Medicines & Healthcare products Regulatory Agency

MHRA

Public Assessment Report

National Procedure

Dapoxetine 30 mg film-coated tablets
Dapoxetine 60 mg film-coated tablets

Dapoxetine hydrochloride

PL 24837/0156-0157

Consilient Health Limited

LAY SUMMARY

Dapoxetine 30 mg film-coated tablets
Dapoxetine 60 mg film-coated tablets
Dapoxetine hydrochloride

This is a summary of the Public Assessment Report (PAR) for Dapoxetine 30 mg and 60 mg film-coated tablets. It explains how these products 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 these products.

These products will be referred to as Dapoxetine tablets in this lay summary for ease of reading.

These products have been authorised by MHRA for the United Kingdom. This procedure takes into account the outcome of decentralised (DC) procedures in European Union Member States (and/or Iceland, Liechtenstein, Norway) on 18 March 2020 (PT/H/2260/001-002/DC). This is known as the MR/DC Decision Reliance Procedure.

These applications were approved under Regulation 51B of the Human Medicines Regulation 2012, as amended (previously Article 10.1 of Directive 2001/83/EC, as amended).

For practical information about using Dapoxetine tablets, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

What are Dapoxetine tablets and what are they used for?
These products are generic medicines. This means that these medicines are the same as, and considered interchangeable with, reference medicines already authorised, called Priliqy 30 mg and 60 mg film-coated tablets.

Dapoxetine tablets are used to treat premature ejaculation in adult men aged 18 to 64 years. Premature ejaculation is when a man ejaculates with little sexual stimulation and before the man wants. This can cause problems for the man and may cause problems in sexual relationships.

How do Dapoxetine tablets work?
Dapoxetine tablets contain an active substance called dapoxetine hydrochloride. This belongs to a group of medicines called ‘selective serotonin reuptake inhibitors’ (SSRIs). Dapoxetine may also be known as a ‘urological’ medicine.

Dapoxetine hydrochloride increases the time it takes to ejaculate and can improve the control over the ejaculation. This may reduce the frustration or worry about fast ejaculation.

How are Dapoxetine tablets used?
The pharmaceutical form of these medicines is a film-coated tablet and the route of administration is oral (by mouth).

The recommended dose is 30 mg. The patient’s doctor may increase the dose to 60 mg. Patients should only take the medicine 1 to 3 hours before sexual activity is anticipated. Patients should not take this medicine more than once every 24 hours or every day.

Patients should swallow the tablets whole to avoid a bitter taste, with at least one full glass of water. This may help lower the chance of fainting (see section 4 of the PIL).

This medicine can be taken with or without food.

Patients should discuss their dapoxetine treatment with their doctor after the first 4 weeks or after 6 doses to see whether they should continue treatment. If treatment is continued, patients should see their doctor again to discuss this at least every six months.

For further information on how Dapoxetine tablets are used, refer to the PIL and Summaries of Product Characteristics (SmPCs) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

These medicines can only be obtained with a prescription.

The patient should always take the medicine exactly as their doctor/pharmacist has told them. The patient should check with their doctor or pharmacist if they are not sure.

What benefits of Dapoxetine tablets have been shown in studies?
Because Dapoxetine tablets are generic medicines, studies in healthy volunteers have been limited to tests to determine that they are bioequivalent to the reference medicines. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Dapoxetine tablets?
For the full list of all side effects reported with these medicines, see Section 4 of the PIL or the SmPCs available on the MHRA website.

If a patient gets any side effects, they should talk to their doctor, pharmacist or nurse. This includes any possible side effects not listed in the product information or the PIL that comes with the medicine. Patients can also report suspected side effects themselves, or a report can be made on their behalf by someone else who cares for them, directly via the Yellow Card scheme at https://yellowcard.mhra.gov.uk or search for 'MHRA Yellow Card' online. By reporting side effects, patients can help provide more information on the safety of this medicine.

Because Dapoxetine tablets are generic medicines and are bioequivalent to the reference medicines, their benefits and possible side effects are considered to be the same as the reference medicines.

Why were Dapoxetine tablets approved?
MHRA decided that the benefits are greater than the risks and recommended that these medicines can be approved for use.

What measures are being taken to ensure the safe and effective use of Dapoxetine tablets?
As for all newly-authorised medicines, a Risk Management Plan (RMP) has been developed for Dapoxetine tablets. The RMP details the important risks of Dapoxetine tablets, how these risks can be minimised, any uncertainties about Dapoxetine tablets (missing information), and how more information will be obtained about the important risks and uncertainties.

There are no safety concerns associated with use of Dapoxetine tablets.

The information included in the SmPC and the PIL is compiled based on the available quality, non-clinical and clinical data, and includes appropriate precautions to be followed by healthcare professionals and patients. Side effects of Dapoxetine tablets are continuously monitored and reviewed including all reports of suspected side-effects from patients, their carers, and healthcare professionals.

An RMP and a summary of the pharmacovigilance system have been provided with these applications and are satisfactory.

Other information about Dapoxetine tablets
Marketing authorisations were granted in the United Kingdom on 29 March 2023.

The full PAR for Dapoxetine tablets follows this summary.

This summary was last updated in April 2023.

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I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) considered that the applications for Dapoxetine 30 mg and 60 mg film-coated tablets (PL 24837/0156-0157) could be approved.

The products are approved for the following indication:
For the treatment of premature ejaculation (PE) in adult men aged 18 to 64 years.
Dapoxetine should only be prescribed to patients who meet all the following criteria:

- An intravaginal ejaculatory latency time (IELT) of less than two minutes; and
- Persistent or recurrent ejaculation with minimal sexual stimulation before, on, or shortly after penetration and before the patient wishes; and
- Marked personal distress or interpersonal difficulty as a consequence of PE; and
- Poor control over ejaculation; and
- A history of premature ejaculation in the majority of intercourse attempts over the prior 6 months.

Dapoxetine should be administered only as on-demand treatment before anticipated sexual activity. Dapoxetine should not be prescribed to delay ejaculation in men who have not been diagnosed with PE.

Dapoxetine is a potent selective serotonin reuptake inhibitor (SSRI) with an IC50 of 1.12 nM, while its major human metabolites, desmethyldapoxetine (IC50 <1.0 nM) and didesmethyldapoxetine (IC50 = 2.0 nM) are equivalent or less potent (dapoxetine-N-oxide (IC50 = 282 nM)).

Human ejaculation is primarily mediated by the sympathetic nervous system. The ejaculatory pathway originates from a spinal reflex centre, mediated by the brain stem, which is influenced initially by a number of nuclei in the brain (medial preoptic and paraventricular nuclei).

The mechanism of action of dapoxetine in premature ejaculation is presumed to be linked to the inhibition of neuronal reuptake of serotonin and the subsequent potentiation of the neurotransmitter's action at pre- and postsynaptic receptors.

In the rat, dapoxetine inhibits the ejaculatory expulsion reflex by acting at a supraspinal level within the lateral paragigantocellular nucleus (LPGi). Post ganglionic sympathetic fibers that innervate the seminal vesicles, vas deferens, prostate, bulbourethral muscles and bladder neck cause them to contract in a coordinated fashion to achieve ejaculation. Dapoxetine modulates this ejaculatory reflex in rats.

These products have been authorised by MHRA for the United Kingdom. This procedure takes into account the outcome of decentralised (DC) procedures in European Union Member States (and/or Iceland, Liechtenstein, Norway) on 18 March 2020 (PT/H/2260/001-002/DC).

For the scientific discussion of the quality, non-clinical and clinical assessment conducted during the MR and/or DC procedures, please refer to the Reference Member State (RMS) Public Assessment Report, available on the RMS regulatory agency website or on the Heads of Medicines Agencies website.

These applications were approved under Regulation 51B of the Human Medicines Regulation 2012, as amended (previously Article 10.1 of Directive 2001/83/EC, as amended).

The MHRA has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for these products at all sites responsible for the manufacture, assembly and batch release of these products.

A Risk Management Plan (RMP) and a summary of the pharmacovigilance system have been provided with these applications and are satisfactory.

Marketing authorisations were granted on 29 March 2023.

II. PRODUCT INFORMATION

Summaries of Product Characteristics (SmPCs)

The SmPCs are in line with current guidelines and are satisfactory.

PATIENT INFORMATION LEAFLET

The PIL is in line with current guidelines and is satisfactory.

LABEL

The labelling is in line with current guidelines and is satisfactory.

III. QUALITY ASPECTS

MHRA considered that the quality data submitted for these applications is satisfactory.

The grant of marketing authorisations was recommended.

IV. NON-CLINICAL ASPECTS

MHRA considered that the non-clinical data submitted for these applications is satisfactory.

The grant of marketing authorisations was recommended.

V. CLINICAL ASPECTS

MHRA considered that the clinical data submitted for these applications is satisfactory.

The grant of marketing authorisations was recommended.

VI. RISK MANAGEMENT PLAN (RMP)

The applicant has submitted an RMP, in accordance with the requirements of Regulation 182 of The Human Medicines Regulation 2012, as amended. The applicant proposes only routine pharmacovigilance and routine risk minimisation measures for all safety concerns. This is acceptable.

VII. USER CONSULTATION

A full colour mock-up of the Patient Information Leaflet (PIL) has been provided with the application, in accordance with legal requirements.

The PIL has been evaluated via a user consultation with target patient groups, in accordance with legal requirements, on the basis of a bridging report making reference to Priligy 30 mg and 60 mg, film-coated tablets (SE/H/718/01-02/DC; Berlin-Chemie AG) and Areston, 12.5 mg, film-coated tablets (NL/H/3773/001/DC; Medochemie Ltd). The bridging report submitted by the MAH is acceptable.

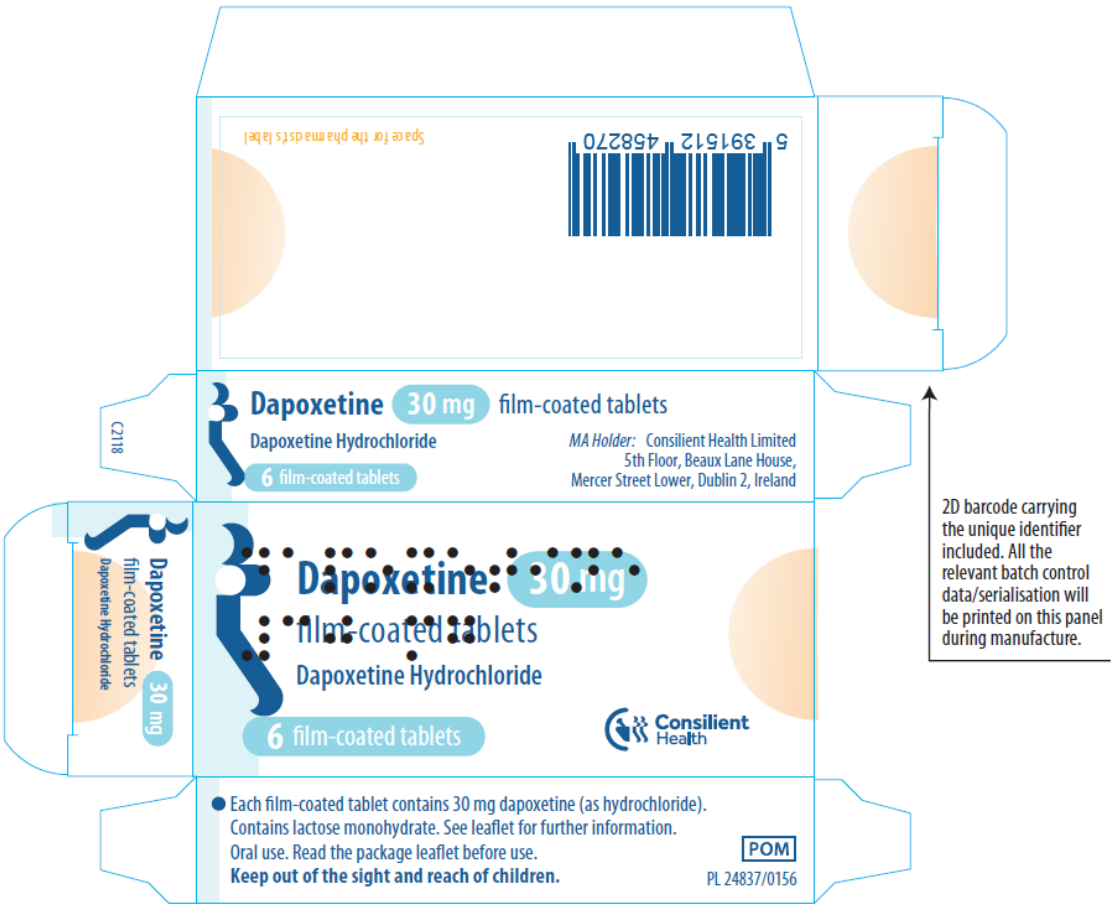
VIII. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION

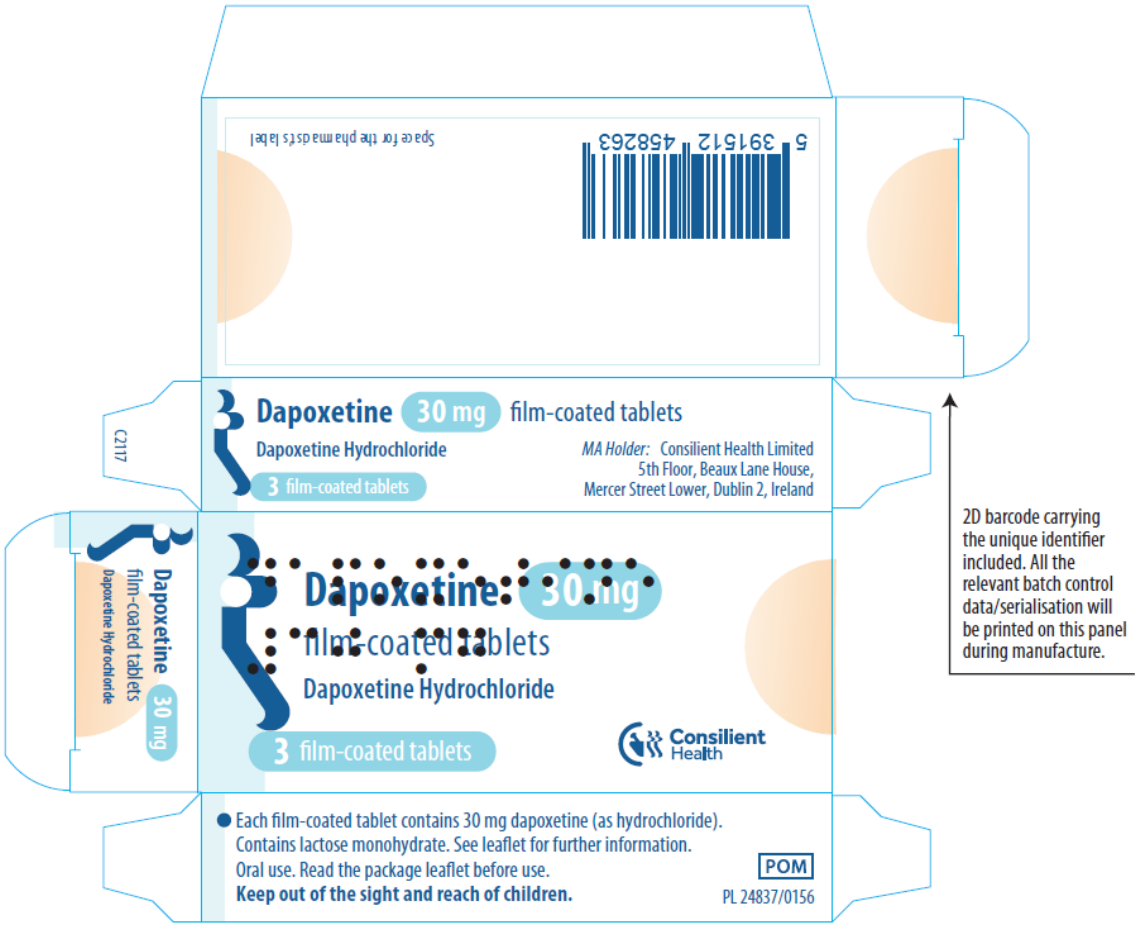
The quality of the products is acceptable, and no new non-clinical or clinical safety concerns have been identified. The benefit/risk balance is, therefore, considered to be positive.

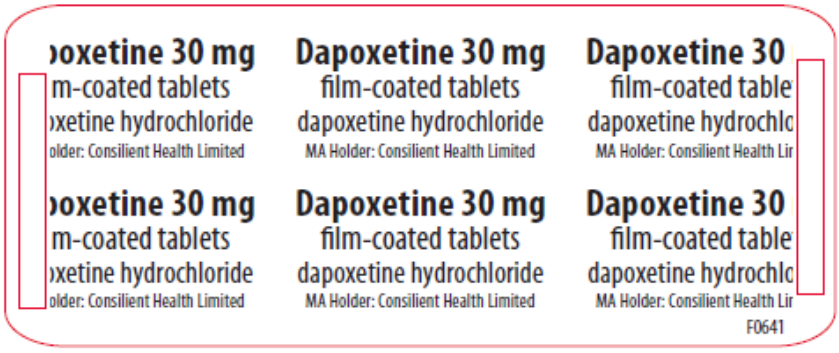
The Summaries of Product Characteristics (SmPCs), Patient Information Leaflet (PIL) and labelling are satisfactory.

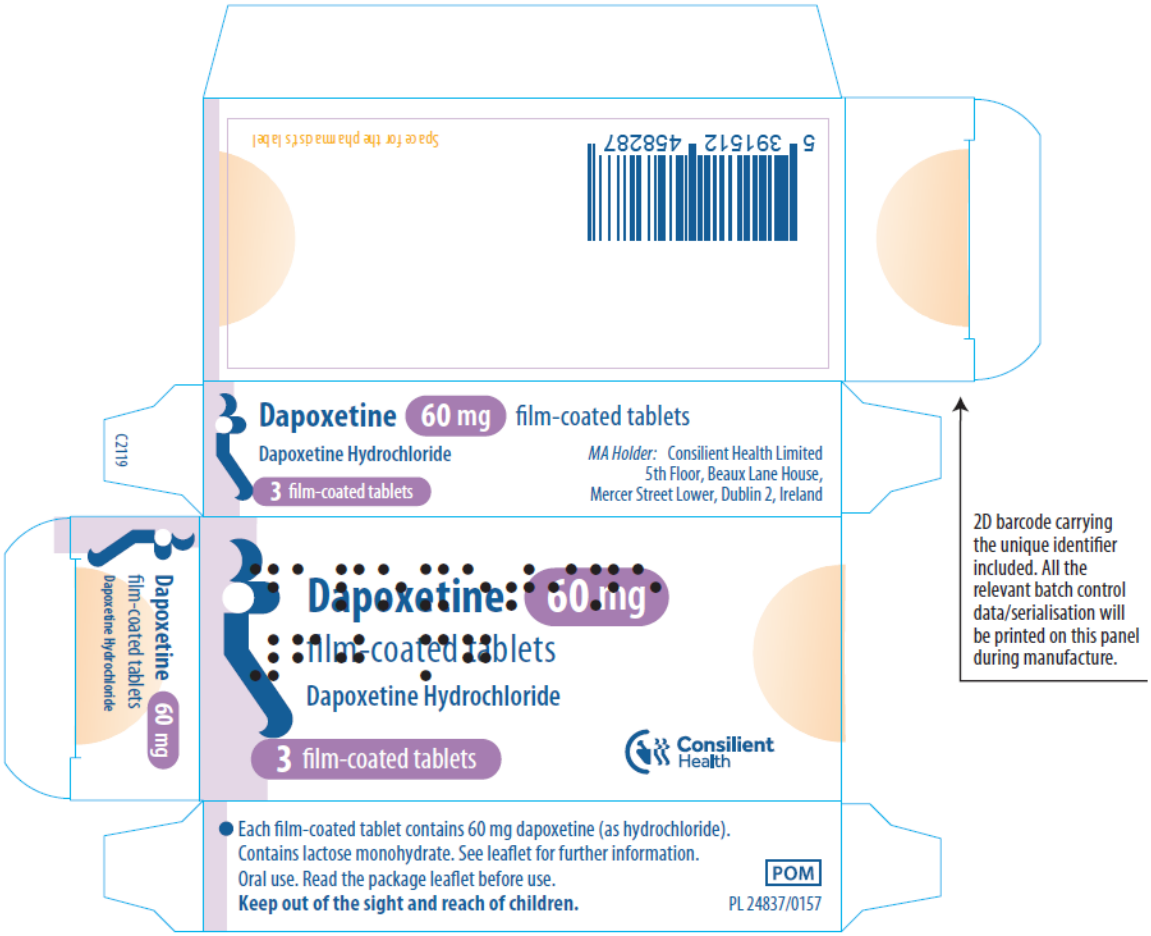
In accordance with legal requirements, the current approved UK versions of the SmPCs and PIL for these products are available on the MHRA website.

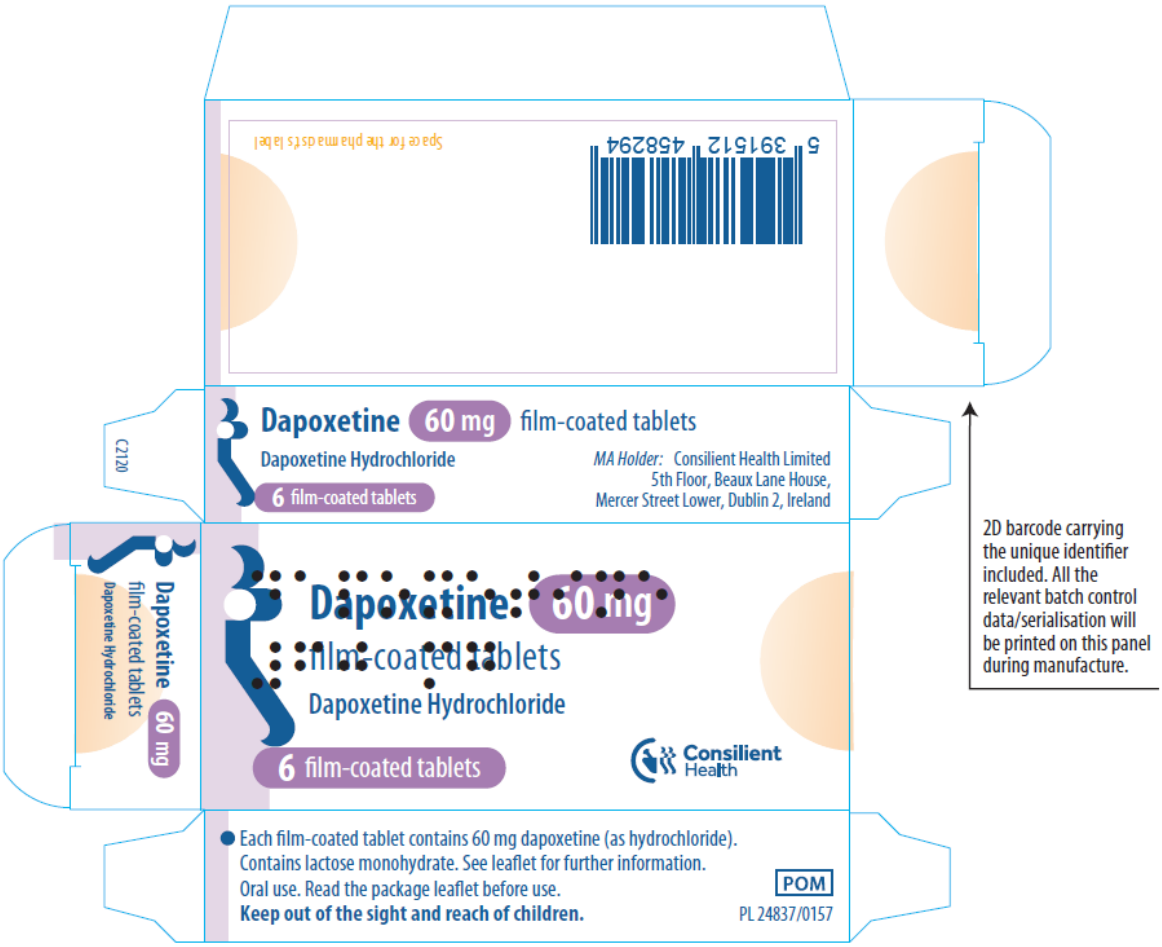
Representative copies of the labels at the time of UK licensing are provided below.

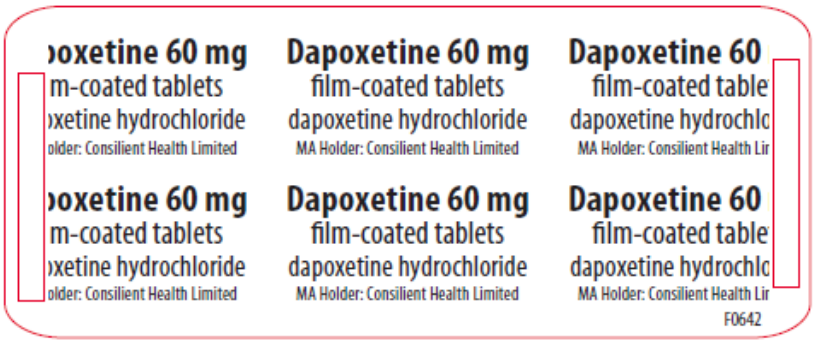



Space for the pharmacist's label
5 391512 458263
Dapoxetine 30 mg film-coated tablets
Dapoxetine Hydrochloride
3 film-coated tablets
MA Holder: Consilient Health Limited
5th Floor, Beaux Lane House,
Mercer Street Lower, Dublin 2, Ireland
C2117
Dapoxetine 30 mg
film-coated tablets
Dapoxetine Hydrochloride
3 film-coated tablets
Consilient Health
2D barcode carrying the unique identifier included. All the relevant batch control data/serialisation will be printed on this panel during manufacture.
Each film-coated tablet contains 30 mg dapoxetine (as hydrochloride).
Contains lactose monohydrate. See leaflet for further information.
Oral use. Read the package leaflet before use.
Keep out of the sight and reach of children.
POM
PL 24837/0156


Dapoxetine 30 mg
film-coated tablets
dapoxetine hydrochloride
MA Holder: Consilient Health Limited
F0641


Space for the pharmacist's label
5 391512 458287
Dapoxetine 60 mg film-coated tablets
Dapoxetine Hydrochloride
3 film-coated tablets
MA Holder: Consilient Health Limited
5th Floor, Beaux Lane House,
Mercer Street Lower, Dublin 2, Ireland
C2119
Dapoxetine 60 mg film-coated tablets Dapoxetine Hydrochloride
Dapoxetine 60 mg
film-coated tablets
Dapoxetine Hydrochloride
3 film-coated tablets
Consilient Health
Each film-coated tablet contains 60 mg dapoxetine (as hydrochloride).
Contains lactose monohydrate. See leaflet for further information.
Oral use. Read the package leaflet before use.
Keep out of the sight and reach of children.
POM
PL 24837/0157
2D barcode carrying the unique identifier included. All the relevant batch control data/serialisation will be printed on this panel during manufacture.


Space for the pharmacist's label
5 391512 458294
Dapoxetine 60 mg film-coated tablets
Dapoxetine Hydrochloride
6 film-coated tablets
MA Holder: Consilient Health Limited
5th Floor, Beaux Lane House,
Mercer Street Lower, Dublin 2, Ireland
C2120
Dapoxetine 60 mg film-coated tablets
Dapoxetine Hydrochloride
6 film-coated tablets
Consilient Health
2D barcode carrying the unique identifier included. All the relevant batch control data/serialisation will be printed on this panel during manufacture.
Each film-coated tablet contains 60 mg dapoxetine (as hydrochloride).
Contains lactose monohydrate. See leaflet for further information.
Oral use. Read the package leaflet before use.
Keep out of the sight and reach of children.
POM
PL 24837/0157


Dapoxetine 60 mg
film-coated tablets
dapoxetine hydrochloride
MA Holder: Consilient Health Limited
F0642

IX. TABLE OF CONTENT OF THE PAR UPDATE

Steps taken after the initial procedure with an influence on the Public Assessment Report (non-safety variations of clinical significance).

Please note that only non-safety variations of clinical significance are recorded below and in the annexes to this PAR. The assessment of safety variations, where significant changes are made, are recorded on the MHRA website or European Medicines Agency (EMA) website. Minor changes to the marketing authorisation are recorded in the current SmPCs and/or PIL available on the MHRA website.

Application type	**Scope**	**Product information affected**	**Date of grant**	**Outcome**	**Assessment report attached Y/N**