Medicines & Healthcare products
Regulatory Agency

Public Assessment Report

National Procedure

Oseltamivir 75 mg hard capsules
oseltamivir (as oseltamivir phosphate)

PL 20416/0983

Crescent Pharma Limited

LAY SUMMARY

Oseltamivir 75 mg hard capsules
oseltamivir (as oseltamivir phosphate)

This is a summary of the Public Assessment Report (PAR) for Oseltamivir 75 mg hard capsules. 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 Oseltamivir hard capsules in this lay summary for ease of reading.

This application was approved under International Recognition procedure (IRP). The Reference Regulator (RR) was the EU/EEA (Bulgaria), with the procedure number IAL-55698/22.11.2021. The procedure followed route B.

This application 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 Oseltamivir hard capsules, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

What are Oseltamivir hard capsules and what are they used for?
This product is a generic medicine. This means that this medicine is the same as, and considered interchangeable with, a reference medicine already authorised, called Tamiflu 75 mg hard capsules.

Influenza, usually called flu, is an infection caused by a virus. The signs of flu often include a sudden fever (more than 37.8°C), cough, runny or stuffy nose, headaches, muscle aches and extreme tiredness. These symptoms can also be caused by other infections. True influenza infection only occurs during annual epidemics when flu viruses are spreading in the local community. Outside epidemic periods, flu-like symptoms are usually caused by a different type of illness.

- Oseltamivir hard capsules are used for adults, adolescents, children and infants (including full-term newborn babies) for **treating flu** (influenza). It can be used when a person has flu symptoms, and the flu virus is known to be going round in their community.
- Oseltamivir hard capsules can also be prescribed for adults, adolescents, children and infants above 1 year of age for **preventing flu**, on a case-by-case basis – for instance, if the person has been in contact with someone who has flu.
- Oseltamivir hard capsules may be prescribed for adults, adolescents, children and infant (including full-term newborn babies) as **preventive treatment** in exceptional circumstances – for example, if there is a global epidemic of flu (a flu pandemic) and the seasonal flu vaccine may not provide sufficient protection.

How do Oseltamivir hard capsules work?
Oseltamivir hard capsules contain the active substance oseltamivir (as oseltamivir phosphate), which belongs to a group of medicines named neuraminidase inhibitors. These

medicines prevent the flu virus from spreading inside the body. They help to ease or prevent the symptoms of the flu virus infection.

How are Oseltamivir hard capsules used?
The pharmaceutical form of this medicine is a hard capsule and the route of administration is oral.

The patient should take Oseltamivir hard capsules as soon as possible, ideally within two days of the flu symptoms starting.

The recommended doses
For treating flu, the patient should take two doses daily. It is usually convenient to take one dose in the morning and one in the evening. **It is important to complete the whole 5-day course**, even if the patient starts to feel better quickly.

For patients with a weak immune system, treatment will continue for 10 days.

For preventing flu or after being exposed to an infected person, the patient should take one dose daily for 10 days. It is best to take this in the mornings with breakfast.

In special situations, such as widespread flu or for patients with a weak immune system, treatment will continue for up to 6 or 12 weeks.

The recommended dose is based on the patient's body weight. The patient must use the amount of oral capsules or suspension prescribed by the doctor.

Adults and adolescents 13 years and over

Body weight	**Treating flu:** dose *for 5 days*	**Treating flu (Immunocompromised Patients):** dose *for 10 days**	**Preventing flu:** dose *for 10 days*
40 kg or more	75 mg** twice daily	75 mg** twice daily	75 mg** once daily

** For patients with a weak immune system, treatment is for 10 days*
***75 mg can be made up of a 30 mg capsule plus a 45 mg capsule*

Children 1 to 12 years

Body weight	**Treating flu:** dose *for 5 days*	**Treating flu (Immunocompromised Patients):** dose *for 10 days**	**Preventing flu:** dose *for 10 days*
10 to 15 kg	30 mg twice daily	30 mg twice daily	30 mg once daily
More than 15 kg and up to 23 kg	45 mg twice daily	45 mg twice daily	45 mg once daily
More than 23 kg and up to 40 kg	60 mg twice daily	60 mg twice daily	60 mg once daily
40 kg and more	75 mg** twice daily	75 mg** twice daily	75 mg** once daily

** For children with a weak immune system, treatment is for 10 days*
***75 mg can be made up of a 30 mg capsule plus a 45 mg capsule*

Infants less than 1 year (0 to 12 months)
Giving Oseltamivir hard capsules to infants less than 1 year old for preventing flu during flu pandemic should be based upon the judgment of a doctor after considering the potential benefit versus any potential risk to the infant.

Body weight	**Treating flu:** dose *for 5 days*	**Treating flu (Immunocompromised Patients):** dose *for 10 days**	**Preventing flu:** dose *for 10 days*
3 kg to 10+ kg	3 mg per kg body weight**, twice daily	3 mg per kg body weight**, twice daily	3 mg per kg**, once daily

** For infants with a weak immune system, treatment is for 10 days.*
** mg per kg = *mg for each kilogram of the infant's body weight.*
For example: If a 6-month-old weighs 8 kg, the dose is 8 kg x 3mg per kg = 24 mg

Method of administration
The patient should swallow the capsules whole with water. They should not break or chew the capsules.

Oseltamivir hard capsules can be taken with or without food, although taking it with food can reduce the chance of nausea or vomiting.

People who find it hard to take capsules can use a liquid medicine, oseltamivir powder for oral suspension, which may be available and is the preferred product.

A pharmacy compounded suspension can not be prepared from the capsules.

If the patient needs a liquid medicine, but it's not available, they can make a liquid form of oseltamivir from these capsules. See the section **"Making liquid oseltamivir at home"** in the PIL.

People who have difficulty swallowing capsules, and in infants and children 1 year of age or older may use appropriate doses of oseltamivir powder for oral suspension, which may be available but not under this commercial brand.

For further information on how Oseltamivir hard capsules are 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 Oseltamivir hard capsules have been shown in studies?
As Oseltamivir hard capsules are a generic medicine, studies in healthy volunteers have been limited to tests to determine that they are bioequivalent to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Oseltamivir hard capsules?
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 were Oseltamivir hard capsules approved?
It was concluded that, Oseltamivir hard capsules have been shown to be bioequivalent 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.

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

The following safety concerns have been recognised for Oseltamivir hard capsules:

Summary of safety concerns	
Important identified risks	• Development of oseltamivir-induced viral resistance
Important potential risks	• Exposure during pregnancy
Missing information	• Treatment of influenza in immunocompromised patients

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 Oseltamivir hard capsules 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 Oseltamivir hard capsules
A marketing authorisation was granted in the United Kingdom on 01 August 2025.

The full PAR for Oseltamivir hard capsules follows this summary.

This summary was last updated in October 2025.

TABLE OF CONTENTS

I. INTRODUCTION 7
II. PRODUCT INFORMATION 8
III. QUALITY ASPECTS 8
IV. NON-CLINICAL ASPECTS 8
V. CLINICAL ASPECTS 8
VI. RISK MANAGEMENT PLAN (RMP) 9
VII. USER CONSULTATION 9
VIII. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION 9
TABLE OF CONTENT OF THE PAR UPDATE 10

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 Oseltamivir 75 mg hard capsules (PL 20416/0983) could be approved. This product will be referred to as Oseltamivir hard capsules in this scientific discussion for ease of reading.

The product is approved for the following indications:

Treatment of influenza
Oseltamivir hard capsules are indicated in adults and children including full term neonates who present with symptoms typical of influenza, when influenza virus is circulating in the community. Efficacy has been demonstrated when treatment is initiated within two days of first onset of symptoms.

Prevention of influenza

- Post-exposure prevention in individuals 1 year of age or older following contact with a clinically diagnosed influenza case when influenza virus is circulating in the community.
- The appropriate use of oseltamivir for prevention of influenza should be determined on a case-by-case basis by the circumstances and the population requiring protection. In exceptional situations (e.g. in case of a mismatch between the circulating and vaccine virus strains, and a pandemic situation) seasonal prevention could be considered in individuals one year of age or older.
- Oseltamivir is indicated for post-exposure prevention of influenza in infants less than 1 year of age during a pandemic influenza outbreak (see section 5.2 of the Summary of Product Characteristics (SmPC)).

Oseltamivir hard capsules are not a substitute for influenza vaccination.

The use of antivirals for the treatment and prevention of influenza should be determined on the basis of official recommendations. Decisions regarding the use of oseltamivir for treatment and prophylaxis should take into consideration what is known about the characteristics of the circulating influenza viruses, available information on influenza drug susceptibility patterns for each season and the impact of the disease in different geographical areas and patient populations (see section 5.1 of the SmPC).

The product contains the active substance oseltamivir phosphate, which is a pro-drug of the active metabolite (oseltamivir carboxylate). The active metabolite is a selective inhibitor of influenza virus neuraminidase enzymes, which are glycoproteins found on the virion surface. Viral neuraminidase enzyme activity is important both for viral entry into uninfected cells and for the release of recently formed virus particles from infected cells, and for the further spread of infectious virus in the body.

Oseltamivir carboxylate inhibits influenza A and B neuraminidases *in vitro*. Oseltamivir phosphate inhibits influenza virus infection and replication *in vitro*. Oseltamivir given orally inhibits influenza A and B virus replication and pathogenicity *in vivo* in animal models of influenza infection at antiviral exposures similar to that achieved in man with 75 mg twice daily.

Antiviral activity of oseltamivir was supported for influenza A and B by experimental challenge studies in healthy volunteers.

Neuraminidase enzyme IC_{50} values for oseltamivir for clinically isolated influenza A ranged from 0.1 nM to 1.3 nM, and for influenza B was 2.6 nM. Higher IC_{50} values for influenza B, up to a median of 8.5 nM, have been observed in published studies.

This application was approved under the International Recognition procedure (IRP). The Reference Regulator (RR) was the EU/EEA (Bulgaria), with the procedure number IAL-55698/22.11.2021. The procedure followed route B.

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 51B of the Human Medicines Regulation 2012, as amended (previously Article 10(1) of Directive 2001/83/EC, as amended), as a generic medicine of a suitable originator medicinal product, Tamiflu 75 mg hard capsules. that has been licensed for a suitable time, in line with the legal requirements.

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 01 August 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

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 PIL was provided with the application in accordance with legal requirements, including user consultation.

VIII. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION

The quality of the product is acceptable, and no non-clinical or clinical safety concerns have been identified. Clinical experience with oseltamivir is considered to have demonstrated the therapeutic value of the compound. The benefit/risk 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.

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 SmPC and/or PIL available on the MHRA website.

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