Medicines & Healthcare products
Regulatory Agency

Public Assessment Report

National Procedure

Osvyrti 60 mg solution for injection in pre-filled syringe

denosumab

PL 20075/1577

ACCORD HEALTHCARE LIMITED

LAY SUMMARY

Osvyrti 60 mg solution for injection in pre-filled syringe
denosumab

This is a summary of the Public Assessment Report (PAR) for Osvyrti 60 mg solution for injection in pre-filled syringe. 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 Osvyrti in this lay summary for ease of reading.

This application was approved under International Recognition procedure (IRP). The Reference Regulator (RR) was the European Medicines Agency (EMA), with the procedure number EMEA/H/C/006399/0000. The procedure followed route A.

This application was approved under Regulation 53B of the Human Medicines Regulation 2012, as amended (previously Article 10(4) of Directive 2001/83/EC, as amended).

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

What is Osvyrti and what is it used for?
This product is a biosimilar medicine. This is biological medicine which is similar to and considered interchangeable with a reference medicine already authorised, called Prolia 60 mg solution for injection in pre-filled syringe.

Osvyrti is used to treat:

- osteoporosis in women after the menopause (postmenopausal) and men who have an increased risk of fracture (broken bones), reducing the risk of spinal, nonspinal and hip fractures.
- bone loss that results from a reduction in hormone (testosterone) level caused by surgery or treatment with medicines in patients with prostate cancer.
- bone loss that results from long-term treatment with glucocorticoids in patients who have an increased risk of fracture.

How does Osvyrti work?
This medicine contains denosumab, a protein (monoclonal antibody) that interferes with the action of another protein, in order to treat bone loss and osteoporosis. Treatment with this medicine makes bone stronger and less likely to break.

Bone is a living tissue and is renewed all the time. Oestrogen helps keep bones healthy. After the menopause, oestrogen level drops which may cause bones to become thin and fragile. This can eventually lead to a condition called osteoporosis. Osteoporosis can also occur in men due to a number of causes including ageing and/or a low level of the male hormone, testosterone. It can also occur in patients receiving glucocorticoids.

Many patients with osteoporosis have no symptoms, but they are still at risk of breaking bones, especially in the spine, hips and wrists. Surgery or medicines that stop the production of oestrogen or testosterone used to treat patients with breast or prostate cancer can also lead to bone loss. The bones become weaker and break more easily.

How is Osvyrti used?

The pharmaceutical form of this medicine is solution for injection and the route of administration is subcutaneous (under the skin).

The recommended dose is one pre-filled syringe of 60 mg administered once every 6 months, as a single injection under the skin (subcutaneous). The best places to inject are the top of the thighs and the abdomen. The patient's carer can also use the outer area of the patient's upper arm.

Patients or their carers should consult the patient's doctor on the date for a potential next injection. Each pack of this medicine contains a peel off label that can be removed from the blister and used to keep a record of the next injection date.

Patients should also take calcium and vitamin D supplements while being on treatment with this medicine. The patient's doctor will discuss this with the patient or their carer.

The patient should ask the administering healthcare practitioner if they have any questions concerning their medicine.

The doctor may decide that it is best for the patient or their carer to inject this medicine. The doctor or healthcare provider will show the patient or their carer how to use this medicine. The patient should always take the medicine exactly as their doctor/pharmacist has told them. The patient or their carer should check with their doctor or pharmacist if they are not sure.

For instructions on how to inject this medicine, please refer directly 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.

What benefits of Osvyrti have been shown in studies?

Laboratory studies comparing Osvyrti with Prolia have shown that the active substance in Osvyrti is highly similar to that in Prolia in terms of structure, purity and biological activity. Studies have also shown that giving Osvyrti produces similar levels of the active substance in the body to those seen with Prolia.

In addition, a study in 522 women with osteoporosis who have been through the menopause compared the effectiveness of Osvyrti with that of Prolia. After a year of treatment, bone mineral density (a measure of how strong the bones are) in the spine increased by around 6% in both women who received Osvyrti and those who received Prolia.

Because Osvyrti is a biosimilar medicine, the studies on the effectiveness of denusomab carried out with Prolia do not all need to be repeated for Osvyrti.

What are the possible side effects of Osvyrti?

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.

This medicine is subject to additional monitoring. This will allow quick identification of new safety information.

Because Osvyrti is a biosimilar medicine, its benefits and possible side effects are considered to be the same as the reference medicine.

Why was Osvyrti approved?
It was concluded that, Osvyrti has been shown to be biosimilar to the reference medicine. Therefore, the MHRA decided that, as for the reference medicine, the benefits are greater than the risks and recommended that it can be approved for use.

Osvyrti has been authorised with the condition to perform further studies and/or to provide additional measures to minimise the risk. See section below "What measures are being taken to ensure the safe and effective use of Osvyrti?"

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

The following safety concerns have been recognised for Osvyrti:

Important identified risks	• Hypocalcemia • Skin infection leading to hospitalisation • Osteonecrosis of the jaw • Hypersensitivity reactions • Atypical femoral fracture • Hypercalcemia in pediatric patients receiving denosumab and after treatment discontinuation
Important potential risks	• Fracture healing complications • Infection • Cardiovascular events • Malignacy
Missing information	• None

The company responsible for this medicine is obliged to provide additional risk minimisation materials. Patient reminder cards will be provided to address the risk 'Osteonecrosis of the jaw'.

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 Osvyrti 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 Osvyrti
A marketing authorisation was granted in the United Kingdom on 30 June 2025.

The full PAR for Osvyrti follows this summary.

This summary was last updated in August 2025.

TABLE OF 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 application for Osvyrti 60 mg solution for injection in pre-filled syringe (PL 20075/1577) could be approved.

The product is approved for the following indications:

- Treatment of osteoporosis in postmenopausal women and in men at increased risk of fractures. In postmenopausal women denosumab significantly reduces the risk of vertebral, non-vertebral and hip fractures.
- Treatment of bone loss associated with hormone ablation in men with prostate cancer at increased risk of fractures. In men with prostate cancer receiving hormone ablation, denosumab significantly reduces the risk of vertebral fractures.
- Treatment of bone loss associated with long-term systemic glucocorticoid therapy in adult patients at increased risk of fracture.

For more information on the indications and usage of this medicine, see the Summary of Product Characteristics available on the MHRA website.

The active ingredient is denosumab. Denosumab is a human monoclonal antibody (IgG2) that targets and binds with high affinity and specificity to RANKL, preventing activation of its receptor, RANK, on the surface of osteoclast precursors and osteoclasts. Prevention of the RANKL/RANK interaction inhibits osteoclast formation, function and survival, thereby decreasing bone resorption in cortical and trabecular bone.

This application was approved under International Recognition procedure (IRP). The Reference Regulator (RR) was the European Medicines Agency (EMA), with the procedure number EMEA/H/C/006399/0000. The procedure followed route A. For the scientific discussion of the quality, non-clinical and clinical assessment conducted by the reference regulator, please refer to the public assessment report on the relevant competent authority's website.

This application was approved under Regulation 53B of the Human Medicines Regulation 2012, as amended (previously Article 10(4) of Directive 2001/83/EC, as amended).

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 was granted on 30 June 2025.

II. PRODUCT INFORMATION

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

The SmPC is in line with current guidelines and is 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
MHRA considered that the quality data submitted for this application is satisfactory. The grant of a marketing authorisation was recommended.

IV. NON-CLINICAL ASPECTS
MHRA considered that the non-clinical data submitted for this application is satisfactory. The grant of a marketing authorisation was recommended.

V. CLINICAL ASPECTS
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. In addition to routine pharmacovigilance and risk minimisation measures, additional risk minimisation measures have been proposed.

See table below for the risk minimisation measures and pharmacovigilance activities for all safety concerns.

Safety Concern	Risk Minimization Measures	Pharmacovigilance Activities
Important Identified Risks		
Hypocalcemia	Routine risk minimization measures: • SmPC Section 4.2, 4.3, 4.4 and 4.8 • PL Section 2 and 4 • Recommendation for correction of hypocalcemia prior to initiating treatment with Osvyrti and clinical monitoring of calcium levels during treatment with Osvyrti is included in SmPC Section 4.4. • The prescription only status of the product. Additional risk minimization measures: • None	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: • Follow-up questionnaire for hypocalcemia Additional pharmacovigilance activities: • None

Skin infection leading to hospitalisation	Routine risk minimization measures: • SmPC Section 4.4 and 4.8 • PL Section 2 and 4 • The prescription only status of the product. Additional risk minimization measures: • None	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: • Follow-up questionnaire for Infection Additional pharmacovigilance activities: • None
Osteonecrosis of the Jaw	Routine risk minimization measures: • SmPC Section 4.8 • PL Section 2 and 4 • Recommendation for oral examination, maintenance of good oral hygiene during treatment, management of patients with unavoidable invasive dental procedures, and temporary interruption of treatment if ONJ occurs is included in SmPC Section 4.4. • The prescription only status of the product. Additional risk minimization measures: • Patient reminder card	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: • Follow-up questionnaire for Osteonecrosis of the Jaw Additional pharmacovigilance activities: • None

Hypersensitivity reactions	Routine risk minimization measures: • SmPC Section 4.3 and 4.8 • PL Section 4 • The prescription only status of the product. Additional risk minimization measures: • None	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: • Follow-up questionnaire for Hypersensitivity Additional pharmacovigilance activities: • None
Atypical femoral fracture	Routine risk minimization measures: • SmPC Section 4.4 and 4.8 • PL Section 2 and 4 • Recommendation for reporting new or unusual thigh, hip, orgroin pain is included in SmPC Section 4.4. • The prescription only status of the product. Additional risk minimization measures: • None	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: • Follow-up questionnaire for Atypical femoral fracture Additional pharmacovigilance activities: • None
Hypercalcemia in pediatric patients receiving denosumab and after treatment discontinuation	Routine risk minimization measures: • SmPC Section 4.2, 4.4, and 4.8 • PL Section 2 • The prescription only status of the product. Additional risk minimization measures: • None	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: • None Additional pharmacovigilance activities: • None

Important Potential Risks		
Fracture healing complications	Routine risk minimization measures: • SmPC Section 5.3 • The prescription only status of the product. Additional risk minimization measures: • None	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: • Follow-up questionnaire for fracture healing complications Additional pharmacovigilance activities: • None
Infection	Routine risk minimization measures: • SmPC Section 4.8 • PL Section 4 • The prescription only status of the product Additional risk minimization measures: • None	*Routine pharmacovigilance* activities beyond adverse reactions reporting and signal detection: • Follow-up questionnaire for infection *A*dditional pharmacovigilance activities: • None
Cardiovascular events	Routine risk minimization measures: • The prescription only status of the product dditional risk minimization measures: • None	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: • None Additional pharmacovigilance activities: • None
Malignancy	Routine risk minimization measures: • The prescription only status of the product Additional risk minimization measures: • None	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: • Follow-up questionnaire for malignancy Additional pharmacovigilance activities: • None
Missing Information		
None		

This is acceptable.

VII. USER CONSULTATION

A full colour mock-up of the Patient Information Leaflet (PIL) was provided with the application in accordance with legal requirements, including user consultation.

VIII. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION

This medicine is considered biosimilar to Prolia 60 mg solution for injection in pre-filled syringe. Therefore, a benefit/risk balance comparable to the reference product can be concluded.

Osvyrti 60 mg solution for injection in pre-filled syringe has been authorised with the condition to provide additional measures to minimise the risk. The Marketing Authorisation Holder shall complete, within the stated timeframe, the following measures:

Description	Due date
The MAH shall ensure that the following educational material regarding osteonecrosis of the jaw is implemented: - Patient Reminder Card (PRC) on the risk of osteonecrosis of the jaw The PRC is aimed at ensuring user awareness of the risk of developing osteonecrosis of the jaw and the necessary precautions required to help manage this risk.	05/07/2030

The Summary of Product Characteristics (SmPC), Patient Information Leaflet (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.

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