Public Assessment Report

Mutual Recognition Procedure

RENNIE DUAL ACTION TABLETS

ALGINIC ACID
CALCIUM CARBONATE
MAGNESIUM CARBONATE HEAVY

UK/H/1600/001/MR

PL 00010/0514

Applicant: Bayer PLC

LAY SUMMARY

Belgium, Czech Republic, Estonia, Finland, France, Germany, Hungary, Ireland, Latvia, Lithuania, Luxembourg, The Netherlands, Poland, and Spain approved Bayer plc marketing authorisation (license) for the medicinal product Rennie dual action tablets. This is a general sale list (GSL) used in the treatment of complaints resulting from gastro-oesophageal reflux and hyperacidity, such as regurgitation and heartburn.

Rennie dual action tablets provide relief from heartburn and acid indigestion.
It works in two different ways:

1. Alginic acid forms a protective barrier in the stomach to stop acid escaping upwards,

2. Calcium carbonate and magnesium carbonate neutralise excess acid in the stomach

No new or unexpected safety concerns arose from this application and it was therefore judged that the benefits of taking Rennie Dual Action Tablets outweigh the risks, hence Marketing Authorisation has been granted.

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Module 1

Product Name	Rennie Dual Action Tablets
Type of Application	Article 10.a
Active Substance	Alginic acid Calcium carbonate Magnesium carbonate heavy
Form	Chewable tablets
Strength	150 milligrams alginic acid, 625 milligrams calcium carbonate and 73.5 milligrams magnesium carbonate heavy
MA Holder	Bayer Plc, Bayer Healthcare Consumer Care, Bayer House, Strawberry Hill, Newbury, Berkshire, RG14 1JA, UK
RMS	UK
CMS	Belgium, Czech Republic, Estonia, Finland, France, Germany, Hungary, Ireland, Latvia, Lithuania, Luxembourg, The Netherlands, Poland, Spain
Procedure Number	UK/H/1600/01/MR
Timetable	Day 90- 23/07/2008

Module 2

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rennie Dual Action Tablets, chewable tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:
Alginic acid 150mg, calcium carbonate 625mg and heavy magnesium carbonate 73.50mg.
Excipients: each chewable tablet contains 14 mg sodium as well as dextrates, sucrose (230 mg) and glucose (520 mg).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Chewable tablet

Off white, speckled circular tablet, flat on both sides with a bevelled edge.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic treatment of complaints resulting from gastro-oesophageal reflux and hyperacidity, such as regurgitation and heartburn.

4.2 Posology and method of administration

The usual dose is 2 tablets to be chewed. It should preferably be taken one hour after meals and before going to bed. An additional dose of 2 tablets can also be taken in between in the case of heartburn. Do not take more than 12 tablets in any 24-hour period. Only for use by adults and children over 12 years of age.

As with all antacids, if symptoms persist in spite of therapy, diagnostic measures are strongly recommended in order to rule out a more serious disease.

For Special warning and precautions for use please also see section 4.4.

4.3 Contraindications

- Severe renal insufficiency
- hypercalcaemia and/or conditions resulting in hypercalcaemia
- pre-existing hypophosphataemia
- nephrolithiasis due to calculi containing calcium deposits
- hypersensitivity to the active substances or to any of the excipients.

4.4 Special warnings and precautions for use

Prolonged use should be avoided.
If the symptoms persist or only partly disappear, further medical advice should be sought.

As with other antacids, Rennie Dual Action tablets may mask a malignancy in the stomach.

Rennie Dual Action tablets should not be used in the following cases:

- Hypercalciuria
- In general, caution should be exercised in patients with impaired renal function.
- If Rennie Dual Action tablets are used in such patients, plasma concentrations of calcium, phosphate and magnesium should be monitored regularly.

In general calcium containing antacids should be carefully administered in patients with constipation, haemorrhoids and sarcoidosis.

Prolonged use of high doses may result in undesirable side-effects such as hypercalcaemia, magnesaemia and the milk alkali syndrome, particularly in patients suffering from renal insufficiency. The product should not be taken with large amounts of milk or dairy products.

Prolonged use increases the risk of formation of renal calculi.

In the literature a possible relationship between calcium carbonate and appendicitis, gastrointestinal haemorrhage, intestinal blockage, or oedema has been reported in single cases.
Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

If symptoms persist after seven days, the clinical situation should be reviewed by a healthcare professional.

4.5. Interaction with other medicinal products and other forms of interaction

Changes in the level of acidity of gastric juice such as those caused by taking antacids may affect the degree and speed of absorption of medicines administered concomitantly. It has been shown that antacids containing calcium and magnesium can hinder the absorption of some antibiotics (such as the tetracyclines and quinolones) and cardiac glycosides (e.g. digoxin, digitoxin).
Calcium salts reduce the absorption of fluoride.
Thiazide diuretics reduce the urinary excretion of calcium. Due to increased risk of hypercalcaemia, serum calcium should be regularly monitored during concomitant use of thiazide diuretics.
Calcium salts and magnesium salts can hinder the absorption of phosphates.
In view of possible changes in the rate of absorption of medicines taken concomitantly, it is recommended that antacids are not administered at the same time as other medicines but taken 1 to 2 hours later.

Effects on laboratory parameters:
The administration of antacids may interfere with physiologic values/analytics: urinary system pH may increase while serum concentration of phosphates and potassium may decrease with excessive and prolonged use.

4.6 Pregnancy and lactation

Up to now, no increased risk of congenital defects has been observed after the use of calcium carbonate, magnesium carbonate and alginic acid during pregnancy. In case of high or prolonged doses or renal insufficiency, the risk for hypercalcaemia and/or hypermagnaesia can not be completely excluded.
Rennie Dual Action tablets can be used during pregnancy if taken as instructed but prolonged intake of high dosages should be avoided. Rennie Dual Action tablets can be used during lactation if taken as instructed.
During pregnancy and lactation, it has to be taken into account that Rennie Dual Action tablets provide a substantial amount of calcium in addition to dietary calcium intake. For this reason, pregnant women should strictly limit their use of Rennie Dual Action chewable tablets to the maximum recommended daily dose and avoid concomitant, excessive intake of milk and dairy products. This warning is to prevent calcium overload which might result in milk alkali syndrome.

4.7 Effects on ability to drive and use machines

Rennie Dual Action tablets are not expected to affect these functions.

4.8. Undesirable effects

Skin and subcutaneous tissue disorders:
Rarely, hypersensitivity reactions, including Quincke oedema and anaphylactic shock, have been reported.

Metabolism and nutrition disorders:
Prolonged use of high doses may possibly result in hypermagnesaemia or hypercalcaemia and alkalosis (GI symptoms such as nausea and vomiting, fatigue, confusion, polyuria, polydypsia, dehydration), particularly in patients with impaired renal function. Prolonged use of high doses of calcium carbonate with milk may lead to Burnett syndrome (milk-alkali syndrome).

Gastrointestinal disorders:
Although magnesium compounds may have a laxative effect, the low magnesium content in Rennie Dual Action tablets is not expected to result in undesirable effects in view of the recommended dose.

4.9. Overdose

Especially in patients with impaired renal function, prolonged use of high doses of calcium carbonate and magnesium carbonate can result in renal insufficiency, hypermagnesemia, hypercalcemia and alkalosis, which may give rise to gastrointestinal symptoms (nausea, vomiting, constipation) and muscular weakness. In these cases the intake of the product should be stopped and adequate fluid intake encouraged. In severe cases of overdosage (e.g. milk-alkali syndrome) other measures of rehydration (e.g. infusions) might be necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antacids, other combinations,
ATC code: AO2 AX

Rennie Dual Action tablets are a combination of two antacids (calcium carbonate and magnesium carbonate) and an alginic acid.

The mode of action of Rennie Dual Action tablets is local and is not dependent on systemic absorption.

Calcium carbonate has a rapid, long-lasting and powerful neutralising action. This effect is increased by the addition of magnesium carbonate which also has a strong neutralising action.
In healthy volunteers, a significant increase in the pH of stomach contents was achieved within 2 minutes. The total neutralising capacity of two tablets of the product is 29 mEq/H^+(titration to end-point pH 2.5). Apart from the neutralising action of the antacids, the alginic acid present in Rennie Dual Action tablets cause a viscous gel to be formed which floats on the stomach contents and acts as a physical barrier against reflux.

5.2 Pharmacokinetic properties

Calcium and magnesium

In the stomach: calcium carbonate and magnesium carbonate react with the acid in the gastric juice, forming soluble salts.
Calcium and magnesium can be absorbed from these (soluble) salts.
However, the degree of absorption is dependent on the patient and the dose. Approx. 10% calcium and 15-20% magnesium is absorbed.
The small quantities of calcium and magnesium absorbed are usually excreted rapidly via the kidneys in healthy individuals. In the case of impaired renal function, serum concentrations of calcium and magnesium may be increased.
Due to the effect of various digestive juices outside the stomach, the soluble salts are converted to insoluble salts in the intestinal canal and then excreted with the faeces.

Alginic acid

After oral ingestion, alginic acid is not converted in the gastro-intestinal tract; 80-100% of the quantity ingested is excreted. Absorption of alginic salts is negligible.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium hydrogen carbonate
Sucrose
Glucose monohydrate
Povidone
Talc
Magnesium stearate
Dextrates
Lemon cream flavour (primarily composed of lemon oil, lime oil, orange oil, l-menthole, vanilline, maltodextrin, gum arabic, ascorbic acid, butylhydroxyanisol)
Peppermint flavour (primarily composed of peppermint oil, maltodextrin, gum arabic, silicon dioxide)
Saccharin sodium.

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
2 years

6.4 Special precautions for storage
Do not store above 30°C. Store in the original package in order to protect from moisture.

6.5 Nature and contents of container
Strips consisting of LDPE/Aluminium foil.

Pack-sizes 12, 24 & 36 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal
No special requirements.

7 MARKETING AUTHORISATION HOLDER
Bayer plc
Bayer House
Strawberry Hill
Newbury
RG14 1JA
United Kingdom

Trading as Bayer plc, Consumer Care Division

8 MARKETING AUTHORISATION NUMBER(S)
PL 00010/0514

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
30th January 2007

10 DATE OF REVISION OF THE TEXT
30/10/2008

Module 3
Patient Information Leaflet

Rennie

DUAL ACTION TABLETS

BAYER

calcium carbonate, magnesium carbonate, alginic acid

Chewable tablets

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to take Rennie Dual Action Tablets carefully to get the best results from them. Keep this leaflet, you may need to read it again. Ask your pharmacist if you need more information or advice. You must contact a doctor if your symptoms worsen or do not improve after 7 days. If you have any unusual effects after taking Rennie Dual Action, please tell your doctor or pharmacist.

In this leaflet

1. WHAT ARE RENNIE DUAL ACTION TABLETS AND WHAT ARE THEY USED FOR?

Rennie Dual Action Tablets provide relief from heartburn and acid indigestion.

Rennie Dual Action tablets work in two different ways:

1. Alginic acid forms a protective barrier in the stomach to stop acid escaping upwards, soothing that burning pain in your chest
2. Calcium carbonate and magnesium carbonate provide rapid and long lasting neutralization of excess acid in the stomach

2. BEFORE YOU TAKE RENNIE DUAL ACTION TABLETS

Do not take Rennie Dual Action Tablets:

- If you have severe kidney disease or suffer from kidney stones.
- If you have high calcium or low phosphate levels in the blood.
- If you are allergic (hypersensitive) to any of the ingredients.

Take special care with Rennie Dual Action Tablets:

As with other antacid products, taking these tablets can mask the symptoms of other, more serious, underlying medical conditions. If symptoms persist after seven days consult your doctor.

Please consult your doctor or pharmacist before taking Rennie Dual Action Tablets if you have any kidney problems, have been diagnosed with sarcoidosis (inflammation disease that affects multiple organs in the body), or suffer from severe or chronic gastro-intestinal symptoms or diseases.

Taking Rennie Dual Action Tablets with food and drink

As with all calcium containing antacid products intake with large amounts of milk or dairy products should be refrained.

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.
- If taking antibiotics (tetracyclines, quinolones), cardiac glycosides (digoxin, digitoxin), or other prescribed medicines (e.g. fluorides, phosphate) speak to your doctor before taking Rennie Dual Action Tablets because it can affect how these medicines work. To maximise the benefit of all medicines being used, take Rennie Dual Action Tablets 1 to 2 hours after taking any other medicines.
- If you are taking any thiazide diuretics (e.g. bendroflumethiazide), which are used to increase urine production, then you should tell your doctor before taking the product because he or she may want to monitor the calcium levels in your blood.

Important information about some of the ingredients in Rennie Dual Action Tablets:

This product contains 28mg of sodium per dose of 2 tablets, which should be taken into consideration by patients on a sodium restricted diet.

This product also contains 460mg sucrose and about 1040mg glucose per dose of 2 tablets, which should be taken into account in patients with diabetes.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE RENNIE DUAL ACTION TABLETS

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

Adults and children over 12 only: 2 tablets to be chewed, preferably 1 hour after meals and before bedtime. For heartburn an extra 2 tablets may be taken between these times. Do not take more than 12 tablets in 24 hours.

If symptoms persist after 7 days consult your doctor in order to exclude a more serious disease. Prolonged use should be avoided.

Pregnancy and breast-feeding: Ask your doctor or pharmacist for advice before taking any medicine. Rennie Dual Action Tablets can be used during pregnancy if taken as instructed and if prolonged use of high doses is avoided. Rennie Dual Action Tablets can be used while breast-feeding if taken as instructed.

As Rennie Dual Action Tablets provide a substantial amount of calcium in addition to dietary calcium intake pregnant women should strictly limit their use of Rennie Dual Action Tablets to the maximum recommended daily dose and avoid concomitant, excessive intake of milk (1 liter contains up to 1.2 g elemental calcium) and dairy products.

If you take more Rennie Dual Action Tablets than you should: Drink plenty of water and consult your doctor or pharmacist. Symptoms of an overdose include nausea and vomiting, constipation, tiredness, increased urine production, increased thirst, dehydration and abnormal muscular weakness.

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

If you forget to take Rennie Dual Action Tablets: Do not take a double dose to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Rennie Dual Action Tablets can cause side effects, although not everybody gets them.

Side effects are unlikely at the recommended dose.

Rarely allergic reactions to ingredients have been reported, e.g rashes, itching, difficulty in breathing and swelling of the face, mouth or throat and anaphylactic shock. If you experience these reactions stop treatment immediately and seek medical advice.

Long term use of high doses can cause high blood levels of calcium and magnesium, especially in people with kidney conditions. This can cause nausea and vomiting, tiredness, confusion, increased urine production, increased thirst and dehydration.

Taking Rennie Dual Action with milk or dairy products over a long period of time may cause milk alkali syndrome, which can cause high blood levels of calcium.

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 RENNIE DUAL ACTION TABLETS

Keep out of the reach and sight of children.

Do not use Rennie Dual Action Tablets after the expiry date which is stated on the carton and foil after "EXP". The expiry date refers to the last day of that month.

Do not store above 30^{0}C. Store in the original package in order to protect from moisture.

Medicines should not be disposed of via waste water 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 Rennie Dual Action Tablets contain:

Each chewable tablet contains the active ingredients calcium carbonate (625 mg), magnesium carbonate (73.5mg) and alginic acid (150mg).

The other ingredients are Sodium hydrogen carbonate, sucrose, glucose monohydrate, povidone, talc, magnesium stearate, dextrates, saccharin sodium, lemon cream flavour (contains lemon oil, lime oil, orange oil, l-menthole, vanilline, maltodextrin, gum arabic, ascorbic acid, butylhydroxyanisol), peppermint flavour (contains peppermint oil, maltodextrin, gum arabic, silicon dioxide).

What Rennie Dual Action Tablets look like and the contents of the pack:

Rennie Dual Action Tablets are off white, speckled circular chewable tablets, flat on both sides with a bevelled edge.

They are supplied in foil strips in a carton with this leaflet.

The tablets are available in pack-sizes of 12, 24 and 36. Not all pack sizes may be marketed.

Marketing Authorisation Holder
Bayer plc
Strawberry Hill
Newbury RG14 1JA
UK

Manufacturer
Bayer Santé Familiale
33 rue de l'Industrie
74240 Gaillard
France

This leaflet was last revised in July 2008.

Bayer

Module 4

Labelling

Module 5

Scientific discussion during initial procedure

I INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the RMS considered that the application for Rennie Dual Action Tablets in the symptomatic treatment of complaints resulting from gastro-oesophageal reflux and hyperacidity, such as regurgitation and heartburn, could be approved. A national marketing authorisation was granted on 30th January 2007.

This application is submitted as a well-established use application (Article 10a), with the applicant cross-referring to their own product Rennie Duo Chewable Tablets (PL 00010/0351) which was authorised in the UK as an incoming MRP from The Netherlands (NL/H/0147/002/MR).

PIL user testing results have been submitted to the RMS. The results indicate that the PIL is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

Rennie Dual Action Tablets contain the active ingredients alginic acid, calcium carbonate and magnesium carbonate, heavy. The composition of Rennie Dual Action Tablets is exactly half that of Rennie Duo Chewable Tablets (which was licensed in the UK via an incoming MRP NL/H/0147/002/MR).

Alginic acid is used to form a gel, which floats on the stomach contents effectively impeding gastro-oesophageal reflux. Calcium carbonate and magnesium carbonate, heavy both neutralise gastric acid to provide relief from indigestion and heartburn.

The objective of the development programme was to develop a product that had exactly half the amounts of active ingredients alginic acid, calcium carbonate and magnesium carbonate as the UK-approved Rennie Duo Chewable Tablets.

No new preclinical studies were conducted, which is acceptable given that the application was made under Article 10a (well-established use).

No clinical studies were conducted, which is acceptable given that the application was made under Article 10a (well-established use) and states to be quantitatively half the amount and qualitatively similar to Rennie Duo Chewable Tablets, which has been granted a UK licence.

The RMS has been assured that acceptable standards of GMP are in place for these product types at all sites responsible for the manufacture and assembly of this product prior to granting its national authorisation.

For manufacturing sites within the community, the RMS has accepted copies of current manufacturer authorisations issued by inspection services of the competent authorities as certification that acceptable standards of GMP are in place at those sites.

SCIENTIFIC OVERVIEW AND DISCUSSION

QUALITY ASPECTS

Alginic Acid

Synthesis of the drug substance from the designated starting material has been adequately described and appropriate in-process controls and intermediate specifications are applied. Satisfactory specification tests are in place for all starting materials and reagents and these are supported by relevant certificates of analysis.

Alginic acid is tested as per Ph Eur specification.

Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specifications.

Alginic acid is stored in appropriate packaging.

All potential known impurities have been identified and characterised.

Batch analysis data are provided and comply with the proposed specification.

Satisfactory certificates of analysis have been provided for working standards used by the active substance manufacturer and finished product manufacturer during validation studies.

Appropriate stability data have been generated that supports the retest period for the drug substance when stored in the proposed packaging.

Calcium carbonate

Manufacture of the drug substance from the designated starting material has been adequately described and appropriate in-process controls and intermediate specifications are applied. Satisfactory specification tests are in place for all starting materials and reagents and these are supported by relevant certificates of analysis.

Calcium carbonate is tested as per Ph Eur specification.

Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specifications.

Calcium carbonate is stored in appropriate packaging.

All potential known impurities have been identified and characterised.

Batch analysis data are provided and comply with the proposed specification.

Satisfactory certificates of analysis have been provided for working standards used by the active substance manufacturer and finished product manufacturer during validation studies.

Appropriate stability data have been generated that supports the retest period of the drug substance when stored in the proposed packaging.

Magnesium Carbonate

Manufacture of the drug substance from the designated starting material has been adequately described and appropriate in-process controls and intermediate specifications are applied. Satisfactory specification tests are in place for all starting materials and reagents and these are supported by relevant certificates of analysis.

Magnesium carbonate is tested as per Ph Eur specification.

Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specifications.

Magnesium carbonate is stored in appropriate packaging. The specifications and typical analytical test reports are provided and appear to be satisfactory.

Batch analysis data are provided and comply with the proposed specification.

Appropriate stability data have been generated that supports the retest period for the drug substance when stored in the proposed packaging.

Drug Product

Description and Composition of the Drug product

Other ingredients consist of pharmaceutical excipients, namely sodium hydrogen carbonate, saccharin sodium, peppermint flavour, lemon cream flavour, sucrose, glucose monohydrate, dextrates, povidone, talc and magnesium stearate.

All excipients used comply with their respective European Pharmacopoeia monograph with the exception of peppermint flavour and lemon cream flavour which comply with in-house specification. Dextrates are controlled to a suitable US Pharmacopoeia monograph. Satisfactory specifications and Certificates of Analysis are provided for typical batches of excipients.

There are no identifiable TSE issues. The applicant has provided declaration that no material of animal origin is used during the process. A declaration from the supplier is provided to state that magnesium stearate is of vegetable origin.

Manufacture

A GMP certificate has been provided for the manufacturing site. A full description and a detailed flow-chart of the manufacturing method, including in-process control steps has been provided.

In-process controls are satisfactory based on process validation data and controls on the finished product. Satisfactory process validation has been carried out.

Satisfactory batch formulae have been provided for the manufacture of the product along with an appropriate account of the manufacturing process. The manufacturing process has been validated and appropriate controls are applied.

Finished Product Specification
The finished product specification is satisfactory. Acceptance limits have been justified with respect to conventional pharmaceutical requirements and, where appropriate, safety. Test methods have been described and have been adequately validated, as appropriate. Batch data for tablets manufactured at the proposed manufacturing site demonstrate that the batches comply with the release specification. Satisfactory certificates of analysis are provided for the reference standards.

Container Closure System
Satisfactory specifications and certificates of analysis have been provided for the packaging components.

Stability
Finished product stability studies have been conducted in accordance with current guidelines. Based on the results, a shelf-life of 24 months with storage conditions ‘Do not store above 30 degree C’ and ‘Store in the original package in order to protect with moisture’ have been set. These are satisfactory.

SPC, PIL and Label
The SPC, PIL and Label are pharmaceutically acceptable.

CONCLUSIONS
It is recommended that a marketing Authorisation is granted for this application. The requirement for a line extension of the reference product has been met with respect to qualitative and quantitative content of the active substance and pharmaceutical form.

PRE-CLINICAL ASSESSMENT

This application is made under Article 10a of Directive 2001/83/EC, a well-established use application. No preclinical assessment has been performed as none is required.

CLINICAL ASSESSMENT

1. INTRODUCTION

This is an outgoing Mutual Recognition application submitted under Article 10a (well-established use). The applicant is cross-referring to their own product Rennie Duo Chewable Tablets (PL 00010/0351), which was originally authorised in the UK to Roche Products Limited as an incoming MRP from The Netherlands (NL/H/0147/002/MR) in 2001.

2. BACKGROUND

Rennie Dual Action Tablets contain the active ingredients alginic acid, calcium carbonate and magnesium carbonate, heavy. The composition of Rennie Dual Action Tablets is exactly half that of Rennie Duo Chewable Tablets (which was licensed in the UK via an incoming MRP).

Alginic acid is used to form a gel, which floats on the stomach contents impeding gastro-oesophageal reflux. Calcium carbonate and magnesium carbonate, heavy both neutralise gastric acid to provide relief from indigestion and heartburn.

3. INDICATIONS

The applicant has submitted the following:
Symptomatic treatment of complaints resulting from gastro-oesophageal reflux and hyperacidity, such as regurgitation and heartburn.

This is consistent with the indications for Rennie Duo Chewable Tablets and is acceptable.

4. DOSE & DOSE SCHEDULE

The applicant has submitted the following:
The usual dose is 2 tablets to be chewed. It should preferably be taken one hour after meals and before going to bed. An additional dose of 2 tablets can also be taken in between in the case of heartburn. Do not take more than 12 tablets in any 24-hour period. Only for use by adults (over 12 years of age).

This is consistent with the dose and dose schedule for Rennie Duo Chewable Tablets and is acceptable.

5. TOXICOLOGY

No new preclinical data are submitted and none are required for this application as it is submitted under Article 10a (well-established use). The toxicology of all actives and excipients are well-known and has been used in many current granted products.

6. CLINICAL PHARMACOLOGY

No new clinical pharmacology data have been provided and none are necessary as the applicant is cross-referring to a previous application for Rennie Duo Chewable Tablets.

7. EFFICACY

No new efficacy data have been submitted and none are necessary as the applicant is cross-referring to a previous application for Rennie Duo Chewable Tablets.

8. SAFETY

No new safety data have been submitted and none are necessary as the applicant is cross-referring to a previous application for Rennie Duo Chewable Tablets.

9. EXPERT REPORTS

The clinical expert report has been written by an appropriately qualified physician and is a suitable summary of the clinical aspects of the dossier.

10. SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

The SPC is medically satisfactory and consistent with that for Rennie Duo Chewable Tablets.

11. PATIENT INFORMATION LEAFLET (PIL)

The PIL is medically satisfactory and consistent with the SPC.

12. LABELLING

The labelling is medically satisfactory.

13. APPLICATION FORM (MAA FORM)

The MAA form is medically satisfactory.

14. DISCUSSION

The application is consistent with that for Rennie Duo Chewable Tablets, where necessary. No new data have been provided and none are necessary as all actives and excipients are well-known, and the product is a direct scale-down of an existing product (exactly half the composition of Rennie Duo Chewable Tablets).

15. MEDICAL CONCLUSION

The grant of a marketing authorisation is recommended.

Module 6

STEPS TAKEN AFTER INITIAL PROCEDURE - SUMMARY

Date submitted	Application type	Scope	Outcome