Amoxicillin Sugar Free 3g Powder for Oral Suspension Sachets

PL 25298/0032

UKPAR

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LAY SUMMARY

Amoxicillin Sugar Free 3g Powder for Oral Suspension Sachets
(amoxicillin trihydrate, powder for oral suspension, 3g)

This is a summary of the Public Assessment Report (PAR) for Amoxicillin Sugar Free 3g Powder for Oral Suspension Sachets (PL 25298/0032). It explains how Amoxicillin Sugar Free 3g Powder for Oral Suspension Sachets were assessed and their authorisation recommended, as well as their conditions of use. It is not intended to provide practical advice on how to use Amoxicillin Sugar Free 3g Powder for Oral Suspension Sachets.

For practical information about using Amoxicillin Sugar Free 3g Powder for Oral Suspension Sachets, patients should read the package leaflet or contact their doctor or pharmacist.
.
The product may be referred to as Amoxicillin 3 g Sachets in this report.

What are Amoxicillin 3g Sachets and what are they used for?
Amoxicillin 3g Sachets are a 'generic' medicine. This means that Amoxicillin 3g Sachets are similar to a reference medicine already authorised in the European Union (EU) called Amoxil 3 g Powder for Oral Suspension Sachets (GlaxoSmithKline (Ireland) Limited, Ireland). The corresponding reference product in the UK is Amoxil Sachets 3 g Sucrose-Free (Beecham Group plc, trading as GlaxoSmithKline UK, UK).

Amoxicillin 3g Sachets contain the active ingredient, amoxicillin (as amoxicillin trihydrate). Amoxicillin 3g Sachets are used to treat infections in different parts of the body caused by bacteria. Amoxicillin 3g Sachets are also used to stop infections when a patient has tooth removed or other surgery, if the patient is likely to have an infection of the heart called bacterial endocarditis.

How does Amoxicillin 3g Sachets work?
Amoxillin 3g Sachets are an antibiotic. The active ingredient, amoxicillin, belongs to a group of medicines called 'penicillins'. Amoxicillin works by killing bacteria that cause infections.

How are Amoxicillin 3g Sachets used?
Amoxillin 3g Sachets can only be obtained on prescription. This medicine should be taken exactly as advised by the prescribing doctor. The prescribing doctor will advise on how many sachets to take.

Each Amoxicillin 3g Sachet contains powder for oral suspension containing 3g of amoxillin (as amoxicillin trihydrate).

When taking Amoxicillin 3g Sachets
Instructions for reconstitution: Check that the sachet is intact before use;
1.Cut sachet along dotted lie.
2.Empty contents in a glass.
3.Half-fill sachet with water.
4.Pour into the glass, stir well and drink immediately

- The maximum recommended dose is 6g per day given as 2 x 3g sachets.
- The doses should be spaced evenly during the day, at least 4 hours apart. If the patient needs to have 2 sachets in a day, one should be taken in the morning and one in the evening unless the doctor has advised otherwise.
- 2 doses should never be taken in 1 hour

The usual dose is:
Children aged under 10 years
Amoxicillin 3g Sachets are not recommended.

Adults, elderly patients and children weighing more than 40 kg
- Severe or recurrent chest infection: 3g (1 x sachet) twice a day.
- Urinary tract (water) infection: 2 x 3g doses (2 x sachets) with 10 to 12 hours between each dose.
- Dental abscess (infection under the gums and teeth): 2 x 3g doses (2 sachets) with 8 hours between each dose.
- Gonorrhoea (sexually transmitted infection): 1 x 3g dose (1 sachet).

To stop infection during surgery
- The dose will vary according to the type of surgery. Other medicines may also be given at the same time.
- The patient can be given more details by his/her doctor, pharmacist or nurse.

Kidney problems
If the patient has kidney problems, the dose might be lower than the usual dose.
Amoxillin 3g Sachets should be taken for as long as prescribed by the doctor.

For further information on how Amoxillin 3g Sachets used, please see the package leaflet and Summary of Product Characteristics available on the MHRA website.

What benefits of Amoxicillin 3g Sachets have been shown in studies?
As Amoxicillin 3g Sachets are a generic medicine, studies in patients have been limited to tests to determine that the product is similar to the reference medicine, Amoxil 3 g Powder for Oral Suspension (GlaxoSmithKline (Ireland) Limited, Ireland). Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

In addition, the Marketing Authoristion Holder, (Brown & Burk UK Limited) provided data from the published literature on amoxicillin.

What are the possible side effects of Amoxicillin 3g Sachets?
Because Amoxillin 3g Sachets are a generic medicine and are bioequivalent to the reference medicine, the benefits and possible side effects are taken as being the same as those for the reference medicine.

Why are Amoxicillin 3g Sachets approved?
It was concluded that, in accordance with EU requirements, Amoxicillin 3g Sachets have been shown to have comparable quality and to be bioequivalent to Amoxil 3 g Powder for Oral Suspension Sachets (GlaxoSmithKline (Ireland) Limited, Ireland). Therefore, the MHRA decided that, as for Amoxil 3 g Powder for Oral Suspension Sachets (GlaxoSmithKline (Ireland) Limited, Ireland), the benefits are greater than the risks and recommended that it can be approved for use.

For the full list of restrictions, see the package leaflet.

What measures are being taken to ensure the safe and effective use of Amoxicillin 3g Sachets?
A risk management plan has been developed to ensure that Amoxicillin 3g Sachets is used as safely as possible. Based on this plan, safety information has been included in the Summary of Product Characteristics and the package leaflet for Amoxicillin 3g Sachets, 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 Amoxicillin 3g Sachets
A Marketing Authorisation was granted in the UK to Burk & Brown UK Limited on 19 June 2014.

The full PAR for Amoxicillin 3g Sachets follows this summary.

For more information about treatment with Amoxicillin 3g Sachets, read the package leaflet, or contact your doctor or pharmacist.

This summary was last updated in August 2014.

Amoxicillin Sugar Free 3g Powder for Oral Suspension Sachets

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SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) granted Brown & Burk UK Limited a Marketing Authorisation for the medicinal product Amoxicillin Sugar Free 3g Powder for Oral Suspension Sachets (PL 25298/0032) on 19 June 2014. The product is a prescription-only medicine (POM) indicated for the:

- treatment of commonly occurring bacterial infections such as:
  - acute sinusitis and bacterial pharyngitis
  - otitis media
  - acute and chronic bronchitis
  - lobar and bronchopneumonia
  - cystitis, urethritis, pyelonephritis
  - bacteriuria in pregnancy
  - gynaecological infections including puerperal sepsis and septic abortion
  - gonorrhoea
  - peritonitis
  - intra-abdominal sepsis
  - bacterial endocarditis
  - typhoid and paratyphoid fever
  - skin and soft tissue infections
  - osteomyelitis
  - dental abscess (as an adjunct to surgical management)

- Prophylaxis of endocarditis: Prevention of bacteraemia, associated with procedures such as dental extraction, in patients at risk of developing bacterial endocarditis.

The active ingredient, amoxicillin (as amoxicillin trihydrate), is one of a group of medicines called 'penicillins'. Amoxicillin is a β-lactam antibiotic, which works by killing the bacteria that cause infections. It has a bactericidal action due to its inhibition of the synthesis of the bacterial cell wall.

The application was submitted under Article 10(1) of Directive 2001/83/EC, as amended, claiming to be a generic medicinal product of Amoxil 3 g Powder for Oral Suspension Sachets (GlaxoSmithKline [Ireland] Limited, Ireland), which was authorised in Ireland on 17 December 1979. The corresponding reference product in the UK is Amoxil Sachets 3 g Sucrose-Free (Beecham Group plc, trading as GlaxoSmithKline UK, UK), which was granted in the UK on 06 March 1986.

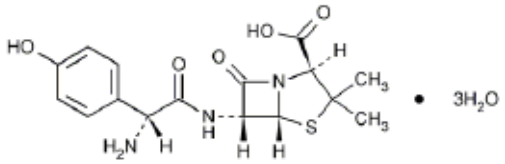
A single-dose bioequivalence study was submitted to support this application, comparing the applicant's test product Amoxicillin 3gm PFOS Sachet and the reference product Amoxil 3 g Powder for Oral Suspension Sachets Sucrose Free (GlaxoSmithKline [Ireland] Limited, Ireland) under fasting conditions. The bioequivalence study was carried out in accordance with Good Clinical Practice (GCP).

With the exception of the bioequivalence study, no new non-clinical or clinical efficacy studies were performed for this application, which is acceptable given that the application was based on being a generic medicinal product of an originator product that has been in clinical use for over 10 years.

No new or unexpected safety concerns arose during review of information provided by the Marketing Authorisation Holder and it was, therefore, judged that the benefits of taking Amoxicillin Sugar Free 3g Powder for Oral Suspension Sachets outweigh the risks and a Marketing Authorisation was granted.

PHARMACEUTICAL ASSESSMENT

ACTIVE SUBSTANCE

INN:	Amoxicillin trihydrate
Chemical Name:	(2S,5R,6R)-6-[[(2R)-2-Amino-2-(4-hydroxyphenyl)acetyl]-amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo [3.2.0] heptane-2-carboxylic acid trihydrate; 4-Thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid,6-[[amino(4-hydroxyphenyl)acetyl] amino-3,3-dimethyl-7-oxo,trihydrate 2S-[2α,[5α,6β (S*)]]; (2S,5R,6R)-6-[(R)-(-)-2-amino-2-(4-hydroxyphenyl) acetamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo [3.2.0] heptane-2-carboxylic acid trihydrate.
Molecular formula:	$C_{16}H_{19}N_3O_5S \cdot 3H_2O$
Structure:	
M_r:	419.4g/mol
Appearance:	A white or almost white, crystalline powder.
Solubility:	Slightly soluble in water, very slightly soluble in ethanol (96%), practically insoluble in fatty oils. It dissolves in dilute solutions of acids and dilute solutions of alkali hydroxides.

Amoxicillin trihydrate is the subject of a European Pharmacopoeia monograph.

All aspects of the manufacture and control of the active substance, amoxicillin trihydrate, are covered by a European Directorate for the Quality of Medicines and Healthcare (EDQM) Certificate of Suitability.

DRUG PRODUCT

Other Ingredients

Other ingredients consist of the pharmaceutical excipients sorbitol (E 420), saccharin sodium (E 954), xanthan gum (E 415), colloidal anhydrous silica (E 551), raspberry flavour, orange flavour and golden caramel flavour. Appropriate justification for the inclusion of each excipient has been provided.

All excipients comply with their respective European Pharmacopoeia monographs, with the exception of raspberry flavour, orange flavour and golden caramel flavour, which comply with suitable in-house specifications. In addition, raspberry flavour, orange flavour and golden caramel flavour comply with current European regulations concerning flavourings. Certificates of Analysis have been provided for all excipients, showing compliance with the proposed specification.

Satisfactory Certificates of Analysis have been provided for all excipients, showing compliance with the proposed specifications.

None of the excipients contains material of animal or human origin.

No genetically modified organisms (GMO) have been used in the preparation of these excipients.

Pharmaceutical Development
The objective of the development programme was to formulate a safe, efficacious, stable, powder for oral containing 3 g amoxicillin (as amoxicillin trihydrate) per sachet comparable in performance to the reference product, Amoxil 3 g Powder for Oral Suspension Sachets (GlaxoSmithKline (Ireland) Limited, Ireland).

Suitable pharmaceutical development data have been provided for this application.

Comparative *in-vitro* dissolution profiles have been provided for this product and the reference product.

Manufacturing Process
A satisfactory batch formula has been provided for the manufacture of the product, along with an appropriate account of the manufacturing process. The manufacturing process has been validated with full-scale batches and has shown satisfactory results. The Marketing Authorisation Holder has committed to performing process validation studies on future full-scale production batches.

Control of Finished Product
The finished product specification is satisfactory. Test methods have been described and adequately validated, as appropriate. Batch data have been provided, which comply with the release specifications.

Container Closure System
The product is packaged in paper laminated aluminium foil sachets. The product is packaged with the Patient Information Leaflet in cardboard outer cartons, in pack sizes of 2 and 14 sachets.

Not all pack sizes may be marketed.

Satisfactory specifications and Certificates of Analysis have been provided for all packaging components. All primary packaging complies with the current European regulations concerning materials in contact with food.

Stability of the product
Finished product stability studies were performed in accordance with current guidelines on batches of finished product packed in the packaging proposed for marketing. The data from these studies support a shelf-life of 18 months for the unopened product, with the storage conditions ‘Store below 25°C.’

The reconstituted product should be used immediately.

Suitable post approval stability commitments have been provided to continue stability studies on batches of finished product.

Bioequivalence
Satisfactory Certificates of Analysis have been provided for the test and reference batches used in the bioequivalence study.

Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and Labelling
The SmPC, PIL and labelling are satisfactory from a pharmaceutical perspective.

A package leaflet has been submitted to the MHRA along with results of consultations with target patient groups ('user testing'), in accordance with Article 59 of Council Directive 2001/83/EC, as amended. The results indicate that the package leaflet 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 the leaflet contains.

MAA (Marketing Authorisation Application) Form
The MAA form is satisfactory from a pharmaceutical perspective.

Expert Report (Quality Overall Summary)
The quality overall summary is written by an appropriately qualified person and is a suitable summary of the pharmaceutical aspects of the dossier.

Conclusion
The grant of a Marketing Authorisation is recommended.

NON-CLINICAL ASSESSMENT

PHARMACODYNAMICS, PHARMACOKINETICS AND TOXICOLOGY

As the pharmacodynamic, pharmacokinetic and toxicological properties of amoxicillin are well-known, no further non-clinical studies are required and none have been provided.

NON-CLINICAL EXPERT REPORT (NON-CLINICAL OVERVIEW)

The applicant's non-clinical overview has been written by an appropriately qualified person and is satisfactory, providing an appropriate review of the relevant non-clinical pharmacology, pharmacokinetics and toxicology.

ENVIRONMENTAL RISK ASSESSMENT

Suitable justification has been provided for non-submission of an Environmental Risk Assessment. As the application is for a generic version of an already authorised product, it is not expected that environmental exposure will increase following approval of the Marketing Authorisation for the proposed product.

CONCLUSION

The grant of Marketing Authorisation is recommended.

CLINICAL ASSESSMENT

CLINICAL PHARMACOLOGY

The clinical pharmacology of amoxicillin is well-known. With the exception of data from the bioequivalence study detailed below, no new pharmacodynamic or pharmacokinetic data are provided or required for this application.

In support of the application, the Marketing Authorisation Holder submitted the following bioequivalence study:

A single-dose, randomized, open-label, two-treatment, two-period, two-sequence, crossover, bioequivalence study of Amoxicillin 3gm PFOS SACHET (Brown and Burk UK Limited, UK) and Amoxil 3 g Powder for Oral Suspension Sachets Sucrose-Free (GlaxoSmithKline [Ireland] Limited, Ireland) in healthy adult male subjects under fasting conditions.

The subjects were administered a single oral dose of either the test (A) or the reference product (B) with 240 ml of water, after at least a 8-hour overnight fast. Blood samples were collected pre-dose and up to 16 hours after each administration. The washout period between the treatment arms was 7 days. The pharmacokinetic results are presented below:

Table 1: Summary of Pharmacokinetic parameters for Amoxicillin – Test Drug A

Summary Statistics	C_{max} (µg/ml)	AUC_{0-t} (hr)*(µg/ml	AUC_{0-inf} (hr)*(µg/ml
Mean	22.1435	72.4823	73.6924
SD	5.87	18.78	18.77
CV (%)	26.53	25.91	25.47

C_{max} maximum plasma concentration
AUC_{0-t} area under the plasma concentration-time curve from time zero to t hours
$AUC_{0-\infty}$ area under the plasma concentration-time curve from time zero to infinity
CV coefficient of variation

Table 2: Summary of Pharmacokinetic parameters for Amoxicillin – Reference Test Drug B

Summary Statistics	C_{max} (µg/ml)	AUC_{0-t} (hr)*(µg/ml	AUC_{0-inf} (hr)*(µg/ml
Mean	22.3953	78.8071	79.9767
SD	6.04	26.29	26.43
CV (%)	26.97	33.36	33.04

C_{max} maximum plasma concentration
AUC_{0-t} area under the plasma concentration-time curve from time zero to t hours
$AUC_{0-\infty}$ area under the plasma concentration-time curve from time zero to infinity
CV coefficient of variation

Table 3: Ratio and 90% Confidence Intervals of Test versus Reference for Amoxicillin

Parameter	Ratio of Means (%)	90% CI (%)	Geometric mean		Intra-subject CV (%)
			A	B	
C_{max}	99.02	92.98 – 105.46	21.3683	21.5793	15.90
AUC_{0-t}	93.99	87.13 – 101.39	70.1004	74.5821	19.18
AUC_{0-inf}	94.16	97.39 – 101.46	71.3539	75.7767	18.88

C_{max} maximum plasma concentration
AUC_{0-t} area under the plasma concentration-time curve from time zero to t hours
$AUC_{0-\infty}$ area under the plasma concentration-time curve from time zero to infinity
CV coefficient of variation
Ratios and 90% CI calculated from ln-transformed data

Conclusion of Bioequivalence study

The *Guidance on the Investigation of Bioequivalence* (CPMP/EWP/QWP/1401/98 Rev 1/ Corr**) defines the 90% confidence limits as 80.00% to 125.00% for C_{max} and AUC values. The confidence intervals of the test/reference ratio for $AUC_{0-t,}$ AUC_{0-inf} and C_{max} lie within the acceptable limits of 80.00% to 125.00%. Thus, the data support the claim that the applicant's test product is bioequivalent to the reference product (Amoxil 3 g Powder for Oral Suspension Sachets Sucrose-Free (GlaxoSmithKline [Ireland] Limited, Ireland) under fasting conditions.

EFFICACY

The efficacy of amoxicillin is well-known. No new efficacy data have been submitted and none are required for an application of this type.

SAFETY

With the exception of the safety data generated during the bioequivalence study, no new safety data were submitted and none are required for this type of application. No new or unexpected safety issues arose during the bioequivalence study.

PHARMACOVIGILANCE SYSTEM AND RISK MANAGEMENT PLAN

The Pharmacovigilance System, as described by the applicant, fulfils the requirements. The applicant has the services of a qualified person responsible for pharmacovigilance, and has the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.

An acceptable Risk Management Plan (RMP) has been submitted. The following table lists the summary of safety concerns which have been identified:

Summary of safety concerns	
Important identified risks	Hypersensitivity & anaphylaxis
	Hepatic & Cholestatic Jaundice
	Severe neutropenia or agranulocytosis
	Prolongation of prothrombin time
	Overgrowth of nonsusceptible organisms with prolonged use
	Antibiotic associated colitis
	Drug interaction with probenecid

Summary of safety concerns	
	Allergic skin reactions with concomitant allopurinol
	Glandular fever
	Severe skin reactions (EM, SJS, TEN & AGEP)
	Impaired renal function
Important potential risks	None
Missing information	None

Routine risk minimisation is provided through the Summary of Product Characteristics and the Patient Information Leaflet and this is sufficient.

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC), PATIENT INFORMATION LEAFLET (PIL) AND LABELLING

The SmPC, PIL and labelling are acceptable from a clinical perspective. The SmPC is consistent with that for the reference product. The PIL text is consistent with the details in the SmPC and in line with current guidance. The labelling is also in line with current guidance.

CLINICAL EXPERT REPORT (CLINICAL OVERVIEW)

The clinical overview is written by an appropriately qualified physician and is a suitable summary of the clinical aspects of the dossier.

CONCLUSION

The grant of a Marketing Authorisation is recommended.

OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

QUALITY

The important quality characteristics of Amoxicillin Sugar Free 3g Powder for Oral Suspension Sachets are well-defined and controlled. The specifications and batch analytical results indicate consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

NON-CLINICAL

No new non-clinical data were submitted and none is required for this type of application. As the pharmacokinetics, pharmacodynamics and toxicology of amoxicillin are well-known, no additional data were required.

EFFICACY

With the exception of the bioequivalence study, no new data were submitted and none are required for this type of application.

Bioequivalence has been demonstrated between the applicant's test product and the reference product Amoxil 3 g Powder for Oral Suspension Sachets Sucrose-Free (GlaxoSmithKline [Ireland] Limited, Ireland).

SAFETY

With the exception of the safety data generated from the bioequivalence study, no new data were submitted and none are required for this type of application. As the safety profile of amoxicillin is well known, no additional safety data were required. No new or unexpected safety concerns arose from the bioequivalence study.

PRODUCT LITERATURE

The SmPC, PIL and labelling are satisfactory and consistent with those for the reference product, where appropriate and in line with current guidance.

BENEFIT/RISK ASSESSMENT

The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. Extensive clinical experience with amoxicillin is considered to have demonstrated the therapeutic value of the compound. The benefit/risk balance is therefore considered to be positive.

Amoxicillin Sugar Free 3g powder for Oral Suspension Sachets

PL 25298/0032

STEPS TAKEN FOR ASSESSMENT

1 The MHRA received the Marketing Authorisation application on 09 August 2013.

2 Following standard checks and communication with the applicant the MHRA considered the application valid on 27 August 2013.

3 Following assessment of the application, the MHRA requested further information relating to the dossier on 02 December 2013, 23 April 2014 and 20 May 2014.

4 The applicant responded to the MHRA's requests, providing further information on the dossier on 27 February 2014, 24 April 2014 and 06 June 2014.

5 The application was granted on 19 June 2014.

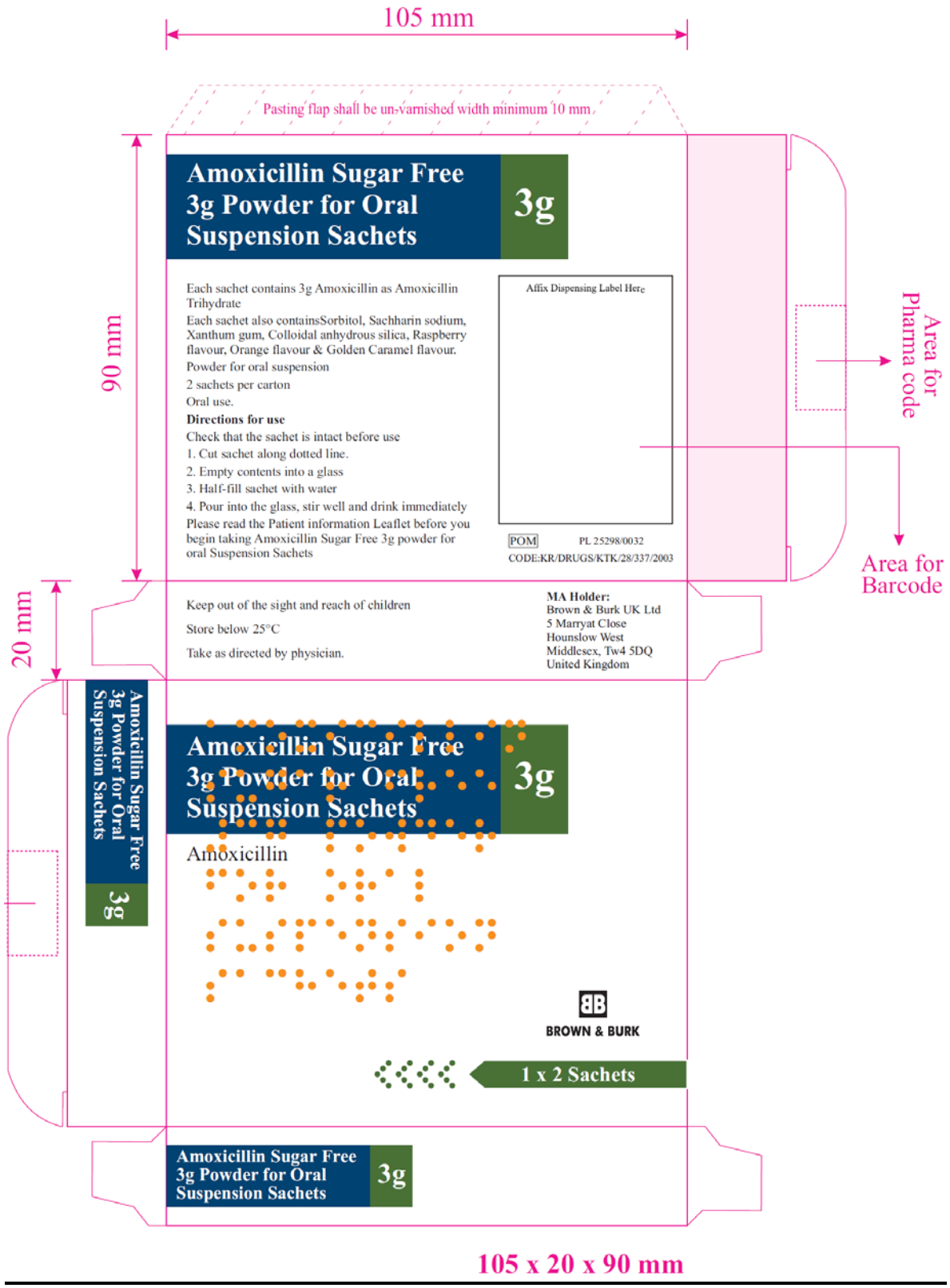
SUMMARY OF PRODUCT CHARACTERISTICS

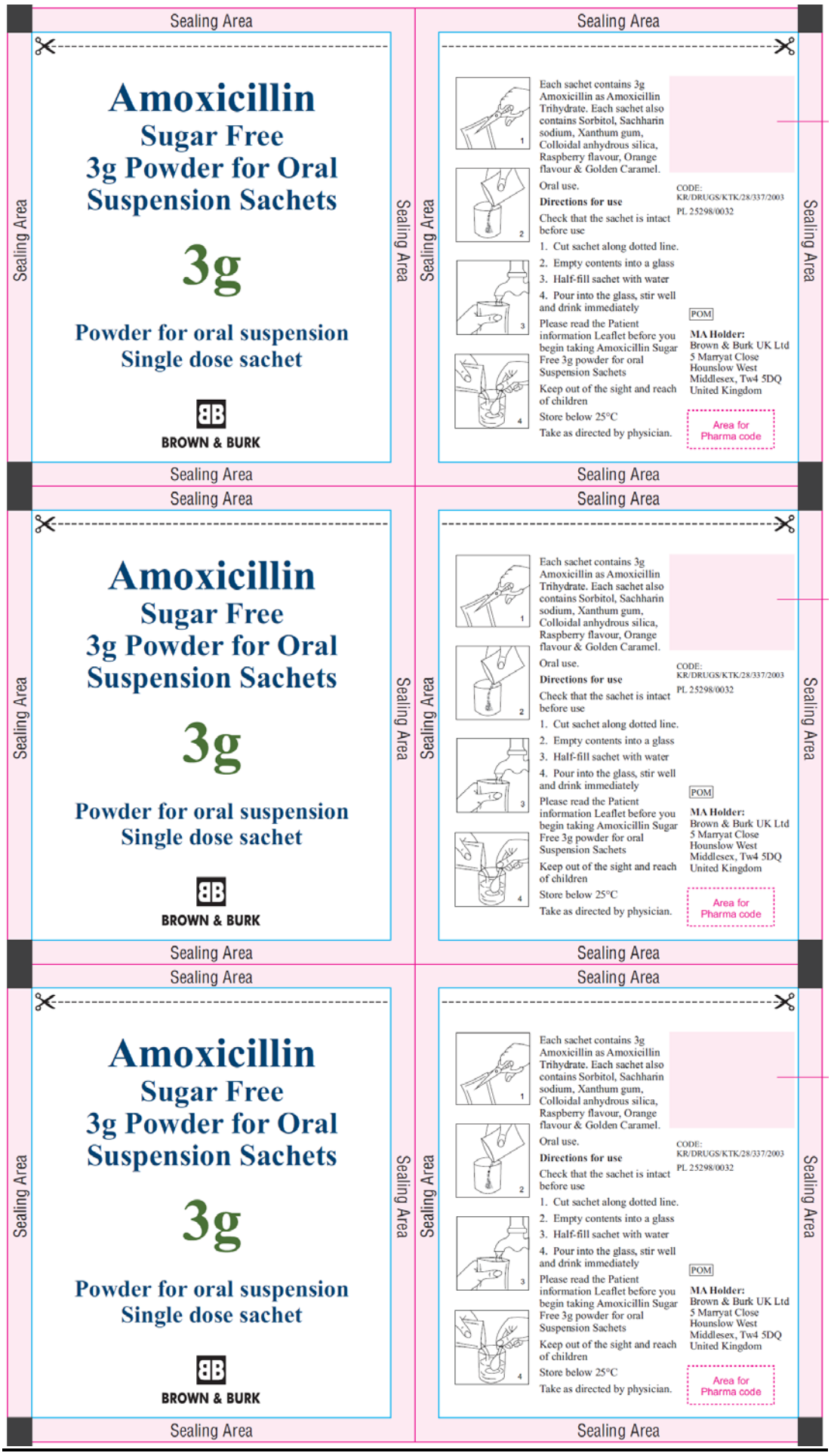
In accordance with Directive 2010/84/EU, the Summaries of Product Characteristics (SmPCs) for products granted Marketing Authorisations at a national level are available on the MHRA website.

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


105 mm
Pasting flap shall be un-varnished width minimum 10 mm
90 mm
20 mm
Amoxicillin Sugar Free 3g Powder for Oral Suspension Sachets
3g
Each sachet contains 3g Amoxicillin as Amoxicillin Trihydrate
Each sachet also containsSorbitol, Sachharin sodium, Xanthum gum, Colloidal anhydrous silica, Raspberry flavour, Orange flavour & Golden Caramel flavour.
Powder for oral suspension
2 sachets per carton
Oral use.
Directions for use
Check that the sachet is intact before use
1. Cut sachet along dotted line.
2. Empty contents into a glass
3. Half-fill sachet with water
4. Pour into the glass, stir well and drink immediately
Please read the Patient information Leaflet before you begin taking Amoxicillin Sugar Free 3g powder for oral Suspension Sachets
Affix Dispensing Label Here
POM
PL 25298/0032
CODE:KR/DRUGS/KTK/28/337/2003
Area for Pharma code
Area for Barcode
Keep out of the sight and reach of children
Store below 25°C
Take as directed by physician.
MA Holder:
Brown & Burk UK Ltd
5 Marryat Close
Hounslow West
Middlesex, Tw4 5DQ
United Kingdom
Amoxicillin
BROWN & BURK
1 x 2 Sachets
105 x 20 x 90 mm


Sealing Area
Amoxicillin
Sugar Free
3g Powder for Oral
Suspension Sachets
3g
Powder for oral suspension
Single dose sachet
BROWN & BURK
Each sachet contains 3g Amoxicillin as Amoxicillin Trihydrate. Each sachet also contains Sorbitol, Sachharin sodium, Xanthum gum, Colloidal anhydrous silica, Raspberry flavour, Orange flavour & Golden Caramel.
Oral use.
Directions for use
Check that the sachet is intact before use
1. Cut sachet along dotted line.
2. Empty contents into a glass
3. Half-fill sachet with water
4. Pour into the glass, stir well and drink immediately
Please read the Patient information Leaflet before you begin taking Amoxicillin Sugar Free 3g powder for oral Suspension Sachets
Keep out of the sight and reach of children
Store below 25°C
Take as directed by physician.
CODE: KR/DRUGS/KTK/28/337/2003
PL 25298/0032
POM
MA Holder:
Brown & Burk UK Ltd
5 Marryat Close
Hounslow West
Middlesex, Tw4 5DQ
United Kingdom
Area for Pharma code