Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Butec 5 microgram/hour Transdermal Patch
Butec 10 microgram/hour Transdermal Patch
Butec 20 microgram/hour Transdermal Patch
(buprenorphine)

PL 40431/0024-0026

UKPAR

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LAY SUMMARY

Butec 5 microgram/hour Transdermal Patch
Butec 10 microgram/hour Transdermal Patch
Butec 20 microgram/hour Transdermal Patch
(buprenorphine)

This is a summary of the Public Assessment Report (PAR) for Butec 5 microgram/hour, 10 microgram/hour and 20 microgram/hour Transdermal Patch (PL 40431/0024-0026). It explains how the applications for Butec 5 microgram/hour, 10 microgram/hour and 20 microgram/hour Transdermal Patch were assessed and their authorisations recommended, as well as the conditions of use. It is not intended to provide practical advice on how to use Butec 5 microgram/hour, 10 microgram/hour and 20 microgram/hour Transdermal Patch.

For practical information about using Butec 5 microgram/hour, 10 microgram/hour and 20 microgram/hour Transdermal Patch, patients should read the package leaflet or contact their doctor or pharmacist.

The products may be referred to as 'Butec Transdermal Patch' or 'Butec Transdermal Patches' in this report.

What are Butec Transdermal Patches and what are they used for?

These medicines are the same as BuTrans 5, 10 and 20 microgram/hour transdermal patch (PL 16950/0136-0138) held by Napp Pharmaceuticals Limited, which are already authorised in the UK. The licence holder (Napp Pharmaceuticals Limited) for BuTrans 5, 10 and 20 microgram/hour Transdermal patch has agreed that its own scientific data can be used as a basis for the grant of identical licences for Butec Transdermal Patches (informed consent).

Butec Transdermal Patches are used to relieve moderate, long-lasting pain that requires the use of a strong painkiller. Butec Transdermal Patches should not be used to relieve acute pain.

How do Butec Transdermal Patches work?

Butec Transdermal Patches contain the active ingredient, buprenorphine, which belongs to a group of medicines called strong analgesics or strong 'painkillers'. Butec Transdermal Patches act through the skin. After application, buprenorphine passes through the skin into the blood. Each patch lasts for seven days.

How are Butec Transdermal Patches used?

Butec Transdermal Patches are applied to the skin on the upper outer arm, upper chest, upper back or side of the chest.

Butec Transdermal Patches are available in three strengths. Each 6.25 cm^2, 12.5 cm^2 or 25 cm^2 patch contains 5 mg, 10 mg or 20 mg of buprenorphine and releases 5, 10 or 20 microgram/hour over a period of 7 days. The prescribing doctor will decide which strength of Butec Transdermal Patch that will best suit the patient. During treatment, the doctor may change the patch used to a smaller or larger one if necessary. The patient should not apply more than two patches at the same time, regardless of the patch strength.

The patient should always use the Butec Transdermal Patch exactly as advised by the doctor and should check with the doctor or pharmacist if not sure.

Adults and elderly patients
Unless the doctor has advised differently, one Butec Transdermal Patch should be attached (as described in the package leaflet) and changed every seventh day, preferably at the same time of day. The patient's doctor may wish to adjust the dose after 3-7 days until the correct level of pain control has been found. If the doctor has advised that other painkillers in addition to the patch should be taken, the doctor's instructions should be strictly followed, otherwise the patient will not fully benefit from treatment with the Butec Transdermal Patch. The patch should be worn for 3 full days before increasing the dose; this is when the maximum effect of a given dose is established.

Patients under 18 years of age
Butec Transdermal Patches should not be used in patients below the age of 18 years.

Patients with kidney disease/ dialysis patients
In patients with kidney disease, no change in dose is necessary.

Patients with liver disease
In patients with liver disease, the effects and period of action of the Butec Transdermal Patch may be affected and the doctor will therefore check more closely on the patient.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

Butec Transdermal Patches can only be obtained with a prescription.

What benefits of Butec Transdermal Patches have been shown in studies?

The applications for Butec Transdermal Patches are considered to be identical to the previously authorised licences for BuTrans 5, 10 and 20 microgram/hour transdermal patch (Napp Pharmaceuticals Limited), with the same benefits and risks. So, no new studies have been provided for Butec Transdermal Patches. However, reference is made to the studies for BuTrans 5, 10 and 20 microgram/hour transdermal patch (Napp Pharmaceuticals Limited).

What are the possible side effects from Butec Transdermal Patches?

Like all medicines, Butec Transdermal Patches can cause side effects, although not everybody gets them.

For the full list of all side effects reported with Butec Transdermal Patches, see section 4 of the package leaflet.

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

Why are Butec Transdermal Patches approved?

No new or unexpected safety concerns arose from these applications. The MHRA, therefore, considered that the benefits of Butec Transdermal Patches outweigh their risks; and the grant of Marketing Authorisations was recommended.

What measures are being taken to ensure the safe and effective use of Butec Transdermal Patches?

A Risk Management Plan has been developed to ensure that Butec Transdermal Patches are used as safely as possible. Based on this plan, safety information has been included in the Summaries of Product Characteristics and the package leaflet for Butec Transdermal Patches, 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.

Other information about Butec Transdermal Patches.

Marketing Authorisations were granted in the UK to Qdem Pharmaceuticals Limited on 18 June 2015.

The full PAR for Butec Transdermal Patches follows this summary.

For more information about treatment with Butec Transdermal Patches, read the package leaflet, or contact your doctor or pharmacist.

This summary was last updated in August 2015.

Butec 5 microgram/hour Transdermal Patch
Butec 10 microgram/hour Transdermal Patch
Butec 20 microgram/hour Transdermal Patch
(buprenorphine)

PL 40431/0024-0026

SCIENTIFIC DISCUSSION

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INTRODUCTION

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Qdem Pharmaceuticals Limited Marketing Authorisations for the medicinal products Butec 5 microgram/hour, 10 microgram/hour and 20 microgram/hour Transdermal Patch (PL 40431/0024-0026) on 18 June 2015. These are prescription-only medicines (POM) that are indicated for the treatment of non-malignant pain of moderate intensity when an opioid is necessary for obtaining adequate analgesia. Butec Transdermal patches are not suitable for the treatment of acute pain.

The applications were submitted as informed consent applications according to Article 10c of Directive 2001/83/EC, as amended, cross-referring to BuTrans 5, 10 and 20 microgram/hour transdermal patch (PL 16950/0136-0138, Napp Pharmaceuticals Limited), which were authorised on 10 June 2005 as hybrid applications, following incoming Mutual Recognition Procedure DK/H/718/001-003/MR, with Denmark as Reference Member State and the UK as a Concerned Member State.
Butec Transdermal Patches contain the active ingredient buprenorphine. Buprenorphine is a partial opioid agonist, acting at the mu opioid receptor. It also has antagonistic activity at the kappa opioid receptor.

No new data were submitted nor were necessary to be submitted for these applications, as the data are identical to that of the previously granted cross-reference products.

PHARMACEUTICAL ASSESSMENT

LICENCE NO(S): PL 40431/0024-0026
PROPRIETARY NAME(S): Butec 5 microgram/hour Transdermal Patch
Butec 10 microgram/hour Transdermal Patch
Butec 20 microgram/hour Transdermal Patch
ACTIVE(S): Buprenorphine
COMPANY NAME: Qdem Pharmaceuticals Limited
E.C. ARTICLE: Article 10c of Directive 2001/83/EC, as amended
LEGAL STATUS: POM

1. INTRODUCTION

These are informed consent applications for the products Butec 5 microgram/hour, 10 microgram/hour and 20 microgram/hour Transdermal Patch (PL 40431/0024-0026) submitted under Article 10c of Directive 2001/83/EC, as amended.

The applications cross-refer to BuTrans 5, 10 and 20 microgram/hour Transdermal patch (PL 16950/0136-0138, Napp Pharmaceuticals Limited), which were granted Marketing Authorisations in the UK on 10 June 2005. The applications are considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1. Name

The proposed names of the products are Butec 5 microgram/hour, 10 microgram/hour and 20 microgram/hour Transdermal Patch. The products have been named in line with current requirements.

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

Each Butec 5 microgram/hour Transdermal Patch contains 5 mg of buprenorphine in a patch size of 6.25 cm^2 and releases 5 micrograms of buprenorphine per hour (over a period of 7 days).

Each Butec 10 microgram/hour Transdermal Patch contains 5 mg of buprenorphine in a patch size of 12.5 cm^2 and releases 10 micrograms of buprenorphine per hour (over a period of 7 days).

Each Butec 20 microgram/hour Transdermal Patch contains 20 mg of buprenorphine in a patch size of 25 cm^2 and releases 20 micrograms of buprenorphine per hour (over a period of 7 days).

The products are packaged in sealed sachets, composed of identical top and bottom layers of heat-sealable laminate, comprising (from outside to inside) paper, low-density polyethylene, aluminium and poly(acrylic acid-co-ethylene). The products are available in pack sizes of 1, 2, 3, 4, 5, 8, 10 and 12 transdermal patches.

Not all pack sizes may be marketed.

The proposed shelf life for the products is 2 years, with the special storage conditions ‘Do not store above 25°C’. The packaging, proposed shelf-life and storage conditions are consistent with the details registered for the respective cross reference products.

2.3. Legal status

On approval, the products will be available as Prescription Only Medicines (POM).

2.4. Marketing Authorisation Holder/Contact Persons/Company
Qdem Pharmaceuticals Limited, Cambridge Science Park, Milton Road, Cambridge, CB4 0AB, United Kingdom.

The Qualified Person (QP) responsible for pharmacovigilance is stated and a satisfactory CV has been provided.

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

2.6. Qualitative and quantitative composition
The proposed compositions are consistent with the details registered for the respective cross-reference products.

2.7. Manufacturing process
The proposed manufacturing processes are consistent with the details registered for the cross-reference products and the maximum batch sizes are stated.

2.8. Finished product/shelf-life specification
The proposed finished product specifications are consistent with the details registered for the cross-reference products.

2.9. Drug substance specification
The proposed drug substance specification is consistent with the details registered for the cross-reference products.

2.10. TSE Compliance
None of the excipients contain materials of animal or human origin. This is consistent with the cross-reference products.

2.11. Bioequivalence
No bioequivalence data are required to support these informed consent applications because the proposed products are manufactured to the same formulae and utilises the same processes as the reference products, BuTrans 5, 10 and 20 microgram/hour transdermal patch (PL 16950/0136-0138; Napp Pharmaceuticals Limited).

3. EXPERT REPORT
The applicant cross-refers to the data for BuTrans 5, 10 and 20 microgram/hour transdermal patch (PL 16950/0136-0138; Napp Pharmaceuticals Limited), to which these applications are claimed to be identical. This is acceptable.

4. PRODUCT NAME & APPEARANCE
See Section 2.1 for details of the proposed product names. The appearance of each product is identical to the respective cross-reference product.

5. SUMMARIES OF PRODUCT CHARACTERISTICS (SmPCs)
The proposed SmPCs are consistent with the details registered for the respective cross-reference products.

6. PATIENT INFORMATION LEAFLET (PIL) AND LABELLING

PIL

The PIL has been prepared in line with the details registered for the cross-reference products.

Napp Pharmaceuticals Limited has previously submitted results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC, as amended, for BuTrans 5, 10 and 20 microgram/hour Transdermal patch (PL 16950/0136-0138).The results indicate that the 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 it contains.

User-testing of the PIL for Butec 5 microgram/hour, 10 microgram/hour and 20 microgram/hour Transdermal Patch (PL 40431/0024-0026) has been accepted based on the bridging report provided by the applicant making reference to the successful user-testing of the PIL for BuTrans 5, 10 and 20 microgram/hour transdermal patch (PL 16950/0136-0138) as the 'parent PIL'.

Carton and label

The proposed artwork is consistent with the artwork registered for the cross-reference products and complies with statutory requirements. In line with current legislation, the applicant has also included the name of each product in Braille on the outer packaging and has included sufficient space for a standard UK pharmacy dispensing label.

7. CONCLUSION

The data submitted with the applications are acceptable. The grant of Marketing Authorisations is recommended.

NON-CLINICAL ASSESSMENT

As these are informed consent applications submitted under Article 10c of Directive 2001/83/EC, as amended, no new non-clinical data have been supplied and none are required.

Suitable justification has been provided for non-submission of an Environmental Risk Assessment. As the applications are identical versions of already authorised products, it is not expected that environmental exposure will increase following approval of the Marketing Authorisations for the proposed products.

The grant of Marketing Authorisations is recommended.

CLINICAL ASSESSMENT

As these are informed consent applications submitted under Article 10c of Directive 2001/83/EC, as amended, no new clinical data have been supplied and none are required.

The Marketing Authorisation Holder has provided details of a suitable pharmacovigilance system that fulfils the requirements and provides adequate evidence that they have the services of a qualified person responsible for pharmacovigilance, and have 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. Please see below a table of the summary of safety concerns.

Summary of safety concerns	
Important identified risks	Respiratory depression Accidental overdose Drug withdrawal syndrome and physical dependence
Important potential risks	Drug abuse Medication error Psychological dependence Off-label use (Cutting of BTDS patch to achieve an intermediate dose)
Important missing information	Use in pregnant or breastfeeding women Paediatric use

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

The grant of Marketing Authorisations is recommended.

OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

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

NON-CLINICAL
No new non-clinical data were submitted and none are required for applications of this type.

EFFICACY
The applications are identical to the previously granted licences for BuTrans 5, 10 and 20 microgram/hour transdermal patch (PL 16950/0136-0138; Napp Pharmaceuticals Limited).

SAFETY
No new safety data were supplied or required for these applications. Buprenorphine has a well-established safety profile. No new or unexpected safety concerns arose from these applications.

PRODUCT LITERATURE
The SmPCs and PIL are satisfactory, and consistent with those for the cross-reference products. The labelling text complies with statutory requirements and is satisfactory.

BENEFIT/RISK ASSESSMENT
The quality of the products is acceptable, and no new non-clinical or clinical safety concerns have been identified. The applicant's products are identical to the cross-reference products. Extensive clinical experience with buprenorphine is considered to have demonstrated the therapeutic value of the compounds. The benefit/risk assessment is, therefore, considered to be positive.

Butec 5 microgram/hour Transdermal Patch
Butec 10 microgram/hour Transdermal Patch
Butec 20 microgram/hour Transdermal Patch
(buprenorphine)

PL 40431/0024-0026

STEPS TAKEN FOR ASSESSMENT

1 The MHRA received the Marketing Authorisation applications on 05 September 2014.

2 Following standard checks and communication with the applicant the MHRA considered the applications valid on 15 September 2014.

3 Following assessment of the application the MHRA requested further information relating to the dossier on 12 December 2014 and 27 March 2015.

4 The applicant responded to the MHRA's request, providing further information on the 27 February 2015 and 20 April 2015.

5 The applications were granted on 18 June 2015.

Butec 5 microgram/hour Transdermal Patch
Butec 10 microgram/hour Transdermal Patch
Butec 20 microgram/hour Transdermal Patch
(buprenorphine)

PL 40431/0024-0026

STEPS TAKEN AFTER AUTHORISATION – SUMMARY

The following table lists non-urgent safety updates to the Marketing Authorisations 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
16/12/2015	Medical Type II	PL 40431/0024-0004, PL 40431/0025-0003 & PL 40431/0026-0003: To update section 4.2 (Posology and administration) of the SmPC in line with the Company Core Data Sheet and to make editorial changes to sections 2, 3 and 4.1 of the SmPC. Consequently, the PIL has been updated.	Approved on 02/02/2016-Annex 1
17/12/2015	Medical Type II	PL 40431/0024-0011, PL 40431/0025-0010 & PL 40431/0026-0010: To update section 5.1 of the SmPC in line with the Company Core Data Sheet and in the QRD template. Consequently, the PIL has been updated.	Approved on 02/02/2016-Annex 2

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


Butec® 5 microgram/hour
Transdermal Patch
Buprenorphine
4 patches
Mon Tue Wed Thur Fri Sat Sun
Time:
Tick the day and enter the time when you apply the first patch. The second application should be made on the same day and time of the following week.
Keep out of sight and reach of children
Use as directed by your doctor.
Do not store above 25ºC
Dispose of used patches carefully using the original pouch
Please read the enclosed leaflet before use
This medicine can make you feel sleepy. Do not drive while taking this medicine until you know how it makes you feel.
See the leaflet inside for more information.
PL 40431/0024
One transdermal patch (active surface area: 6.25 cm²) contains 5 mg of buprenorphine and releases 5 micrograms/hour over a period of 7 days.
Also includes: Levulinic acid; Oleyl oleate; Povidone (PVP); Polyacrylate (Durotak 387-2051 & 387-2054); Polyethylene terephthalate foil/backing layer/liner.
POM
For use on the skin
Do not use the patch if the pouch seal is broken
Butec® 5 microgram/hour
Transdermal Patch
Buprenorphine
New advice for drivers – see leaflet inside
4 patches
7 day duration per patch
Qdem pharmaceuticals
FK00132
79x17x81mm
V3
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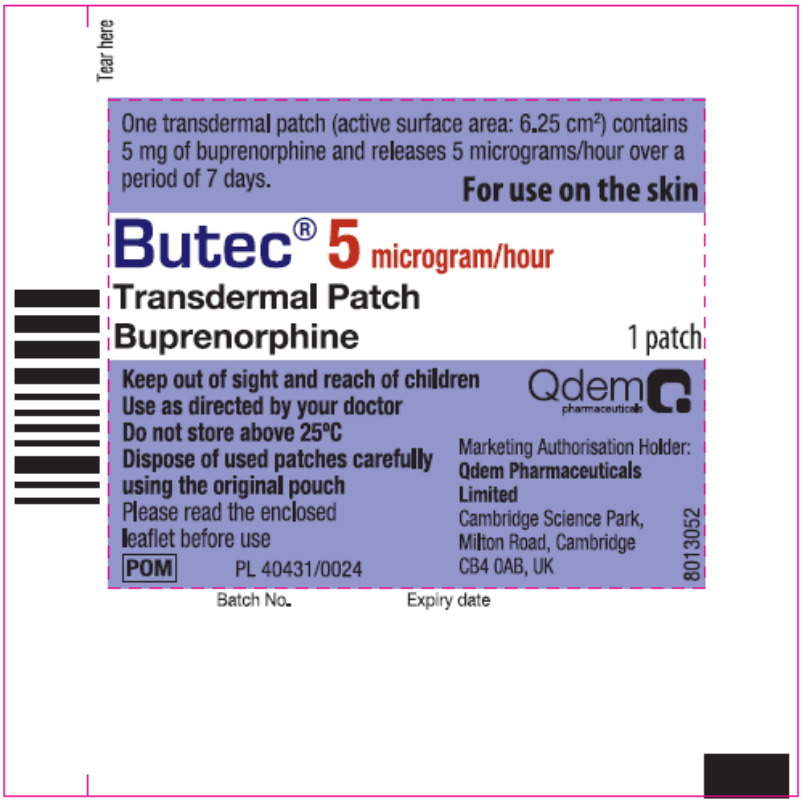
5 060307 902046
Marketing Authorisation Holder:
Qdem Pharmaceuticals Limited
Cambridge Science Park, Milton Road,
Cambridge CB4 0AB, UK
Batch No.
Expiry date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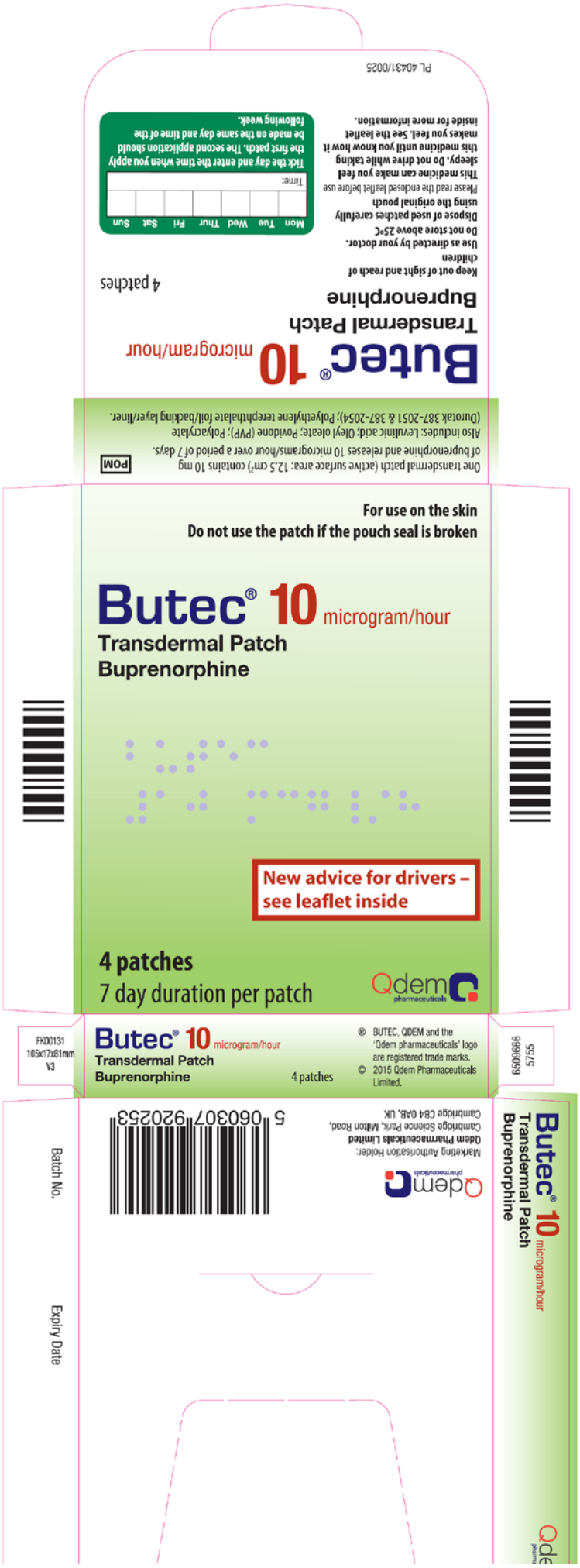
One transdermal patch (active surface area: 6.25 cm²) contains 5 mg of buprenorphine and releases 5 micrograms/hour over a period of 7 days.
For use on the skin
Butec® 5 microgram/hour
Transdermal Patch
Buprenorphine
1 patch
Keep out of sight and reach of children
Use as directed by your doctor
Do not store above 25°C
Dispose of used patches carefully using the original pouch
Please read the enclosed leaflet before use
POM
PL 40431/0024
Qdem pharmaceuticals
Marketing Authorisation Holder:
Qdem Pharmaceuticals Limited
Cambridge Science Park,
Milton Road, Cambridge
CB4 0AB, UK
8013052
Batch No.
Expiry date


PL 40431/0025
Butec® 10 microgram/hour
Transdermal Patch
Buprenorphine
4 patches
Keep out of sight and reach of children
Use as directed by your doctor.
Do not store above 25ºC
Dispose of used patches carefully
Please read the enclosed leaflet before use
This medicine can make you feel sleepy. Do not drive while taking this medicine until you know how it makes you feel. See the leaflet inside for more information.
Tick the day and enter the time when you apply the first patch. The second application should be made on the same day and time of the following week.
Mon Tue Wed Thur Fri Sat Sun
Time:
One transdermal patch (active surface area: 12.5 cm²) contains 10 mg of buprenorphine and releases 10 micrograms/hour over a period of 7 days.
Also includes: Levulinic acid; Oleyl oleate; Povidone (PVP); Polyacrylate (Duratak 387-2051 & 387-2054); Polyethylene terephthalate foil/backing layer/liner.
POM
For use on the skin
Do not use the patch if the pouch seal is broken
Butec® 10 microgram/hour
Transdermal Patch
Buprenorphine
New advice for drivers – see leaflet inside
4 patches
7 day duration per patch
Qdem pharmaceuticals
FK00131
105x17x81mm
V3
Butec® 10 microgram/hour
Transdermal Patch
Buprenorphine
4 patches
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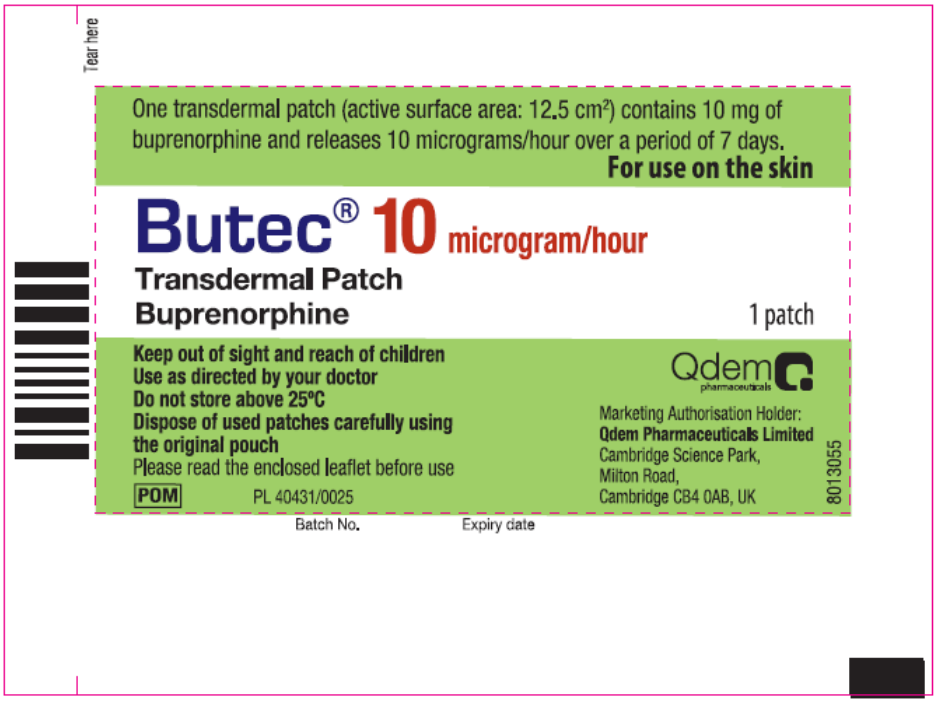
Marketing Authorisation Holder:
Qdem Pharmaceuticals Limited
Cambridge Science Park, Milton Road,
Cambridge CB4 0AB, UK
Batch No.
Expiry Date
Butec® 10 microgram/hour
Transdermal Patch
Buprenorphine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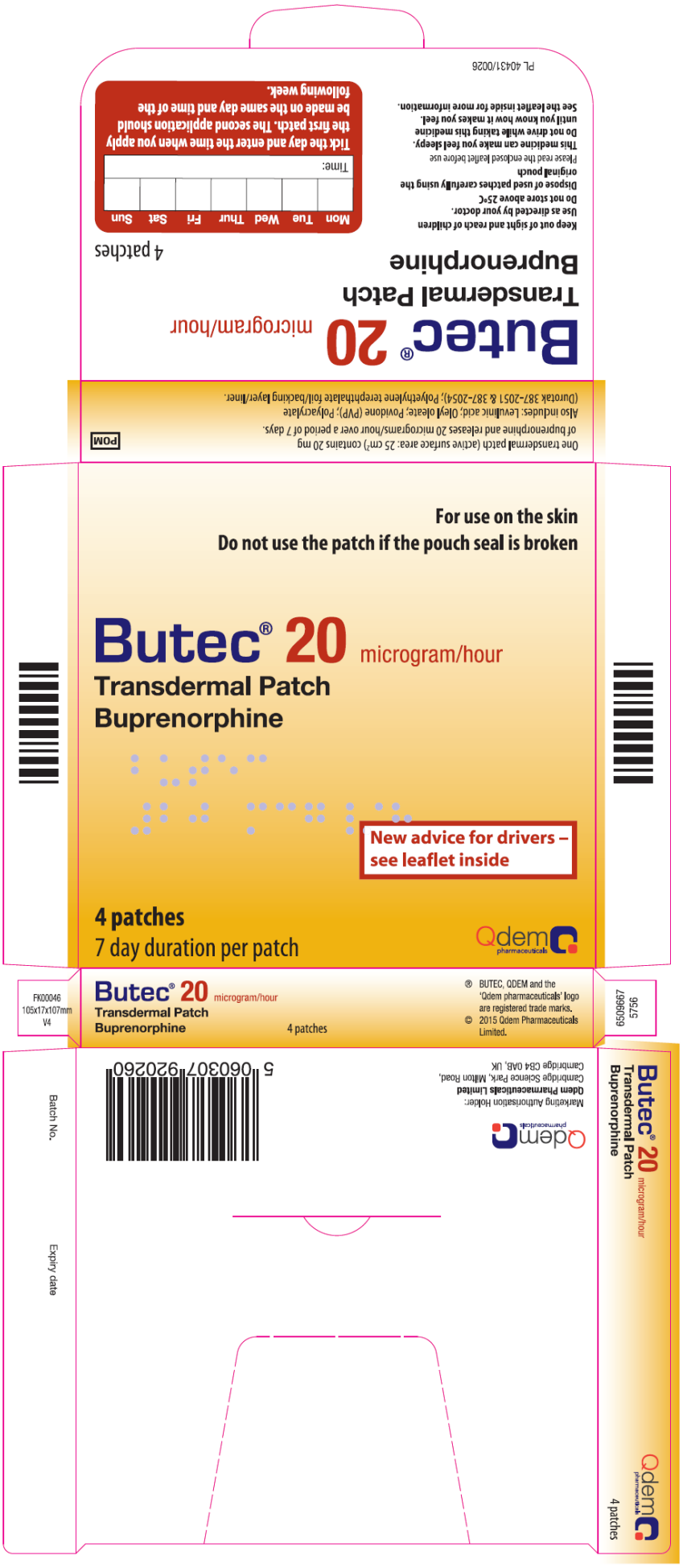
One transdermal patch (active surface area: 12.5 cm²) contains 10 mg of buprenorphine and releases 10 micrograms/hour over a period of 7 days.
For use on the skin
Butec® 10 microgram/hour
Transdermal Patch
Buprenorphine
1 patch
Keep out of sight and reach of children
Use as directed by your doctor
Do not store above 25ºC
Dispose of used patches carefully using the original pouch
Please read the enclosed leaflet before use
POM
PL 40431/0025
Batch No.
Expiry date
Qdem pharmaceuticals
Marketing Authorisation Holder:
Qdem Pharmaceuticals Limited
Cambridge Science Park,
Milton Road,
Cambridge CB4 0AB, UK
8013055


PL 40431/0026
Keep out of sight and reach of children
Use as directed by your doctor.
Do not store above 25°C
Dispose of used patches carefully using the original pouch
Please read the enclosed leaflet before use
This medicine can make you feel sleepy.
Do not drive while taking this medicine until you know how it makes you feel.
See the leaflet inside for more information.
Mon Tue Wed Thur Fri Sat Sun
Time:
Tick the day and enter the time when you apply the first patch. The second application should be made on the same day and time of the following week.
4 patches
Butec® 20 microgram/hour
Transdermal Patch
Buprenorphine
One transdermal patch (active surface area: 25 cm²) contains 20 mg of buprenorphine and releases 20 micrograms/hour over a period of 7 days.
Also includes: Levulinic acid; Oleyl oleate; Povidone (PVP); Polyacrylate (Durotak 387-2051 & 387-2054); Polyethylene terephthalate foil/backing layer/liner.
POM
For use on the skin
Do not use the patch if the pouch seal is broken
Butec® 20 microgram/hour
Transdermal Patch
Buprenorphine
New advice for drivers – see leaflet inside
4 patches
7 day duration per patch
Qdem pharmaceuticals
FK00046
105x17x107mm
V4
Butec® 20 microgram/hour
Transdermal Patch
Buprenorphine
4 patches
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57/56
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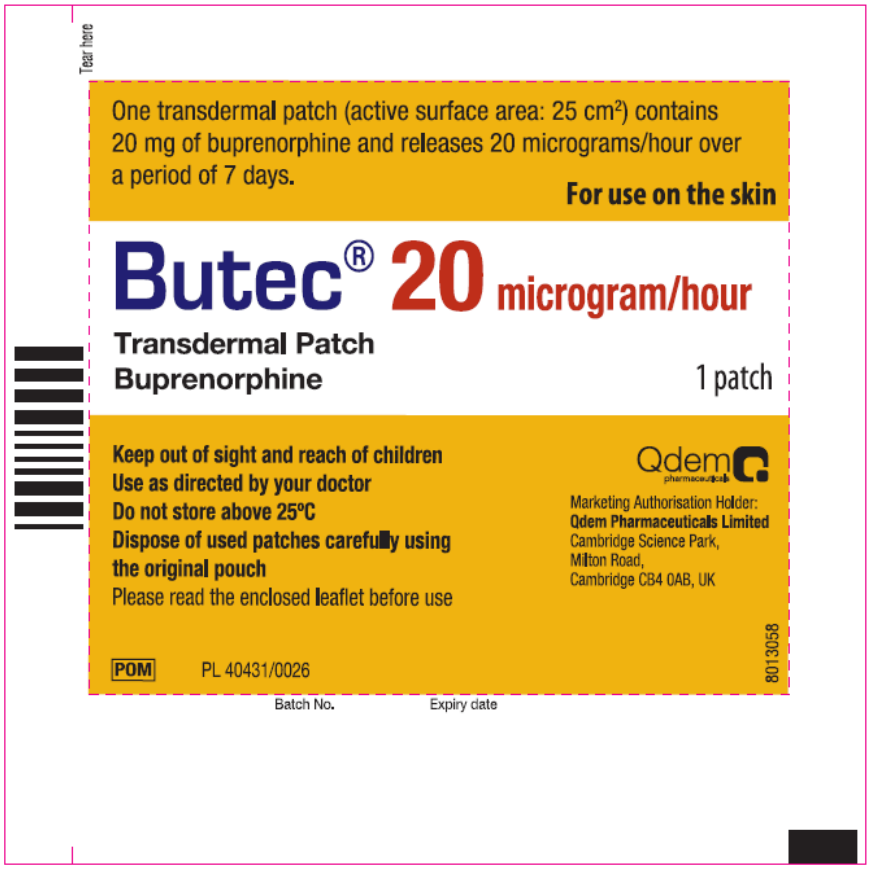
Marketing Authorisation Holder:
Qdem Pharmaceuticals Limited
Cambridge Science Park, Milton Road,
Cambridge CB4 0AB, UK
Batch No.
Expiry date
Butec® 20 microgram/hour
Transdermal Patch
Buprenorphine
4 patches


Tear here
One transdermal patch (active surface area: 25 cm²) contains 20 mg of buprenorphine and releases 20 micrograms/hour over a period of 7 days.
For use on the skin
Butec® 20 microgram/hour
Transdermal Patch
Buprenorphine
1 patch
Keep out of sight and reach of children
Use as directed by your doctor
Do not store above 25ºC
Dispose of used patches carefully using the original pouch
Please read the enclosed leaflet before use
Qdem pharmaceuticals
Marketing Authorisation Holder:
Qdem Pharmaceuticals Limited
Cambridge Science Park,
Milton Road,
Cambridge CB4 0AB, UK
POM
PL 40431/0026
8013058
Batch No.
Expiry date

ANNEX 1

Our Reference:	PL 40431/0024-0004 PL 40431/0025-0003 PL 40431/0026-0003
Product:	Butec 5 microgram/hour transdermal patch Butec 10 microgram/hour transdermal patch Butec 20 microgram/hour transdermal patch
Marketing Authorisation Holder:	Qdem Pharmaceuticals Limited
Active Ingredient(s):	Buprenorphine
Type of Procedure:	National
Submission Type:	Variation
Submission Category:	Type II
Submission Complexity:	Standard
EU Procedure Number (if applicable):	Not applicable

Reason:
To update section 4.2 (Posology and administration) of the SmPC in line with the Company Core Data Sheet and to make editorial changes to sections 2, 3 and 4.1 of the SmPC. Consequently, the PIL has been updated.

Supporting Evidence
Revised SmPC fragments and PIL.

Evaluation
The proposed changes to the SmPC and PIL are acceptable. The updated SmPC fragments and PIL have been incorporated into the Marketing Authorisations.

Conclusion
The proposed changes are acceptable.

Decision- Approved on 02 February 2016.

ANNEX 2

Our Reference:	PL 40431/0024-0011 PL 40431/0025-0010 PL 40431/0026-0010
Product:	Butec 5 microgram/hour transdermal patch Butec 10 microgram/hour transdermal patch Butec 20 microgram/hour transdermal patch
Marketing Authorisation Holder:	Qdem Pharmaceuticals Limited
Active Ingredient(s):	Buprenorphine
Type of Procedure:	National
Submission Type:	Variation
Submission Category:	Type II
Submission Complexity:	Standard
EU Procedure Number (if applicable):	Not applicable

Reason:
To update section 5.1 of the SmPC in line with the Company Core Data Sheet and in the QRD template. Consequently, the PIL has been updated.

Supporting Evidence
Revised SmPC fragments and PIL.

Evaluation
The proposed changes to the SmPC and PIL are acceptable. The updated SmPC fragments and PIL have been incorporated into the Marketing Authorisations.

Conclusion
The proposed changes are acceptable.

Decision- Approved on 02 February 2016.