

Pravastatin sodium 10mg Tablets
Pravastatin sodium 20mg Tablets
Pravastatin sodium 30mg Tablets
Pravastatin sodium 40mg Tablets

PL 11311/0495-0498

UKPAR

TABLE OF CONTENTS

Lay Summary	Page 2
Scientific Discussion	Page 6
Steps Taken for Assessment	Page 14
Steps taken after authorisation	Page 15
Summary of Product Characteristics	Page 16
Patient Information Leaflet	Page 17
Labelling	Page 18
Annex 1	Page 26

LAY SUMMARY

Pravastatin sodium 10mg, 20mg, 30mg and 40mg Tablets. (pravastatin sodium)

This is a summary of the Public Assessment Report (PAR) for Pravastatin sodium 10mg Tablets (PL 11311/0495, previously PL 32019/0013), Pravastatin sodium 20mg Tablets (PL 11311/0496, previously PL 32019/0014), Pravastatin sodium 30mg Tablets (PL 1311/0497, previously PL 32019/0015) and Pravastatin sodium 40mg Tablets (PL 11311/0498, previously PL 32019/0016). It explains how Pravastatin sodium 10mg, 20mg, 30mg and 40 mg Tablets were assessed and their authorisation recommended, as well as the conditions of use. It is not intended to provide practical advice on how to use Pravastatin sodium 10mg, 20mg, 30mg and 40mg Tablets.

For practical information about using Pravastatin sodium 10mg, 20mg, 30mg and 40mg Tablets, patients should read the package leaflet or contact their doctor or pharmacist.

What are Pravastatin sodium 10mg, 20mg, 30mg and 40mg Tablets and what are they used for?

Pravastatin sodium 10mg, 20mg, 30mg and 40mg Tablets contain the active ingredient pravastatin, which belongs to a group of medicines called statins (HMG-CoA reductase inhibitors). This medicine is used to treat the following:

- Primary hypercholesterolaemia, an inherited condition in which the level of cholesterol in the blood is higher than normal from birth. Pravastatin is used to treat this condition when diet, exercise and weight reduction have been insufficient to correct the condition.
- High levels of triglycerides, cholesterol and other fats in the blood (mixed dyslipidaemia). Pravastatin is used to treat this condition when diet, exercise and weight reduction have been insufficient to correct the condition.
- To prevent heart-related illness or death in patients with moderate to severely high cholesterol levels who are at high risk for first-time heart problems (primary prevention).
- To prevent heart-related illness or death in patients with a history of heart problems (secondary prevention)
- To reduce high concentration of triglycerides (fats) or cholesterol in the blood (hyperlipidaemia) in patients who have had an organ transplant and are taking medication to reduce the body's immunity (immunosuppressants)

These applications are identical to Pravastatin Sodium 10, 20, 30 and 40mg Tablets (PL 11311/0271-4) which are also held by the marketing authorisation holder (Tillomed Laboratories Limited) and were granted on 22 April 2004.

How are Pravastatin sodium 10mg, 20mg, 30mg and 40mg Tablets used?

Pravastatin sodium 10mg, 20mg, 30mg and 40mg Tablets can be obtained only with a prescription. This medicine should be taken exactly as advised by the prescribing doctor. The patient should check with their doctor or pharmacist if they are not sure.

Before taking this medicine, secondary causes of very high cholesterol levels in the blood (hypercholesterolemia) should be excluded and the doctor should put the patient on a standard low-fat diet, which should be continued during treatment.

The dose advised for treatment and its duration will depend on the reason why this medicine has been prescribed:

- The recommended dose range for the treatment of patients with very high cholesterol levels in the blood (hypercholesterolemia) is 10-40mg, once daily. The doctor will do periodic blood tests and adjust the dose if necessary. The response to treatment is seen within a week, with full effect of a given dose within four weeks.
- The starting and maintenance dose to prevent heart problems is 40mg daily.
- The recommended starting dose for patients who have received an organ transplant is 20mg daily which may be increased up to 40mg daily, under close medical supervision.
- The recommended dose range in children to treat an inherited condition that causes high levels of cholesterol in the blood (heterozygous familial hypercholesterolaemia) is 10-20mg once daily for children of between 8 and 13 years of age and 10-40mg daily for children and adolescents of between 14-18 years of age.
- For patients with moderate to severe kidney or liver problems, the recommended starting dose is 10mg daily. The doctor will adjust the dose according to the patient's response to treatment.

The tablets are to be taken orally, in the evening and can be taken with or without food. The score line on the tablet is only to facilitate breaking for ease of swallowing and not to divide the tablet into equal doses.

Pravastatin sodium 10mg, 20mg, 30mg and 40mg Tablets should be taken for as long as prescribed by the doctor.

For further information on how Pravastatin sodium 10mg, 20mg, 30mg and 40mg Tablets are used, refer to the package leaflet and Summary of Product Characteristics available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

How do Pravastatin sodium 10mg, 20mg, 30mg and 40mg Tablets work?

The active ingredient in this medicine is pravastatin which belongs to a group of medicines called statins (HMG-CoA reductase inhibitors). These work by helping to reduce cholesterol and fats (triglycerides) in the blood by inhibiting an enzyme called HMG-CoA reductase, which controls cholesterol production in the liver.

What benefits of Pravastatin sodium 10mg, 20mg, 30mg and 40mg Tablets have been shown in studies?

The applications for Pravastatin sodium 10mg, 20mg, 30mg and 40mg Tablets are considered to be identical to the previously authorised applications for Pravastatin Sodium 10, 20, 30 and 40mg Tablets (PL 11311/0271-4), with the same benefits and risks. So, no new studies have been provided for Pravastatin sodium 10mg, 20mg, 30mg and 40mg Tablets; however, the marketing authorisation holder (Tillomed Laboratories Limited) has referred to their own data held for the grant of the licences for Pravastatin Sodium 10, 20, 30 and 40mg Tablets (PL 11311/0271-4) as the basis for the grant of the licences for Pravastatin sodium 10mg, 20mg, 30mg and 40mg Tablets.

What are the possible side effects of Pravastatin sodium 10mg, 20mg, 30mg and 40mg Tablets?

Like all medicines, this medicine can cause side effects, although not everybody gets them. Some side effects are more likely to occur than others.

Pravastatin sodium 10mg, 20mg, 30mg and 40mg Tablets are considered to be identical to the previously authorised applications for Pravastatin Sodium 10, 20, 30 and 40mg Tablets (PL 11311/0271-4) with the same benefits and risks.

For a full list of all the side effects reported with Pravastatin sodium 10mg, 20mg, 30mg and 40mg Tablets, see section 4 of the package leaflet, available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

Why are Pravastatin sodium 10mg, 20mg, 30mg and 40mg Tablets approved?

No new or unexpected safety concerns arose from these applications. The MHRA, therefore, considered that the benefits of Pravastatin sodium 10mg, 20mg, 30mg and 40mg Tablets outweigh their risks; and the grant of Marketing Authorisations (licences) was recommended.

What measures are being taken to ensure the safe and effective use of Pravastatin sodium 10mg, 20mg, 30mg and 40mg Tablets?

Safety information has been included in the Summaries of Product Characteristics and the package leaflet for Pravastatin sodium 10mg, 20mg, 30mg and 40mg Tablets, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Pravastatin sodium 10mg, 20mg, 30mg and 40mg Tablets

Marketing Authorisations (PL 32019/0013-6) were first granted in the UK to Roger Oakes Limited on 08 February 2011.

Subsequent to a Change of Ownership procedure, the Marketing Authorisations (PL 11311/0495-0498) were granted to Tillomed Laboratories Limited on 23 May 2011.

The full PAR for Pravastatin sodium 10mg, 20mg, 30mg and 40mg Tablets follows this summary.

For more information about treatment with Pravastatin sodium 10mg, 20mg, 30mg and 40mg Tablets, read the package leaflet, or contact your doctor or pharmacist.

This summary was last updated in November 2014.

PRAVASTATIN 10, 20, 30 AND 40MG TABLETS

PL 11311/0495-8

SCIENTIFIC DISCUSSION

TABLE OF CONTENTS

Introduction	Page 7
Pharmaceutical assessment	Page 8
Preclinical assessment	Page 11
Clinical assessment (including statistical assessment)	Page 12
Overall conclusions and risk benefit assessment	Page 13

INTRODUCTION

MHRA granted marketing authorisations for medicinal products Pravastatin Sodium 10, 20, 30 and 40mg Tablets (PL 32019/0013-6) to Roger Oakes Limited on the 8th February 2011. These are prescription only medicines (POM) used in the treatment of hypercholesterolemia, for reduction of risk of myocardial infarction or unstable angina pectoris and post transplantation hyperlipidaemia.

These applications were submitted as simple abridged applications according to Article 10c of Directive 2001/83/EC, cross-referring to Pravastatin Sodium 10, 20 30 and 40mg Tablets (PL 11311/0271-4), held by Tillomed Laboratories Ltd, which were granted marketing authorisations on 22nd April 2004.

No new data were submitted nor were they necessary for these simple applications, as the data are identical to those of the previously granted cross-reference products. As the cross-reference products were granted prior to the introduction of current legislation, a public assessment report is not available for them.

Pravastatin is a competitive inhibitor of 3-hydroxy-3-methylglutaryl-coenzyme A (HMG CoA) reductase, the enzyme catalysing the early rate-limiting step in cholesterol biosynthesis, and produces its lipid- lowering effect in two ways. Firstly, with the reversible and specific competitive inhibition of HMG-CoA reductase, it effects modest reduction in the synthesis of intracellular cholesterol. This results in an increase in the number of LDL-receptors on cell surfaces and enhanced receptor-mediated catabolism and clearance of circulating LDL-cholesterol. Secondly, pravastatin inhibits LDL production by inhibiting the hepatic synthesis of VLDL cholesterol, the LDL-cholesterol precursor.

A detailed description of the applicant's pharmacovigilance system has been provided with these applications and this is satisfactory.

No environmental risk assessment has been undertaken, as this is not considered necessary. This is justified as it is not anticipated that the grant of this new marketing authorisation will result in an increase in the environmental exposure of the drug.

The applicant's justification for absence of ERA is satisfactory.

Subsequent to a Change of Ownership procedure, the Marketing Authorisations (PL 11311/0495-8) were granted to Tillomed Laboratories Limited on 23 May 2011.

PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 32019/0013-6

PROPRIETARY NAME: Pravastatin Sodium 10, 20, 30 and 40mg Tablets

COMPANY NAME: Roger Oakes Limited

E.C. ARTICLE: Article 10c of Directive 2001/83/EC

LEGAL STATUS: POM

1 INTRODUCTION

These are simple, informed consent applications for Pravastatin Sodium 10, 20, 30 and 40mg Tablets, submitted under Article 10c of Directive 2001/83/EC. The applications cross-refer to Pravastatin Sodium 10, 20 30 and 40mg Tablets (PL 11311/0271-4), approved on 22nd April 2004 to the marketing authorisation holder Tillomed Laboratories Ltd. The current applications are considered valid.

2 MARKETING AUTHORISATION APPLICATION (MAA)

2.1 Name(s)

The proposed names of the products are Pravastatin Sodium 10, 20 30 and 40mg Tablets. The products have been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes

The product contains the active ingredient pravastatin sodium.

The tablets are packed in Blister (Al/PVC/COC/PVdC) and Blister (Al/OPA/Al/PVC) containing 7, 10, 14, 20, 28, 30, 50, 56, 60, 98, 100x1 and 100 tablets.

And

Polyethylene tablet container and polypropylene cap with desiccant (silica gel) insert containing 28, 30, 98, 100 and 250 tablets.

Specification and Certificate of Analysis for all packaging components used have been provided and are satisfactory. The packaging and pack sizes are the same as those for the reference products.

The proposed shelf life is 3 years for blister (Al/OPA/Al/PVC) and tablet container and 1 year for Blister (Al/PVC/COC/PVdC). The storage conditions are 'Do not store above 30°C and Store in the original package' for Blister (Al/OPA/Al/PVC), 'Do not store above 25°C and Store in the original package' for Blister (Al/PVC/COC/PVdC) and 'Keep the tablet container tightly closed' for Tablet container.

The shelf-life and storage conditions are identical to those for the reference products and are satisfactory.

2.3 Legal status

These products are prescription only medicines (POM).

2.4 Marketing authorisation holder/Contact Persons/Company

The proposed Marketing Authorisation holder is Roger Oakes Ltd, Allstoe House, Church Lane, Greetham, Rutland LE15 7NF

2.5 Manufacturers

The proposed manufacturing sites are consistent with those registered for the cross referenced products and evidence of Good Manufacturing Practice (GMP) compliance has been provided.

2.6 Qualitative and quantitative composition

The proposed composition is consistent with the details registered for the cross reference products.

2.7 Manufacturing process

The proposed manufacturing process is consistent with the details registered for the cross referenced products and the maximum batch size is stated.

2.8 Finished product/shelf-life specifications

The proposed finished product and shelf-life specifications are in line with the details registered for the cross referenced products.

2.9 Drug substance specification

The proposed drug substance specifications conform to the current European Pharmacopoeia monograph for pravastatin sodium, and are in-line with those for the cross referenced products.

European Directorate for the Quality of Medicines (EDQM) certificates of suitability for the manufacturer of pravastatin sodium has been provided. The active substance manufacturer is in line with those for the cross referenced products.

2.10 TSE Compliance

No materials of human or animal origin have been used in the manufacture of these products. This is consistent with the cross referenced products.

2.11 Bioequivalence

No bioequivalence data are required to support these informed consent applications, as the proposed products are manufactured to the same formula utilising the same process as the cross reference products Pravastatin Sodium 10, 20 30 and 40mg Tablets (PL 11311/0271-4).

3 EXPERT REPORT

The applicant has included detailed expert reports of the application. Signed declarations and copies of the experts' CVs are enclosed for the quality, non-clinical and clinical experts. All are considered to have sufficient experience for their responsibilities.

4. PRODUCT NAME & APPEARANCE

See 2.1 for details of the proposed product names. The appearance of the product is identical to those of the cross reference products.

5. SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

The proposed SmPCs are consistent with the details registered for the cross reference products.

6. PATIENT INFORMATION LEAFLET (PIL)/LABELLING

User testing of the package leaflet has been accepted, based on a bridging report provided by the applicant making reference to a user-testing of the PIL for Simvastatin 5mg, 10mg, 20mg and 40mg Film-coated Tablets. This is acceptable as it is a medicine in the same therapeutic class with similar key messages for safe use. The bridging report has successfully demonstrated how the key messages in the daughter PIL are covered within the parent PIL and has justified any differences. The design and layout are sufficiently identical to permit a comparison. The justification on the rationale for bridging is accepted.

The proposed artwork complies with the relevant statutory requirements. In line with current legislation the applicant has also included the name of the product in Braille on the outer packaging and has included sufficient space for a standard UK pharmacy dispensing label.

7. CONCLUSIONS

The data submitted with the applications are acceptable. The grant of marketing authorisations is recommended.

PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with these applications and none are required for applications of this type.

CLINICAL ASSESSMENT

No new clinical data have been supplied with these applications and none are required for applications of this type.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The data for these applications are consistent with those previously assessed for the cross reference products and, as such, have been judged to be satisfactory.

PRECLINICAL

No new preclinical data were submitted and none are required for applications of this type.

EFFICACY

These applications are identical to the previously granted applications for Pravastatin Sodium 10, 20, 30 and 40mg Tablets (PL 11311/0271-4), granted to Tillomed Laboratories Ltd on 22nd April 2004.

Pharmaceutical, preclinical and clinical expert statements have been provided, together with CVs showing the experts are appropriately qualified. The experts confirm that the products are identical in composition, manufacture and pharmaceutical characteristics to the respective cross reference products and that there are no toxicological or clinical issues.

No new or unexpected safety concerns arise from these applications.

The SmPC, PIL and labelling are satisfactory and consistent with those for the reference products.

RISK BENEFIT ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant's products are identical to the cross reference products. Extensive clinical experience with pravastatin sodium is considered to have demonstrated the therapeutic values of the compounds. The risk benefit is, therefore, considered to be positive.

PRAVASTATIN 10, 20, 30 AND 40MG TABLETS**PL 11311/0495-8****STEPS TAKEN FOR ASSESSMENT**

1	The MHRA received the marketing authorisation applications on 28 th November 2008
2	Following standard checks and communication with the applicant the MHRA considered the applications are valid on 5 th December 2008
3	Following assessment of the applications the MHRA requested further information on 27 th February 2009, 22 nd January 2010, 29 th July 2010 and 6 th October 2010
4	The applicant responded to the MHRA's request, providing further information on 20 th November 2009, 25 th June 2010, 10 th September 2010 and 5 th November 2010
5	The applications were determined on 8 th February 2011

PRAVASTATIN 10, 20, 30 AND 40MG TABLETS**PL 11311/0495-8****STEPS TAKEN AFTER AUTHORISATION-SUMMARY**

The following table lists non-safety updates to the Marketing Authorisations (PL 11311/0495-8) for these products that have been approved by the MHRA since the products were first licensed. The table includes updates that have been added as an annex to this PAR. This is not a complete list of the post-authorisation changes that have been made to these Marketing Authorisations.

Date submitted	Application type	Scope	Outcome
26 September 2014	Type 1B	To update sections 2, 3, 4.2, 4.3, 4.4, 4.6, 4.7, 4.8, 5.1, 5.2, 5.3 & 6.6 of the Summary of Product Characteristics (SmPC) in line with the innovator and current QRD requirements. As a consequence, the Patient Information Leaflet (PIL) and labels (carton/label/foil) have been updated.	Approved 24 October 2014







SUMMARY OF PRODUCT CHARACTERISTICS

In accordance with Directive 2010/84/EU, the Summaries of Product Characteristics (SmPCs) for products granted Marketing Authorisations at a national level are available on the MHRA website.

PATIENT INFORMATION LEAFLET








In accordance with Directive 2010/84/EU, the Patient Information Leaflets (PILs) for products granted Marketing Authorisations at a national level are available on the MHRA website.



LABELLING

	<p>28 Tablets</p> <p>Pravastatin sodium 10mg Tablets</p> <p>Each tablet contains 10mg pravastatin sodium</p> <p>Read the package leaflet before use.</p> <p>These tablets are to be taken orally (as directed by your doctor).</p> <p>Keep out of the sight and reach of children.</p> <p>Do not store above 25°C. Store in the original package.</p> <p>POM</p> 	<p>MAN:</p> <p>BN:</p> <p>EXPIRES:</p> 
<p>TIL-Ver:3s</p>	<p>28 Tablets</p> <p>Pravastatin sodium 10mg Tablets</p> <p>Each tablet contains 10mg pravastatin sodium</p> 	<p>P00174</p>
<p>Pravastatin sodium 10mg Tablets</p> <p>Each tablet contains 10mg pravastatin sodium</p> 	<p>Attach dispensing label here</p> 	
	 <p>5 024655 002313 ></p> <p>PL 11311/0495</p> <p>Product Licence Holder: Tilomed Laboratories Limited, 3 Howard Road, Eaton Socon, St Neots, Cambridgeshire, PE19 8ET, United Kingdom</p>	

<p>100 Tablets</p> <p>Pravastatin sodium 10mg Tablets</p> <p>Each tablet contains 10mg pravastatin sodium</p> <p>Read the package leaflet before use.</p> <p>These tablets are to be taken orally (as directed by your doctor).</p> <p>Keep out of the sight and reach of children.</p> <p>Store in the original package. Keep the tablet container tightly closed.</p> <p>POM</p> 	<p>BN:</p> <p>EXP:</p> <p>Attach dispensing label here</p>  <p>5 024655 003501 ></p> <p>Product Licence Holder: Tilomed Laboratories Limited, 3 Howard Road, Eaton Socon, St. Neots, Cambridgeshire, PE19 8ET, United Kingdom</p> <p>PL 11311/0495</p>
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Pravastatin sodium 10mg Tablets PL Holder: Tillomed Laboratories Ltd. PL 11311/0495	Pravastatin sodium 10mg Tablets PL Holder: Tillomed Laboratories Ltd. PL 11311/0495	Pravastatin sodium 10mg Tablets PL Holder: Tillomed Laboratories Ltd. PL 11311/0495
Pravastatin sodium 10mg Tablets PL Holder: Tillomed Laboratories Ltd. PL 11311/0495	Pravastatin sodium 10mg Tablets PL Holder: Tillomed Laboratories Ltd. PL 11311/0495	Pravastatin sodium 10mg Tablets PL Holder: Tillomed Laboratories Ltd. PL 11311/0495

	<p>28 Tablets</p> <p>Pravastatin sodium 20mg Tablets</p> <p>Each tablet contains 20mg pravastatin sodium</p> <p>Read the package leaflet before use.</p> <p>These tablets are to be taken orally (as directed by your doctor).</p> <p>Keep out of the sight and reach of children.</p> <p>Do not store above 25°C. Store in the original package.</p> <p>POM</p> 	<p>MAN:</p> <p>BN:</p> <p>EXPIRES:</p> 
<p>Till-Ver-3s</p>	<p>28 Tablets</p> <p>Pravastatin sodium 20mg Tablets</p> <p>Each tablet contains 20mg pravastatin sodium</p> 	<p>P00176</p>
<p>Pravastatin sodium 20mg Tablets</p> <p>Each tablet contains 20mg pravastatin sodium</p> 	<p>Attach dispensing label here</p> 	
 <p>5 024655 002320 ></p>	<p>PL 11311/0496</p> <p>Product Licence Holder: Tillomed Laboratories Limited, 3 Howard Road, Eaton Socon, St Neots, Cambridgeshire, PE19 8ET, United Kingdom</p>	

<p>100 Tablets</p> <p>Pravastatin sodium 20mg Tablets</p> <p>Each tablet contains 20mg pravastatin sodium</p> <p>Read the package leaflet before use.</p> <p>These tablets are to be taken orally (as directed by your doctor).</p> <p>Keep out of the sight and reach of children.</p> <p>Store in the original package. Keep the tablet container tightly closed.</p> <p>POM</p> 	<p>BN:</p> <p>EXP:</p> <p>Attach dispensing label here</p>  <p>5 024655 003518 ></p> <p>Product Licence Holder: Tillomed Laboratories Limited, 3 Howard Road, Eaton Socon, St. Neots, Cambridgeshire, PE19 8ET, United Kingdom PL 11311/0496</p>
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Pravastatin sodium 20mg Tablets PL Holder: Tillomed Laboratories Ltd. PL 11311/0496	Pravastatin sodium 20mg Tablets PL Holder: Tillomed Laboratories Ltd. PL 11311/0496	Pravastatin sodium 20mg Tablets PL Holder: Tillomed Laboratories Ltd. PL 11311/0496
Pravastatin sodium 20mg Tablets PL Holder: Tillomed Laboratories Ltd. PL 11311/0496	Pravastatin sodium 20mg Tablets PL Holder: Tillomed Laboratories Ltd. PL 11311/0496	Pravastatin sodium 20mg Tablets PL Holder: Tillomed Laboratories Ltd. PL 11311/0496

The following text is the approved label text for Pravastatin sodium 30mg Tablets (PL 11311/0497). No label mock-ups have been provided. In accordance with medicines legislation, the product shall not be marketed in the UK until approval of the label mock-ups has been obtained.

PROPOSED
Pravastatin sodium 30mg Tablets Each tablet contains 30mg pravastatin sodium
Read the package leaflet before use. These tablets are to be taken orally (as directed by your doctor). Keep out of the sight and reach of children. Do not store above 25°C. Store in the original package. PL 11311/0497 Product Licence Holder: Tillomed Laboratories Limited 3 Howard Road Eaton Socon St Neots Cambridgeshire PE19 8ET United Kingdom Till-Ver.3s

PROPOSED
Pravastatin sodium 30mg Tablets Each tablet contains 30mg pravastatin sodium
Read the package leaflet before use. These tablets are to be taken orally (as directed by your doctor). Keep out of the sight and reach of children. Store in the original package. Keep the tablet container tightly closed.
Product Licence Holder: Tillomed Laboratories Limited 3 Howard Road Eaton Socon St Neots Cambridgeshire PE19 8ET United Kingdom PL 11311/0497 Till-Ver.3s

PROPOSED
Pravastatin sodium 30mg Tablets PL Holder: Tillomed Laboratories Ltd. PL 11311/0497



Pravastatin sodium 40mg Tablets PL Holder: Tillomed Laboratories Ltd. PL 11311/0498	Pravastatin sodium 40mg Tablets PL Holder: Tillomed Laboratories Ltd. PL 11311/0498	Pravastatin sodium 40mg Tablets PL Holder: Tillomed Laboratories Ltd. PL 11311/0498
Pravastatin sodium 40mg Tablets PL Holder: Tillomed Laboratories Ltd. PL 11311/0498	Pravastatin sodium 40mg Tablets PL Holder: Tillomed Laboratories Ltd. PL 11311/0498	Pravastatin sodium 40mg Tablets PL Holder: Tillomed Laboratories Ltd. PL 11311/0498

ANNEX 1

Our Reference:	PL 11311/0495-0024 PL 11311/0496-0023 PL 11311/0497-0018 PL 11311/0498-0022
Product:	Pravastatin sodium 10mg Tablets Pravastatin sodium 20mg Tablets Pravastatin sodium 30mg Tablets Pravastatin sodium 40mg Tablets
Marketing Authorisation Holder:	Tillomed Laboratories Limited
Active Ingredient(s):	Pravastatin sodium.
Type of Procedure:	National
Submission Type:	Variation
Submission Category:	Type IB
Submission Complexity:	Standard
EU Procedure Number (if applicable):	

Reason:

To update sections 2, 3, 4.2, 4.3, 4.4, 4.6, 4.7, 4.8, 5.1, 5.2, 5.3 & 6.6 of the Summary of Product Characteristics (SmPC) for Pravastatin sodium 10mg, 20mg, 30mg & 40mg Tablets in line with the innovator and current QRD requirements. As a consequence, the Patient Information Leaflet (PIL) and labelling (carton/label/foil) have been updated.

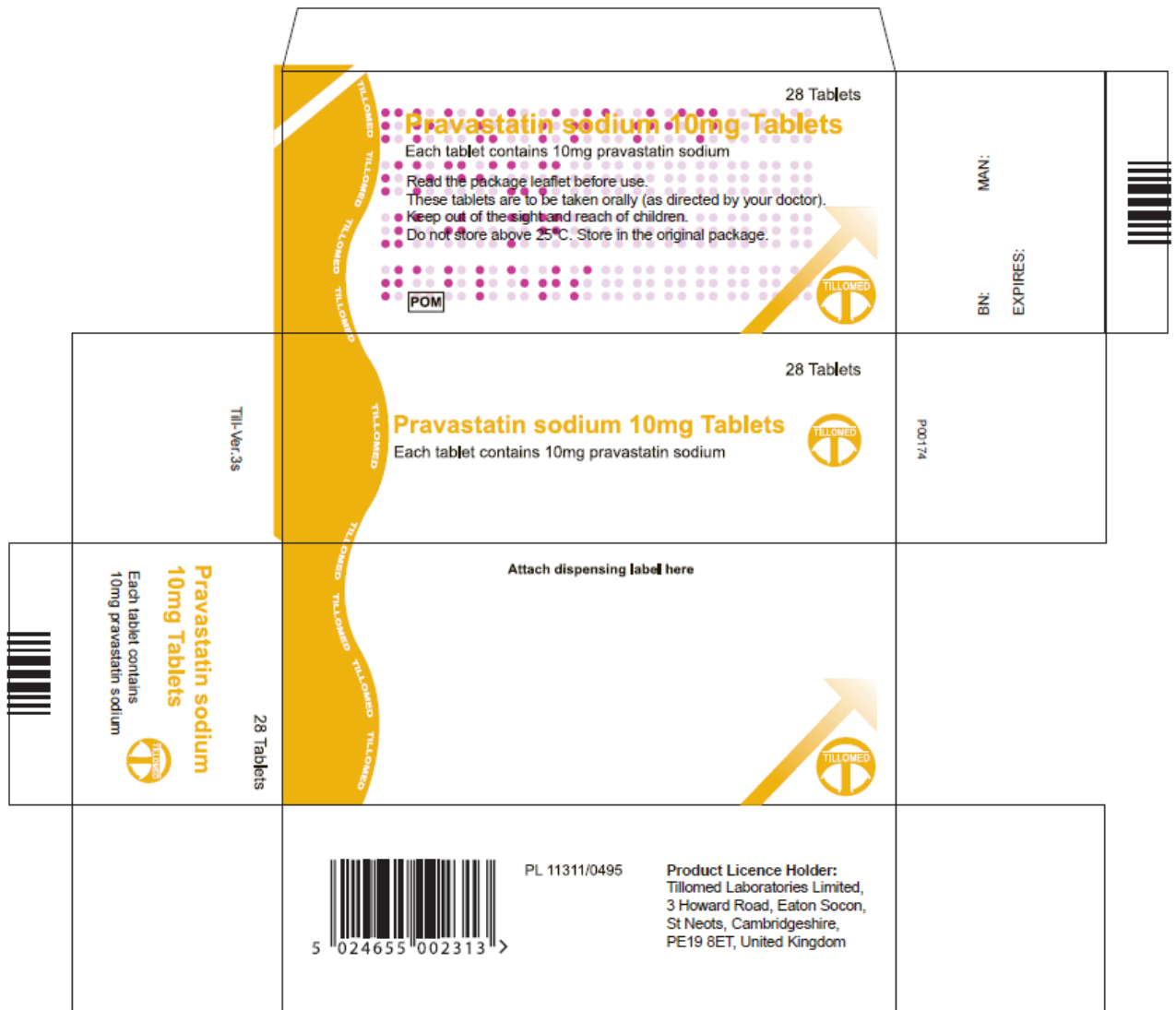
Supporting Evidence

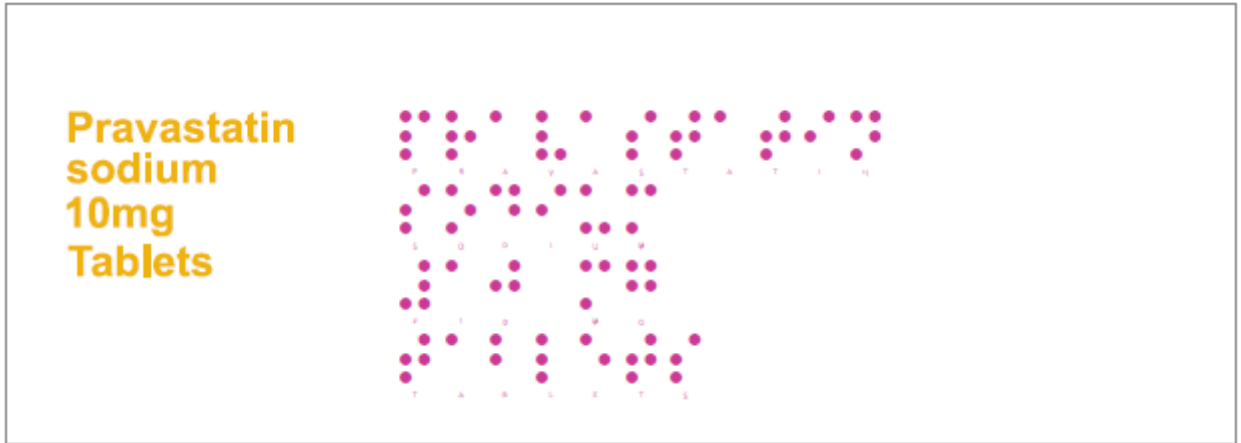
Revised SmPC fragments, PILs and labelling.

Evaluation








The proposed changes to the SmPCs, PILs and labelling are in line with the innovator and current QRD requirements. The updated SmPC fragments and PIL have been incorporated into the Marketing Authorisations. The following updated labelling has also been incorporated into the Marketing Authorisations:



Labelling-updated.

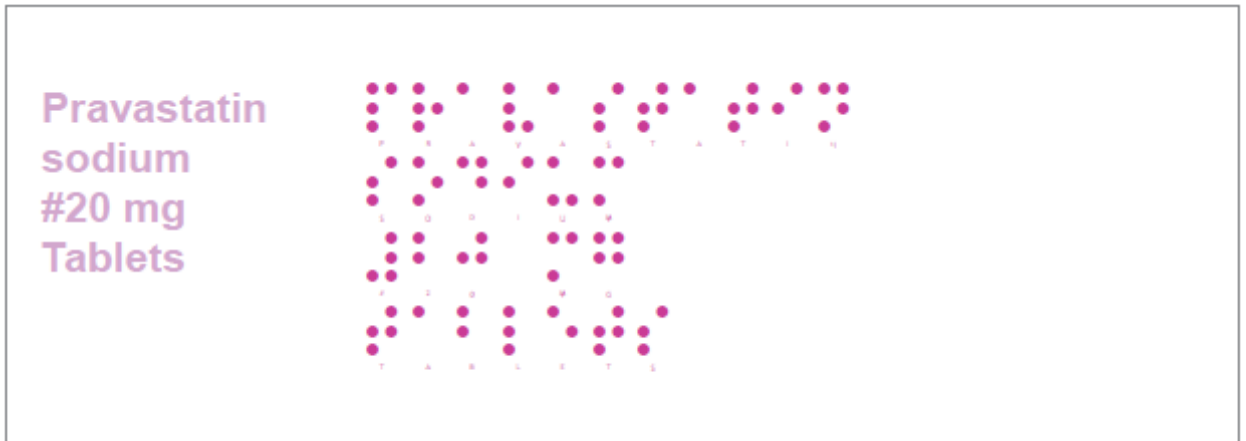




Pravastatin sodium 10mg Tablets PL Holder: Tillomed Laboratories Ltd. PL 11311/0495	Pravastatin sodium 10mg Tablets PL Holder: Tillomed Laboratories Ltd. PL 11311/0495	Pravastatin sodium 10mg Tablets PL Holder: Tillomed Laboratories Ltd. PL 11311/0495
Pravastatin sodium 10mg Tablets PL Holder: Tillomed Laboratories Ltd. PL 11311/0495	Pravastatin sodium 10mg Tablets PL Holder: Tillomed Laboratories Ltd. PL 11311/0495	Pravastatin sodium 10mg Tablets PL Holder: Tillomed Laboratories Ltd. PL 11311/0495

	<p>28 Tablets</p> <p>Pravastatin sodium 20mg Tablets</p> <p>Each tablet contains 20mg pravastatin sodium</p> <p>Read the package leaflet before use. These tablets are to be taken orally (as directed by your doctor). Keep out of the sight and reach of children. Do not store above 25°C. Store in the original package.</p> <p>POM</p> 	<p>MAN:</p> <p>BN:</p> <p>EXPIRES:</p>	
<p>TIL-Ver.3s</p>	<p>28 Tablets</p> <p>Pravastatin sodium 20mg Tablets</p> <p>Each tablet contains 20mg pravastatin sodium</p> 	<p>P00178</p>	
<p>Pravastatin sodium 20mg Tablets</p> <p>Each tablet contains 20mg pravastatin sodium</p> 	<p>Attach dispensing label here</p> 		
	<p>5 024655 002320 ></p> <p>PL 11311/0496</p> <p>Product Licence Holder: Tillomed Laboratories Limited, 3 Howard Road, Eaton Socon, St Neots, Cambridgeshire, PE19 8ET, United Kingdom</p>		

<p>100 Tablets</p> <p>Pravastatin sodium 20mg Tablets</p> <p>Each tablet contains 20mg pravastatin sodium</p> <p>Read the package leaflet before use. These tablets are to be taken orally (as directed by your doctor). Keep out of the sight and reach of children. Store in the original package. Keep the tablet container tightly closed.</p> <p>POM</p> 	<p>BN:</p> <p>EXP:</p> <p>Attach dispensing label here</p>  <p>5 024655 003518 ></p> <p>Product Licence Holder: Tillomed Laboratories Limited, 3 Howard Road, Eaton Socon, St. Neots, Cambridgeshire, PE19 8ET, United Kingdom PL 11311/0496</p>
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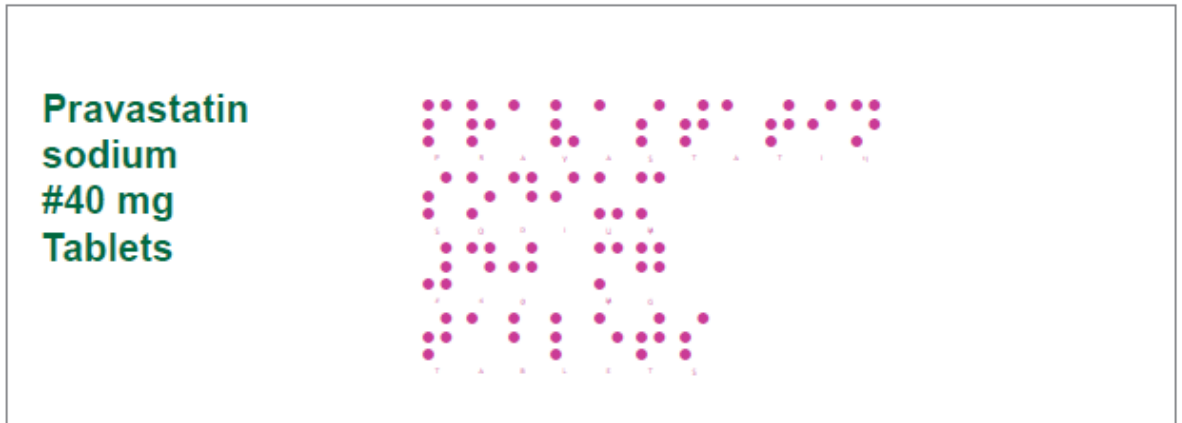
Pravastatin sodium 20mg Tablets PL Holder: Tillomed Laboratories Ltd. PL 11311/0496	Pravastatin sodium 20mg Tablets PL Holder: Tillomed Laboratories Ltd. PL 11311/0496	Pravastatin sodium 20mg Tablets PL Holder: Tillomed Laboratories Ltd. PL 11311/0496
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The following text is the approved label text for Pravastatin sodium 30mg Tablets (PL 11311/0497). No label mock-ups have been provided. In accordance with medicines legislation, the product shall not be marketed in the UK until approval of the label mock-ups has been obtained.

PROPOSED
<p>Pravastatin sodium 30mg Tablets</p> <p>Each tablet contains 30mg pravastatin sodium</p>
<p>Read the package leaflet before use. These tablets are to be taken orally (as directed by your doctor). Keep out of the sight and reach of children. Do not store above 25°C. Store in the original package.</p> <p>PL 11311/0497</p> <p>Product Licence Holder: Tillomed Laboratories Limited 3 Howard Road Eaton Socon St Neots Cambridgeshire PE19 8ET United Kingdom</p> <p>Till-Ver.3s</p>

PROPOSED
Pravastatin sodium 30mg Tablets Each tablet contains 30mg pravastatin sodium
Read the package leaflet before use. These tablets are to be taken orally (as directed by your doctor). Keep out of the sight and reach of children. Store in the original package. Keep the tablet container tightly closed.
Product Licence Holder: Tillomed Laboratories Limited 3 Howard Road Eaton Socon St Neots Cambridgeshire PE19 8ET United Kingdom PL 11311/0497 Till-Ver.3s

PROPOSED
Pravastatin sodium 30mg Tablets PL Holder: Tillomed Laboratories Ltd. PL 11311/0497



<p>Pravastatin sodium 40mg Tablets PL Holder: Tillomed Laboratories Ltd. PL 11311/0498</p>	<p>Pravastatin sodium 40mg Tablets PL Holder: Tillomed Laboratories Ltd. PL 11311/0498</p>	<p>Pravastatin sodium 40mg Tablets PL Holder: Tillomed Laboratories Ltd. PL 11311/0498</p>
<p>Pravastatin sodium 40mg Tablets PL Holder: Tillomed Laboratories Ltd. PL 11311/0498</p>	<p>Pravastatin sodium 40mg Tablets PL Holder: Tillomed Laboratories Ltd. PL 11311/0498</p>	<p>Pravastatin sodium 40mg Tablets PL Holder: Tillomed Laboratories Ltd. PL 11311/0498</p>

Conclusion

The proposed changes to the SmPCs, PIL and labelling are acceptable.

Decision - Approved on 24 October 2014.