denmark	Glucomed
Estonia	Glucomed
Finland	Glucomed
France	[To be completed nationally]
Germany	Glucomed
Greece	Glucomed
Hungary	Flexove

Iceland	Glucomed
Ireland	Flexove
Italy	Glucomed
Latvia	Glucomed
Lithuania	Glucomed
Luxembourg	Glucomed
Netherlands	Glucomed
Norway	Flexove
Poland	Glucomed
Portugal	Glucomed
Slovakia	Glucomed
Spain	Glucomed
Sweden	Glucomed
United Kingdom	[To be completed nationally]

This leaflet was last approved on: {date}

[To be completed nationally]