Medicines & Healthcare products Regulatory Agency

MHRA

Public Assessment Report

National Procedure

Orgovyx 120 mg film-coated tablets (relugolix)

PLGB 00142/1272

Accord-UK Ltd

LAY SUMMARY

Orgovyx 120 mg film-coated tablets (relugolix)

This is a summary of the Public Assessment Report (PAR) for Orgovyx 120 mg film-coated tablets. It explains how this product was assessed and its authorisation recommended, as well as its conditions of use. It is not intended to provide practical advice on how to use this product.

This product will be referred to as Orgovyx in this lay summary for ease of reading.

This product has been authorised by MHRA for Great Britain (consisting of England, Scotland and Wales). In coming to its decision, MHRA has relied on a European Commission (EC) decision on 29 April 2022 (EMEA/H/C/005353/0000), in accordance with the advice from the Committee for Medicinal Products for Human Use (CHMP). This is known as the EC Decision Reliance Procedure.

This application was approved under Regulation 50 of the Human Medicines Regulation 2012, as amended (previously Article 8.3 of Directive 2001/83/EC, as amended).

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

What is Orgovyx and what is it used for?
Orgovyx is used for the treatment of adult patients with advanced prostate cancer who respond to hormone therapy.

How does Orgovyx work?
Orgovyx contains the active substance relugolix that works by blocking a step in the process that signals the testes to produce testosterone (the male sex hormone). As testosterone can stimulate the growth of prostate cancer, by decreasing it to very low levels, relugolix prevents prostate cancer cells from growing and dividing.

How is Orgovyx used?
The pharmaceutical form of this medicine is film-coated tablets and the route of administration is oral (taken by mouth). The patient should swallow the tablets whole. The tablets can be taken with or without food with some liquid.

The recommended dose is:
• three tablets on the first day of treatment.
• one tablet once a day after that, taken around the same time each day.

The doctor may change the patient's dose if needed.

For further information on how Orgovyx is used, refer to the PIL and Summary of Product Characteristics (SmPC) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

This medicine 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 Orgovyx have been shown in studies?
A main study involving 934 men with advanced hormone-sensitive prostate cancer showed that Orgovyx is effective at reducing the amount of testosterone to levels seen in men whose testicles have been surgically removed.

During the first year, 97% of the patients receiving Orgovyx had the required reduction of testosterone levels, compared with 89% of patients receiving leuprorelin (another medicine for prostate cancer). These results showed that Orgovyx was as effective as leuprorelin.

What are the possible side effects of Orgovyx?
The most common side effects with Orgovyx (which may affect more than 1 in 10 people) are:
- hot flush
- diarrhoea
- constipation
- muscle and joint pain
- tiredness

For the full list of all side effects reported with this medicine, see Section 4 of the PIL or the SmPC 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.

Why was Orgovyx approved?
A main study showed that Orgovyx was as effective as standard treatment with another medicine (leuprorelin) in reducing testosterone levels of patients with advanced hormone-sensitive prostate cancer. Orgovyx was generally well-tolerated by most of the patients. Its side effects were mild and manageable.

The MHRA decided that the benefits are greater than the risks and recommended that this medicine can be approved for use.

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

There are no safety concerns associated with use of Orgovyx.

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 Orgovyx 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 this application and are satisfactory.

Other information about Orgovyx
A Marketing Authorisation (PLGB 55917/0001) was granted in Great Britain to Myovant Sciences Ireland Limited on 17 June 2022. Subsequent to a Change of Ownership (COA) procedure, a Marketing Authorisation was transferred on 29 July 2022 to the Marketing Authorisation Holder (MAH) Accord-UK Ltd (PLGB 00142/1272).

The full PAR for Orgovyx follows this summary.

This summary was last updated in June 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 application for Orgovyx 120 mg film-coated tablets (PLGB 00142/1272) could be approved.

The product is approved for the treatment of adult patients with advanced hormone-sensitive prostate cancer.

The active substance, relugolix is a nonpeptide GnRH receptor antagonist that competitively binds to GnRH receptors in the anterior pituitary gland preventing native GnRH from binding and signalling the secretion of luteinizing hormone (LH) and follicle-stimulating hormone (FSH). Consequently, the production of testosterone from the testes is reduced. In humans, FSH and LH concentrations rapidly decline upon initiating treatment with Orgovyx 120 mg film-coated tablets and testosterone concentrations are suppressed to below physiologic concentrations. Treatment is not associated with the initial increases in FSH and LH concentrations and subsequently testosterone ("potential symptomatic flare") observed upon initiation of treatment with a GnRH analogue. Following discontinuation of treatment, pituitary and gonadal hormone concentrations return to physiologic concentrations.

This product has been authorised by MHRA for Great Britain (consisting of England, Scotland and Wales). In coming to its decision, MHRA has relied on a European Commission (EC) decision on 29 April 2022 (EMEA/H/C/005353/0000), in accordance with the advice from the Committee for Medicinal Products for Human Use (CHMP).

For the scientific discussion of the quality, non-clinical and clinical assessment conducted by the European Medicines Agency (EMA), please refer to the European Public Assessment Report, available on the EMA website.

This application was approved under Regulation 50 of the Human Medicines Regulation 2012, as amended (previously Article 8.3 of Directive 2001/83/EC, as amended).

In line with the legal requirements for children's medicines, the application included a licensing authority decision on the agreement of a full product specific waiver (CW/001/2015).

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

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

A Marketing Authorisation (PLGB 55917/0001) was granted in Great Britain to Myovant Sciences Ireland Limited on 17 June 2022. Subsequent to a Change of Ownership (COA) procedure, a Marketing Authorisation was transferred on 29 July 2022 to the Marketing Authorisation Holder (MAH) Accord-UK Ltd (PLGB 00142/1272).

II. PRODUCT INFORMATION

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

The SmPC is in line with current guidelines and was satisfactory.

PATIENT INFORMATION LEAFLET (PIL)
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
The MHRA considered that the quality data submitted for this application is satisfactory.

The grant of a marketing authorisation was recommended.

IV. NON-CLINICAL ASPECTS
The MHRA considered that the non-clinical data submitted for this application is satisfactory.

The grant of a marketing authorisation was recommended.

V. CLINICAL ASPECTS
The MHRA considered that the clinical data submitted for this application is satisfactory.

The grant of a marketing authorisation 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.

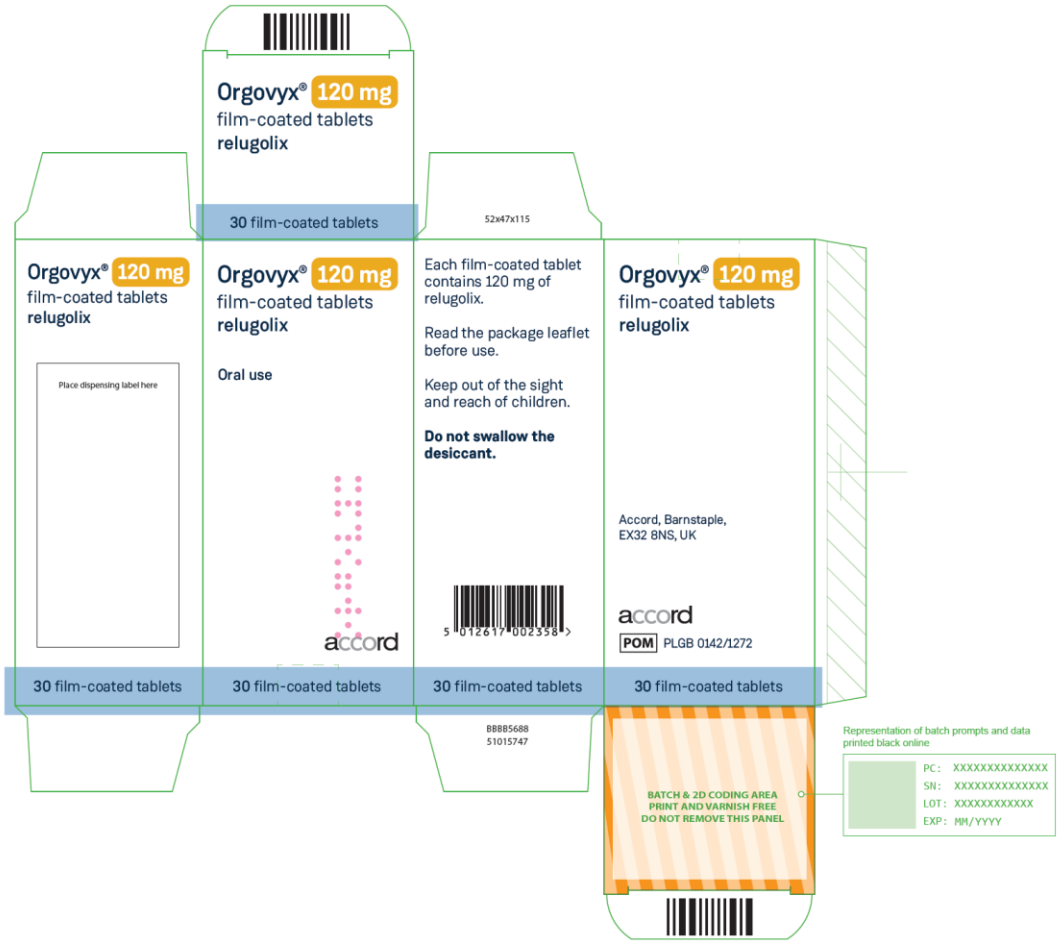
The PIL has been evaluated via a user consultation study in accordance with legal requirements. The results show that the PIL meets the criteria for readability as set out in the Guideline on the readability of the label and package leaflet of medicinal products for human use.

VIII. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION
The quality of the product 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 SmPC, PIL and labelling are satisfactory.

In accordance with legal requirements, the current approved UK versions of the SmPC and PIL for this product are available on the MHRA website.

Representative copies of the labels at the time of UK licensing of Orgovyx 120 mg film-coated tablets (PLGB 00142/1272) are provided below.


Orgovyx® 120 mg
film-coated tablets
relugolix
30 film-coated tablets
52x47x115
Orgovyx® 120 mg
film-coated tablets
relugolix
Place dispensing label here
30 film-coated tablets
Orgovyx® 120 mg
film-coated tablets
relugolix
Oral use
accord
30 film-coated tablets
Each film-coated tablet contains 120 mg of relugolix.
Read the package leaflet before use.
Keep out of the sight and reach of children.
Do not swallow the desiccant.
5 012617 002358
30 film-coated tablets
BBBB5688
51015747
Orgovyx® 120 mg
film-coated tablets
relugolix
Accord, Barnstaple, EX32 8NS, UK
accord
POM PLGB 0142/1272
30 film-coated tablets
BATCH & 2D CODING AREA
PRINT AND VARNISH FREE
DO NOT REMOVE THIS PANEL
Representation of batch prompts and data printed black online
PC: XXXXXXXXXXXXX
SN: XXXXXXXXXXXXX
LOT: XXXXXXXXXXX
EXP: MM/YYYY


Orgovyx® 120 mg
film-coated tablets
relugolix
Oral use
30 film-coated tablets
Each film-coated tablet contains 120 mg of relugolix.
Read the package leaflet before use.
Keep out of the sight and reach of children.
Do not swallow the desiccant.
Accord, Barnstaple, EX32 8NS, UK
accord
POM PLGB 0142/1272
BBBB5689
51015755
BATCH & 2D CODING AREA
PRINT FREE
DO NOT REMOVE THIS PANEL
Representation of data matrix code and human readable data printed black online
PC: (8)GTIN
EXP: MM/YYYY
Lot: Batch Number
2D code*
10mm
Pharmacode

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, is recorded on the MHRA website or European Medicines Agency (EMA) website. Minor changes to the marketing authorisation are recorded in the current SmPC and/or PIL available on the MHRA website.

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

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