Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

UK Public Assessment Report

Yacella 0.03 mg/3 mg Tablets

PL 20117/0134

Morningside Healthcare Limited

Lay Summary

Yacella 0.03 mg/3 mg Tablets
(ethinylestradiol and drospirenone)

This is a summary of the public assessment report (PAR) for Yacella 0.03 mg/3 mg Tablets (PL 20117/0134). It explains how Yacella 0.03 mg/3 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 Yacella 0.03 mg/3 mg Tablets.

For practical information about using Yacella 0.03 mg/3 mg Tablets, patients should read the package leaflet or contact their doctor or pharmacist.

What are Yacella 0.03 mg/3 mg Tablets and what are they used for?
Yacella 0.03 mg/3 mg Tablets are a 'generic medicine'. This means that they are similar to a 'reference medicine', already authorised in the European Union (EU) called Jasmine 0.03 mg/3 mg tablets.

Yacella 0.03 mg/3 mg Tablets are contraceptive pills and are used to prevent pregnancy.

How do Yacella 0.03 mg/3 mg Tablets work?
Yacella 0.03 mg/3 mg Tablets contain small amounts of two different female hormones, namely drospirenone and ethinylestradiol. This contraceptive pill is called a "combination pill" owing to the presence of these two hormones (active substances).

How are Yacella 0.03 mg/3 mg Tablets used?
One Yacella 0.03 mg/3 mg Tablet should be swallowed every day, with a glass of water if necessary. These tablets may be taken with or without food but must be taken around the same time every day. After 21 days (equivalent to a strip of 21 tablets), treatment should be stopped for a 7 day period, a so-called 'stop' or 'gap' week, where the "withdrawal bleeding" occurs. On day 8, treatment should resume with a second strip of 21 tablets, such that every strip should be started on the same day each month.

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

This medicine can only be obtained with a prescription.

How have Yacella 0.03 mg/3 mg Tablets been studied?
Because Yacella 0.03 mg/3 mg Tablets are a generic medicine, studies in patients have been limited to tests to determine that these tablets are bioequivalent to the reference medicine, Jasmine 0.03 mg/3 mg tablets. Two medicines are bioequivalent when they produce the same levels of the active substances in the body.

What are the possible side-effects of Yacella 0.03 mg/3 mg Tablets?
Because Yacella 0.03 mg/3 mg Tablets are a generic medicine, their benefits and possible side-effects are taken as being the same as the reference medicine, Jasmine 0.03 mg/3 mg tablets.

For further information, please see the package leaflet.

Why are Yacella 0.03 mg/3 mg Tablets approved?

It was concluded that, in accordance with EU requirements, Yacella 0.03 mg/3 mg Tablets have been shown to have comparable quality and be bioequivalent to Jasmine 0.03 mg/3 mg tablets. Therefore, the view was that, as for Jasmine 0.03 mg/3 mg tablets, the benefits outweigh the identified risks and it was recommended that Yacella 0.03 mg/3 mg Tablets can be approved for use.

What measures are being taken to ensure the safe and effective use of Yacella 0.03 mg/3 mg Tablets?

A Risk Management Plan (RMP) has been developed to ensure that Yacella 0.03 mg/3 mg Tablets are used as safely as possible. Based on this plan, safety information has been included in the Summary of Product Characteristics (SmPC) and the package leaflet for Yacella 0.03 mg/3 mg 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 and healthcare professionals will be monitored and reviewed continuously as well.

Other information about Yacella 0.03 mg/3 mg Tablets

The Marketing Authorisation for Yacella 0.03 mg/3 mg Tablets was granted on 09 March 2015.

The full PAR for Yacella 0.03 mg/3 mg Tablets follows this summary.

For more information about the use of Yacella 0.03 mg/3 mg Tablets, read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in December 2015.

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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) granted a Marketing Authorisation (MA) to Morningside Healthcare Limited for the medicinal product Yacella 0.03 mg/3 mg Tablets.

This product is a prescription only medicine (legal status POM) indicated for oral contraception. The decision to prescribe Yacella 0.03 mg/3 mg Tablets should take into consideration the individual woman's current risk factors, particularly those for venous thromboembolism (VTE), and how the risk of VTE with Yacella Tablets compares with other combined hormonal contraceptives.

This application was made under Article 10(1) of Directive 2001/83/EC, as amended, as a generic medicinal product. The reference medicinal product, which has been authorised in accordance with Community provisions in force for not less than 10 years in the European Economic Area is Jasmine 0.03 mg/3 mg (Drospirenone 3 mg/Ethinylestradiol 0.03 mg) Tablets. This product was authorised to Bayer Sante, in France, on 05 February 2001 (356 055-0). The equivalent UK reference product, Yasmin 0.03 mg/3 mg tablets, was authorised to Schering Health Care Limited on 23 November 2000 (PL 00053/0292) via a Repeat-Use Mutual Recognition procedure with the Netherlands as the RMS (NL/H/0215/001). Following a subsequent change of ownership procedure on 01 May 2008, the current marketing authorisation holder for Yasmin 0.03 mg/3 mg tablets in the UK is Bayer PLC (PL 00010/0571). Jasmine 0.03 mg/3 mg Tablets and Yasmin 0.03 mg/3 mg tablets are considered to be interchangeable.

Yacella 0.03 mg/3 mg Tablets contain two female hormones drospirenone and ethinylestradiol. Drospirenone is a spironolactone analogue with antimineralocorticoid activity and ethinylestradiol increases levels of the sex hormone binding globulin (SHBG). Drosperinone and ethinylestradiol 'combination oral contraceptives' (COCs) act by suppression of gonadotropins. Although the primary mechanism of this action is inhibition of ovulation, other alterations include changes in the cervical mucus (which increases the difficulty of sperm entry into the uterus) and the endometrium (which reduces the likelihood of implantation).

No new non-clinical studies were conducted, which is acceptable given that the application is based on being a generic medicinal product of an originator product that has been licensed for over 10 years.

A suitable Environmental Risk Assessment (ERA) has been submitted.

With the exception of one bioequivalence study, no new clinical data were provided with this application. A bioequivalence study was performed, which compared the pharmacokinetics of the applicant's Yacella 0.03 mg/3 mg Tablets with those of the reference product, Jasmine tablets, in healthy subjects under fasting conditions. According to the study report the bioequivalence study was conducted in line with current Good Clinical Practice (GCP).

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

For manufacturing sites within the Community, the MHRA has accepted copies of current manufacturer authorisations issued by inspection services of the competent authorities as certification that acceptable standards of GMP are in place at those sites.

For manufacturing sites outside the Community, the MHRA has accepted copies of current GMP Certificates of satisfactory inspection summary reports, as certification that acceptable standards of GMP are in place at those non-Community sites.

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

The MHRA considered that the application could be approved and the licence was granted to Morningside Healthcare Limited on 09 March 2015.

II Quality aspects

II.1 Introduction

The application was submitted according to Article 10(1) of Directive 2001/83/EC, as amended.

Yacella 0.03 mg/3 mg Tablets are formulated as round, yellow, uncoated biconvex tablets, debossed with '143' on one side and plain on the other side.

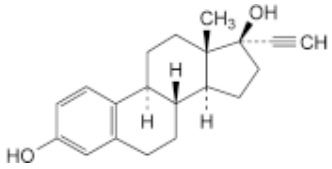
Each tablet contains 0.03 mg of the active substance ethinylestradiol and 3 mg of the active substance drospirenone. The excipients in each tablet are: lactose monohydrate, maize starch, povidone K25, magnesium stearate, crospovidone (type B), tartrazine aluminium lake (E102), sunset yellow FCF aluminium lake (E110) and indigo carmine aluminium lake (E132).

The tablets are presented in polyvinylchloride-polyvinylidene chloride/aluminium (PVC-PVdC/aluminium) blisters of 21 tablets, which are further packed into a polyester/aluminium/natural polyethylene pouches, in pack sizes of 3 x 21 tablets, 6 x 21 tablets and 13 x 21 tablets.

II.2 Drug Substance

Ethinylestradiol

INN: Ethinylestradiol
Chemical Name: 19-Nor-17α-pregna-1,3,5(10)-trien-20-yne-3,17-diol
Structure:



Molecular formula: $C_{20}H_{24}O_2$
Molecular weight: 296.4
Appearance: White or slightly yellowish-white, crystalline powder.
Solubility: Practically insoluble in water, freely soluble in ethanol (96 %). It dissolves in dilute alkaline solutions.

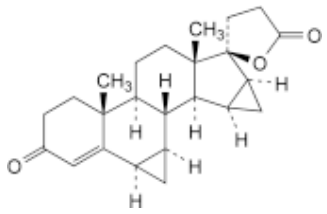
Ethinylestradiol is the subject of a European Pharmacopoeia monograph.

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

Drospirenone

INN: Drospirenone
Chemical Name: 3-Oxo-6α,7α,15α,16α-tetrahydro-3 *H′*,3″ *H*-dicyclopropa-[6,7:15,16]-17α-pregn-4-en-21,17-carbolactone

Structure:



Molecular formula:	$C_{24}H_{30}O_3$
Molecular weight:	366.5
Appearance:	White or almost white powder.
Solubility:	Practically insoluble in water, freely soluble in methylene chloride, soluble in methanol, sparingly soluble in ethanol (96 per cent).

Drospirenone is the subject of a European Pharmacopoeia monograph.

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

II.3 Medicinal Product

Pharmaceutical development

The pharmaceutical development was aimed at producing a generic version of the reference product Jasmine 0.03 mg/3 mg tablets.

The development of the product has been adequately described. Comparative dissolution profiles have been demonstrated between Yacella 0.03 mg/3 mg Tablets and Jasmine 0.03 mg/3 mg tablets.

In order to show that Yacella 0.03 mg/3 mg Tablets are equivalent to the reference medicinal product, Jasmine 0.03 mg/3 mg tablets, with regard to bioavailability, a bioequivalence study was performed. This is discussed in Section IV.2 – Clinical aspects.

All the excipients used in the manufacture of the proposed formulation, other than the tartrazine aluminium lake (E102), sunset yellow FCF aluminium lake (E110) and indigo carmine aluminium lake (E132), comply with their respective European Pharmacopoeia monographs. The three aluminium lake excipients comply with satisfactory in-house specifications.

Satisfactory certificates of analysis have been provided for all excipients showing compliance with their proposed specifications.

None of the excipients, with the exception of lactose monohydrate, are sourced from animal or human origin. The supplier of lactose monohydrate certifies that the pharmaceutical grade lactose is prepared in accordance with the relevant requirements laid down in *Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products* (EMEA/410/01 rev.3). It has been confirmed that magnesium stearate is prepared from stearic acid of vegetable origin.

No genetically modified organisms (GMO) have been used in the preparation of this product.

Manufacture of the product
A satisfactory batch formula has been provided for the manufacture of the finished product, together with an appropriate account of the manufacturing process. Validation has been undertaken on three pilot-scale/validation batches and the applicant has committed to validating the first three commercial-scale batches.

Product Specifications
The finished product specification is satisfactory. Satisfactory batch analysis was performed on three validation batches of the finished product. Certificates of analysis have been provided for all working standards used.

Stability of the product
Stability studies were performed in accordance with current guidelines on batches of the finished product, packed in the packaging proposed for marketing. The data from these studies support a shelf-life of 2 years. This medicinal product does not require any special storage conditions.

Suitable post approval stability commitments have been provided.

II.4 Discussion on chemical, pharmaceutical and biological aspects
The grant of a Marketing Authorisation is recommended for this application.

III Non-clinical aspects
The pharmacodynamic, pharmacokinetic and toxicological properties of ethinylestradiol and drospirenone are well-known. The applicant has not provided additional studies and further studies are not required. No new non-clinical data are required for this type of application. An overview based on literature review is, thus, appropriate.

A suitable Environmental Risk Assessment (ERA) has been provided for this product.

There are no objections to the approval of this product from a non-clinical viewpoint**.**

IV Clinical aspects

IV.1 Introduction
With the exception of bioequivalence data, no new clinical data have been submitted and none are required for an application of this type. The applicant's clinical overview has been written by an appropriately qualified person and is considered acceptable.

IV.2 Pharmacokinetics
In support of this application, the marketing authorisation holder has submitted the following bioequivalence study:

An open-label, randomized, two-period, two-treatment, two-sequence, crossover, balanced, single dose, oral bioequivalence study of Drospirenone 3.0 mg and Ethinyl Estradiol 0.03 mg Tablets (test product) and 'Jasmine' (Drospirenone 3.0 mg and Ethinyl Estradiol 0.03 mg; reference product) Tablets in healthy adult female subjects conducted under fasting conditions.

Subjects received the test or reference treatment after an overnight fast of 10 hours. Blood samples were taken for the measurement of pharmacokinetic parameters pre-dose and up to 72 hours post-dose. Each study drug administration was separated by a 28-day washout period.

The main pharmacokinetic results for drospirenone are presented below:

(Reference Product: Jasmine ® (Drospirenone 3.0 mg and Ethinyl Estradiol 0.03 mg) Tablets)

Pharmacokinetic parameter	Arithmetic mean	Standard deviation	Coeff of Variation (%)
AUC72 (ng.hr/ml)	1078.817	238.859	22.141
Cmax (ng/ml)	68.701	17.787	25.891
Tmax*	2.500		

(Test Product: Drospirenone 3.0 mg and Ethinyl Estradiol 0.03 mg Tablets)

Pharmacokinetic parameter	Arithmetic mean	Standard deviation	Coeff of Variation (%)
AUC72 (ng.hr/ml)	1040.081	235.188	22.612
Cmax (ng/ml)	62.830	15.534	24.724
Tmax*	2.500		

Pharmacokinetic parameter	Geometric mean (Test)	Geometric mean (Reference)	(Test/ Reference) Ratio (%)	Intra-Subject CV (%)	Power	90% Confidence Intervals
LnAUC72 (ng.hr/ml)	1008.178	1047.553	96.24	11.272	1.0000	(91.75%; 100.95%)
LnCmax (ng/ml)	60.305	66.184	91.12	17.811	0.9989	(84.52%; 98.23%)

The main pharmacokinetic results for ethinylestradiol are presented below:

(Reference Product: Jasmine ® (Drospirenone 3.0 mg and Ethinyl Estradiol 0.03 mg) Tablets)

Pharmacokinetic parameter	Arithmetic mean	Standard deviation	Coeff of Variation (%)
AUCt (pg.hr/ml)	2125.781	648.967	30.528
AUCi (pg.hr/ml)	2290.074	790.814	34.532
Cmax (pg/ml)	169.955	52.363	30.810
Tmax*	2.500		

(Test Product: Drospirenone 3.0 mg and Ethinyl Estradiol 0.03 mg Tablets)

Pharmacokinetic parameter	Arithmetic mean	Standard deviation	Coeff of Variation (%)
AUCt (pg.hr/ml)	2088.635	595.128	28.494
AUCi (pg.hr/ml)	2257.929	748.720	33.160
Cmax (pg/ml)	164.785	45.062	27.346
Tmax*	1.517		

Pharmacokinetic parameter	Geometric Mean (Test)	Geometric mean (Reference)	(Test/ Reference) Ratio (%)	Intra-Subject CV (%)	Power	90% Confidence Intervals
LnAUCt (pg.hr/ml)	1993.928	2013.002	99.05	8.822	1.0000	(95.34%; 102.91%)
LnAUCi (pg.hr/ml)	2131.523	2145.521	99.35	8.640	1.0000	(95.70%; 103.13%)
LnCmax (pg/ml)	158.829	161.765	98.19	11.995	1.0000	(93.23%; 103.41%)

The 90% confidence intervals were within the acceptance criteria of 80.00%-125.00%. Based on these results, the proposed product, Yacella 0.03 mg/3 mg Tablets, can be considered to be bioequivalent with the reference product, Jasmine 0.03 mg/3 mg tablets.

IV.3 Pharmacodynamics

No new pharmacodynamics data are required for this application and none have been submitted.

IV.4 Clinical efficacy

No new clinical efficacy data are required for this application and none have been submitted.

IV.5 Clinical safety

With the exception of the data collected during the bioequivalence study, no new data have been provided and none are required. The bioequivalence study appears to have been conducted safely. A total of 12 adverse events were reported by 8 subjects during the entire study.

IV.6 Risk Management Plan (RMP)

The marketing authorisation holder has submitted an RMP, in accordance with the requirements of Directive 2001/83/EC, as amended, describing the pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to Yacella 0.03 mg/3 mg Tablets.

A summary of safety concerns and planned risk minimisation activities, as approved in the RMP, are listed below:

Summary of safety concerns	
Important identified risks	• Venous thromboembolism • Arterial thromboembolism • Hepatobiliary disorders • Migraine
Important potential risks	• Effect on hereditary angioedema • Pancreatitis (in patients with hypertriglyceridemia) • Breast cancer • Benign and malignant liver tumours • Cervical cancer • Crohn's disease and ulcerative colitis • Insulin resistance / decreased glucose tolerance • Increased blood pressure • Hyperkalemia • Worsening of depression
Missing information	• Use during pregnancy and lactation

Planned risk minimisation activities

Safety concern	Routine risk minimisation measures	Additional risk minimisation measures
Important identified risks		
Venous thromboembolism	The risks of VTE associated with the use of the drug product are described in the SPC Sections 4.3, 4.4, 4.8, and appropriate advice is provided to the prescriber to minimise these risks.	Physician education material and patient education material
Arterial thromboembolism	The risks of arterial thromboembolism associated with the use of the drug product are described in the SPC Sections 4.3, 4.4, 4.8, and appropriate advice is provided to the prescriber to minimise these risks.	Physician education material and patient education material
Hepatobiliary disorders	The risks of hepatobiliary disorders associated with the use of drug product are described in the SPC Sections 4.3, 4.4, 4.8 and appropriate advice is provided to the prescriber to minimise these risks.	None
Migraine	The risks of migraine associated with the use of drug product are described in the SPC Sections 4.3, 4.4, 4.8 and appropriate advice is provided to the prescriber to minimise these risks.	None
Important potential risk		
Effect on hereditary angioedema	The risks associated with effect on hereditary angioedema with the use of the drug product are described in the SPC Sections 4.4, 4.8, and appropriate advice is provided to the prescriber to minimise these risks.	None
Pancreatitis (in patients with hypertriglyceridemia)	The risks of pancreatitis (in patients with hypertriglyceridaemia)	None

Safety concern	Routine risk minimisation measures	Additional risk minimisation measures
	associated with the use of the drug product are described in the SPC Section 4.4, and appropriate advice is provided to the prescriber to minimise these risks.	
Breast cancer	The risks of breast cancer associated with the use of the drug product are described in the SPC Sections 4.4, 4.8 and appropriate advice is provided to the prescriber to minimise these risks.	None
Benign and malignant liver tumours	The risks of benign and malignant liver tumours associated with the use of the drug product are described in the SPC Sections 4.3, 4.4, 4.8 and appropriate advice is provided to the prescriber to minimise these risks.	None
Cervical cancer	The risks of cervical cancer associated with the use of the drug product are described in the SPC Section 4.4 and appropriate advice is provided to the prescriber to minimise these risks.	None
Crohn's disease and ulcerative colitis	The risks of Crohn's disease and ulcerative colitis associated with the use of the drug product are described in the SPC Sections 4.4, 4.8 and appropriate advice is provided to the prescriber to minimise these risks.	None
Insulin resistance / decreased glucose tolerance	The risks of insulin resistance / decreased glucose tolerance associated with the use of the drug product are described in the SPC Section 4.4 and appropriate advice is provided to the prescriber to minimise these risks.	None
Increased blood pressure	The risks of increased blood pressure associated with the use	None

Safety concern	Routine risk minimisation measures	Additional risk minimisation measures
	of the drug product are described in the SPC Section 4.4, 4.8 and appropriate advice is provided to the prescriber to minimise these risks.	
Hyperkalemia	The risks of hyperkalemia associated with the use of the drug product are described in the SPC Sections 4.4, 4.5 and appropriate advice is provided to the prescriber to minimise these risks.	None
Worsening of depression	The risks of worsening of depression with the use of the drug product are described in the SPC Sections 4.4, 4.8 and appropriate advice is provided to the prescriber to minimise these risks.	None
Missing information		
Use during pregnancy and lactation	The SPC Sections 4.4, 4.6, 4.8 states that drug product should not be indicated used during pregnancy and also small amounts of the contraceptive steroids and/or their metabolites may be excreted with the milk during COC use which may affect the child.	Not applicable

V.7 Discussion on the clinical aspects

The grant of a Marketing Authorisation is recommended for this application.

V User consultation

The package leaflet has been evaluated via a user consultation study in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC, as amended. The language used for the purpose of user testing the package leaflet was English.

The results show that the package leaflet meets the criteria for readability as set out in the *Guideline on the readability of the label and package leaflet of medicinal products for human use*.

VI Overall conclusion, benefit/risk assessment and recommendation

The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. The application includes an adequate review of published non-clinical and clinical data concerning the efficacy and safety of ethinylestradiol and drospirenone. The test product, Yacella 0.03 mg/3 mg Tablets, can be considered bioequivalent with the reference product, Jasmine 0.03 mg/3 mg Tablets. The benefit/risk assessment is, therefore, considered to be positive.

The Summary of Product Characteristics (SmPC), package leaflet and labelling are satisfactory, in line with current guidelines and consistent with the reference product. In accordance with Directive 2012/84/EU, the current approved UK versions of the SmPC and package leaflet for this product are available on the Medicines and Healthcare products Regulatory Agency website.

The currently approved labels are listed below:


63 Tablets
Yacella 3 mg/0.03mg Tablets
Drospirenone/Ethinylestradiol
Please affix dispensary label here
Each tablet contains 3 mg of Drospirenone and 0.03 mg of Ethinylestradiol.
Also contains lactose, tartrazine (E102) and sunset yellow FCF (E110).
Read the package leaflet for further information.
Dosage: To be taken as directed by your doctor.
Read the package leaflet before use.
KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
This medicinal product does not require any special storage conditions.
Yacella 3 mg/0.03mg Tablets
Yacella 3 mg/0.03mg Tablets
Drospirenone/Ethinylestradiol
63 Tablets
200007526-000
Yacella 3 mg/0.03mg Tablets
Drospirenone/Ethinylestradiol
FOR ORAL USE
63 Tablets
MA Holder:
Morningside Healthcare Ltd
115 Narborough Road
Leicester, LE3 0PA, UK
PL 20117/0134
POM
GUHDRUG5AG/1297
5 055132 715365
Unvarnished area for batch details. "Lot & Exp." as applicable
GTIN :
Lot
Exp.
Serial No.


SEALING AREA - BACKGROUND COLOUR ONLY
NO TEXT - BACKGROUND COLOUR ONLY
SEALING AREA - BACKGROUND COLOUR ONLY
For oral use.
1 blister containing 21 Tablets
KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
GUJ-DRUGS/G/1297
Yacella 3 mg/0.03mg Tablets
Drospirenone/Ethinylestradiol
Each tablet contains 3 mg of Drospirenone and 0.03 mg of Ethinylestradiol.
Also contains lactose, tartrazine (E102) and sunset yellow FCF (E110).
Read the package leaflet for further information.
Dosage: To be taken as directed by your doctor. Read the package leaflet before use.
This medicinal product does not require any special storage conditions.
MA Holder: Morningside Healthcare Ltd
115 Narborough Road, Leicester, LE3 0PA, UK
PL 20117/0134
POM
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SEALING AREA - BACKGROUND COLOUR ONLY
Space for Batch details "Lot & Exp." as applicable
Total height 150 mm

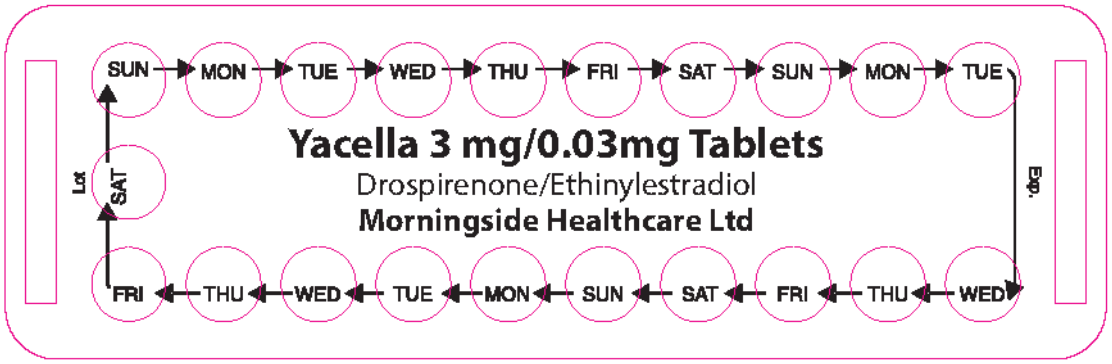
SUN MON TUE WED THU FRI SAT SUN MON TUE
Lot
SAT
Yacella 3 mg/0.03mg Tablets
Drospirenone/Ethinylestradiol
Morningside Healthcare Ltd
Exp.
FRI THU WED TUE MON SUN SAT FRI THU WED

Table of content of the PAR update

Steps taken after the initial procedure with an influence on the Public Assessment Report (Type II variations, PSURs, commitments)

Scope	**Product information affected**	**Date of start of the procedure**	**Date of end of procedure**	**Approval/ non approval**	**Assessment report attached Y/N (version)**