Medicines & Healthcare products Regulatory Agency

MHRA

Public Assessment Report

National Procedure

Hydventia 10 mg Tablets
Hydventia 20 mg Tablets

(hydrocortisone)

Resolution Chemicals Limited

Product Licence Numbers: PL 10321/0210-0211

Resolution Chemicals Limited

LAY SUMMARY

Hydventia 10 mg Tablets
Hydventia 20 mg Tablets

(hydrocortisone)

This is a summary of the Public Assessment Report (PAR) for Hydventia 10 mg Tablets (PL 10321/0210) and Hydventia 20 mg Tablets (PL 10321/0211). It explains how Hydventia 10 mg Tablets and Hydventia 20 mg Tablets 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 Hydventia 10 mg Tablets and Hydventia 20 mg Tablets.

These products will be referred to as Hydventia 10 mg and 20 mg Tablets in this lay summary, for ease of reading.

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

What are Hydventia 10 mg and 20 mg Tablets and what are they used for?
These applications are the same as Hydrocortisone 10 mg Tablets (PL 10321/0204) and Hydrocortisone 20 mg Tablets (PL 10321/0205), which are already authorised.

The Company responsible for Hydrocortisone 10 mg Tablets and Hydrocortisone 20 mg Tablets has agreed that its scientific data can be used as a basis for the grant of identical licences for Hydventia 10 mg and 20 mg Tablets.

Hydventia 10 mg and 20 mg Tablets are used:
- as replacement therapy for children with congenital adrenal hyperplasia which affects the body's natural production of steroids.
- to treat severe asthma and allergic reactions in adults and children.

How do Hydventia 10 mg and 20 mg Tablets work?
The active ingredient in Hydventia 10 mg and 20 mg Tablets is hydrocortisone. Hydrocortisone belongs to a group of medicines called steroids. Their full name is corticosteroids. These medicines are used to replace the adrenal hormones in the body, which may be lacking.

These corticosteroids occur naturally in the body and help to maintain health and well-being. Boosting the body with extra corticosteroid is an effective way to treat various illnesses involving inflammation in the body.

Hydventia 10 mg and 20 mg Tablets reduce this inflammation, which could otherwise go on making the patient's condition worse.

How are Hydventia 10 mg and 20 mg Tablets used?
The pharmaceutical form of these medicines is a tablet and the route of administration is oral (by mouth).

Taking these medicines
The amount the patient takes each day will depend on their illness. The number of tablets to be taken will be on the label of the medicine. If the patient is unsure about the dose to take, they must talk to their doctor or pharmacist.

Dosage for Acute Emergencies
The usual dose for adults is 60-80mg every 4-6 hours for 24 hours then gradually lowering over several days.

Use as replacement therapy in children
When used in replacement therapy, the usual dose for children is 10-30mg divided into two doses each day. The first dose taken in the morning may be larger than the second dose taken in the evening.

For further information on how Hydventia 10 mg and 20 mg Tablets is used, refer to the package leaflet and Summaries of Product Characteristics 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 these medicines exactly as their doctor has told them. The patient should check with their doctor or pharmacist if they are not sure.

What benefits of Hydventia 10 mg and 20 mg Tablets have been shown in studies?
Hydventia 10 mg and 20 mg Tablets are considered identical to the previously authorised products with the same benefits and risks. |No new studies have been provided for Hydventia 10 mg and 20 mg Tablets, however, reference is made to the studies for Hydrocortisone 10 mg Tablets and Hydrocortisone 20 mg Tablets.

What are the possible side effects of Hydventia10 mg and 20 mg Tablets?
Hydventia 10 mg and 20 mg Tablets are considered to be identical to the previously authorised products with the same benefits and risks.

For the full list of all side effects reported with these medicines, see Section 4 of the package leaflet or the Summaries of Product Characteristics (SmPC) available on the MHRA website.

Why was Hydventia 10 mg and 20 mg Tablets approved?
The MHRA decided that the benefits of Hydventia 10 mg and 20 mg Tablets are greater than the risks and recommended that these medicines are approved for use.

What measures are being taken to ensure the safe and effective use of Hydventia10 mg and 20 mg Tablets?
A Risk Management Plan (RMP) has been developed to ensure that Hydventia 10 mg and 20 mg Tablets are used as safely as possible. Based on this plan, safety information has been included in the SmPCs and the package leaflet, 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 and reviewed continuously.

Other information about Hydventia 10 mg and 20 mg Tablets
Marketing Authorisations were granted in the UK on 15 March 2019.

The full PAR for Hydventia 10 mg and 20 mg Tablets follows this summary.

This summary was last updated in May 2019.

TABLE OF CONTENTS

Contents

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 Hydventia 10 mg Tablets (PL 10321/0210) and Hydventia 20 mg Tablets (PL 10321/0211) could be approved.

Hydventia Tablets are indicated for replacement therapy in congenital adrenal hyperplasia in children.

Hydventia Tablets are also used for the emergency treatment of severe bronchial asthma, drug hypersensitivity reactions, serum sickness, angioneurotic oedema and anaphylaxis in adults and children.

The name of the active substance is hydrocortisone, which is an adrenal corticosteroid having glucocorticoid and some mineralocorticoid properties.

These are national abridged applications submitted under Article 10c of Directive 2001/83/EC, as amended (informed consent applications). The applications cross-refer to the reference products Hydrocortisone 10 mg Tablets (PL 10321/0204) and Hydrocortisone 20 mg Tablets (PL 10321/0205), currently held by Resolution Chemicals Limited, which were originally granted in the UK on 01 March 2016.

No new non-clinical or clinical data have been supplied and none are required for these informed consent applications.

Suitable justification has been provided for non-submission of an Environmental Risk Assessment (ERA). As the applications are for identical versions of already authorised products, no increase in environmental exposure is anticipated and no ERA is required.

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 15 March 2019.

II. EXPERT REPORT

The applicant cross-refers to the data for Hydrocortisone 10 mg Tablets (PL 10321/0204; Resolution Chemicals Limited) and Hydrocortisone 20 mg Tablets (PL 10321/0205; Resolution Chemicals Limited), to which these applications are claimed to be identical. This is acceptable.

III. ASSESSOR'S COMMENTS ON THE PRODUCT INFORMATION

SUMMARY OF PRODUCT CHARACTERITICS (SmPC)

The SmPCs are in line with those for Hydrocortisone 10 mg Tablets (PL 10321/0204; Resolution Chemicals Ltd) and Hydrocortisone 20 mg Tablets (PL 10321/0205; Resolution Chemicals Ltd), dated for October 2017.

PATIENT INFORMATION LEAFLET

A leaflet mock-up has been provided which has been aligned with that for product names of cross-reference products(s) (PL 10321/0204-0205), dated for January 2018. The user test report submitted for PL 10321/0204-0205has been provided.

LABEL

Label mock-ups have been provided.

IV. QUALITY ASPECTS

IV.1 Drug Substance

Drug substance specification

The source of the active is in line with the cross-reference products. The proposed drug substance specification is consistent with the details registered for the cross-reference product.

IV.2. Drug Products

Name

The products have been named in line with current requirements.

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

Hydventia 10 mg and 20 mg Tablets are available in AquaBa polyvinylchloride/polyvinylidene chloride aluminium blisters, in a pack size of 30 tablets.

The appearance of each product is identical to that of the respective cross-reference product.

The proposed shelf life of the products is 36 months with the recommended storage condition ‘Do not store above 25°C. Store in the original package in order to protect from light.’

The proposed packaging, shelf life and storage conditions are consistent with the details registered for the respective reference products.

Legal status

Prescription Only Medicines (POM).

Manufacturers

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

Qualitative and quantitative compositions

The proposed product compositions are consistent with the details registered for the reference products.

Manufacturing process & control of critical steps

The proposed manufacturing processes and process controls are consistent with the details registered for the reference products and the maximum batch sizes is stated.

Finished product release/shelf-life specifications

The proposed finished product specifications are in line with the details registered for the reference products

TSE Compliance

No excipients of animal or human origin are used in the final products.

Confirmation has been given that the magnesium stearate used in the tablets is of vegetable origin.

These products do not contain or consist of genetically modified organisms (GMO).

V. NON-CLINICAL ASPECTS

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

VI. CLINICAL ASPECTS

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

VII. RISK MANAGEMENT PLAN (RMP)

The Applicant has submitted a RMP, in accordance with the requirements of Directive 2001/83/EC, as amended. The Applicant proposes only routine pharmacovigilance and routine risk minimisation measures for all safety concerns. This is acceptable.

VIII. USER CONSULTATION

A user consultation with target patient groups on the PIL has been performed on the basis of a bridging report making reference to the PIL for Hydrocortisone 10 mg Tablets (PL 10321/0204; Resolution Chemicals Ltd) and Hydrocortisone 20 mg Tablets (PL 10321/0205; Resolution Chemicals Ltd). The bridging report submitted by the Marketing Authorisation Holder (MAH) is acceptable.

IX. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION

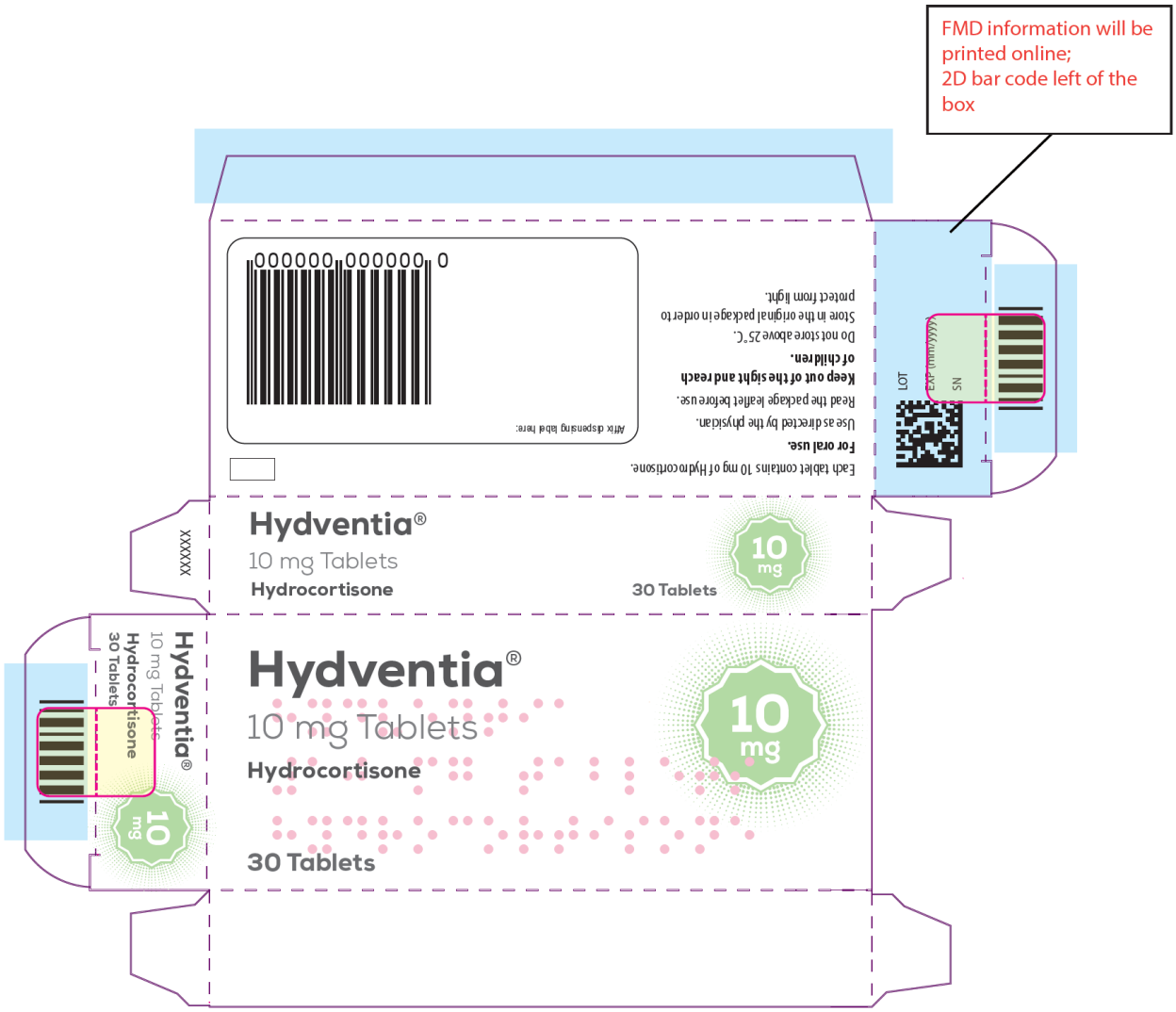
The quality of the products is acceptable, and no new non-clinical or clinical safety concerns have been identified. The applicant's products are identical to the cross-reference products. The benefit/risk balance is, therefore, considered to be the same as the cross-reference products and positive.

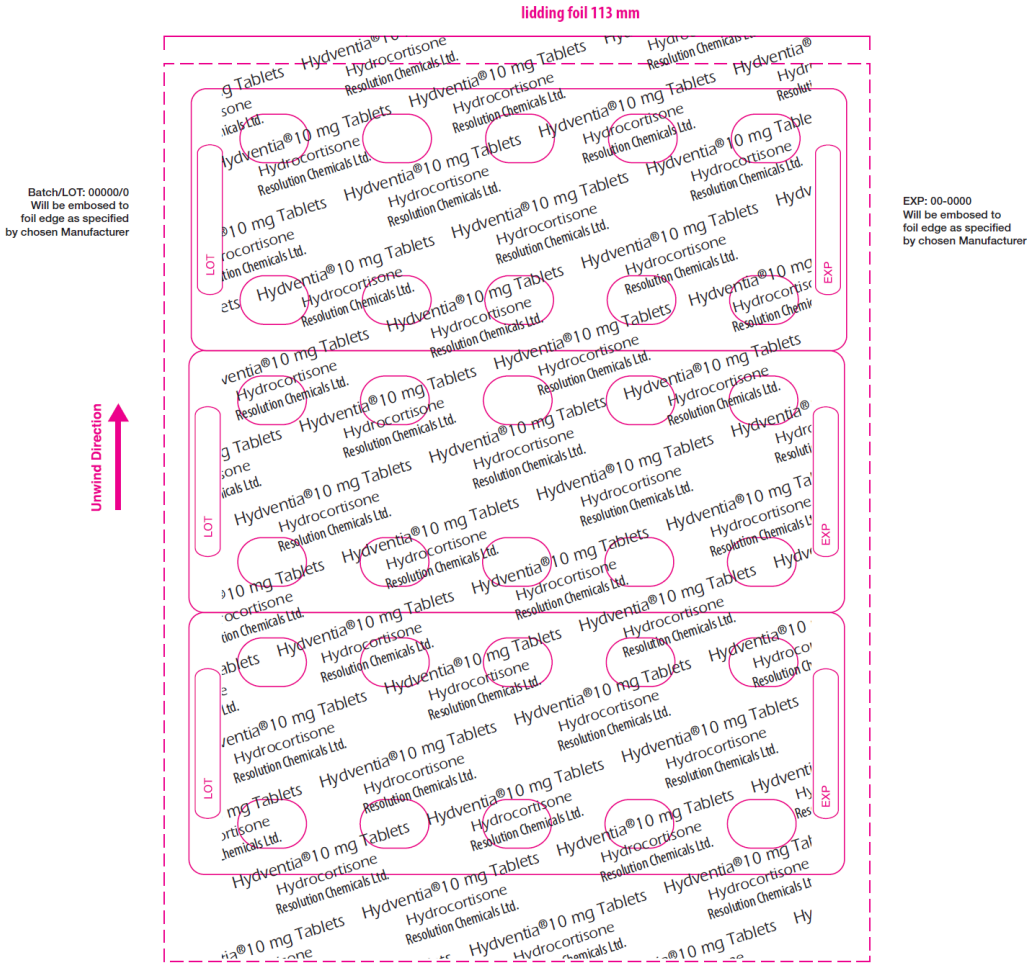
The Summaries of Product Characteristics (SmPCs), Patient Information Leaflet (PIL) and labelling are satisfactory, in line with current guidelines and consistent with the cross-reference products.

In accordance with Directive 2012/84/EU, 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.

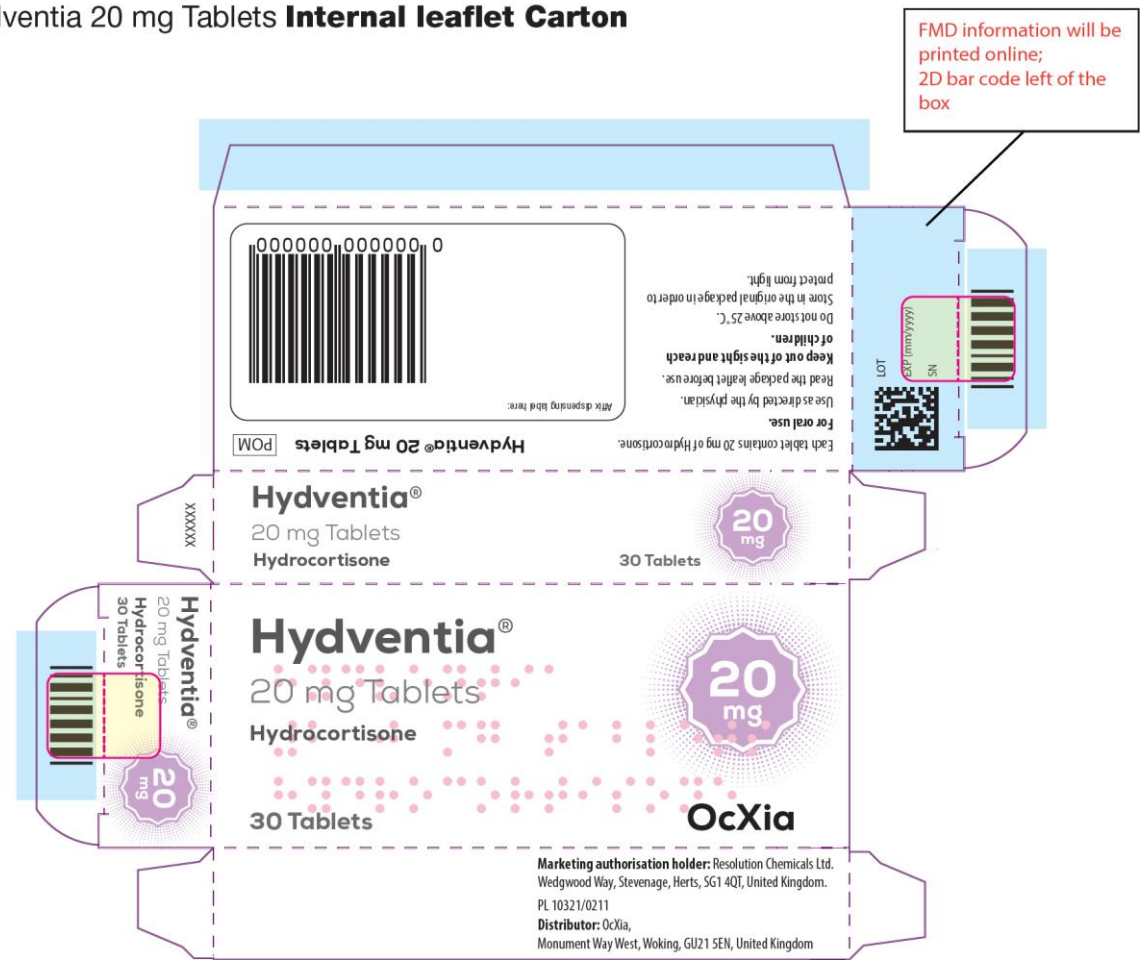
Hydventia 10 mg Tablets:




lidding foil 113 mm
Batch/LOT: 00000/0
Will be embosed to
foil edge as specified
by chosen Manufacturer
EXP: 00-0000
Will be embosed to
foil edge as specified
by chosen Manufacturer
Unwind Direction
LOT
EXP
Hydventia®10 mg Tablets
Hydrocortisone
Resolution Chemicals Ltd.

Hydventia 20 mg Tablets:

Hydventia 20 mg Tablets **Internal leaflet Carton**



Blister size 105 x 42 mm
Profile as supplied by manufacturer

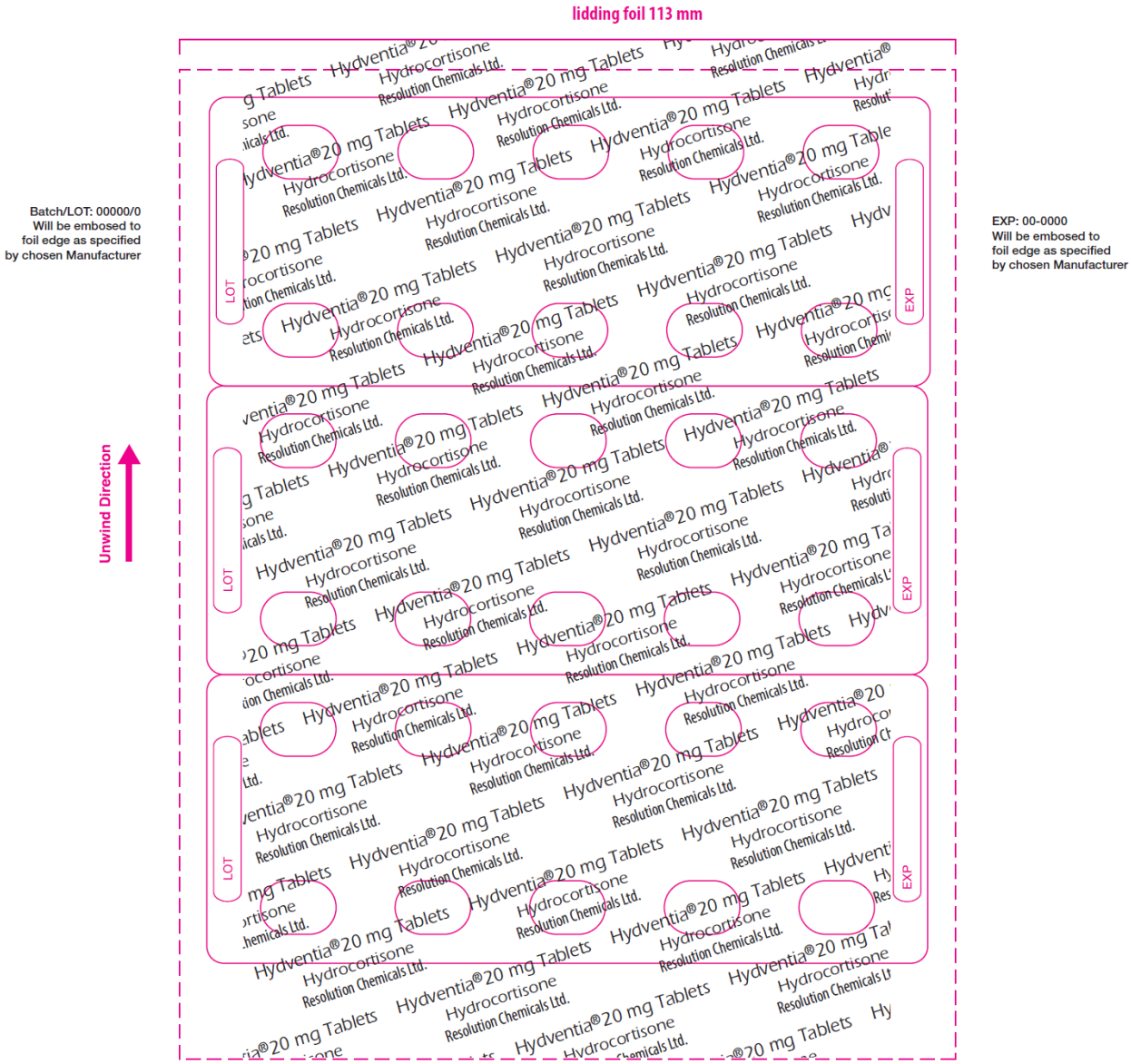


TABLE OF CONTENT OF THE PAR UPDATE

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 product licence are recorded in the current SmPC and/or PIL available on the MHRA website.

Application type	**Scope**	**Product information affected**	**Date of start of the procedure**	**Date of end of procedure**	**Outcome**	**Assessment report attached Y/N**