Direct Healthcare Professional Communication

Integrilin (eptifibatide): Discontinuation of manufacturing of Integrilin

Dear Healthcare Professional,

GlaxoSmithKline (Ireland) Limited, in agreement with the European Medicines Agency and the <*National Competent Authority* >, would like to inform you of the following:

Summary

- **GlaxoSmithKline (GSK) will discontinue manufacturing of Integrilin with immediate effect. This decision is based on a supply issue with eptifibatide, the active pharmaceutical ingredient in Integrilin.**
- **Both formulations of Integrilin [2mg/ml solution for injection and 0.75mg/ml solution for infusion] currently available in the European Union (EU) will be discontinued. This means that Integrilin will be withdrawn from the EU market.**
- **Due to the discontinuation of Integrilin, healthcare professionals should;**
    - **Not initiate new patients on Integrilin if there are insufficient vials to complete the course of treatment (bolus injection followed by up to 72 hours of infusion).**
    - **Consider prescribing an alternative formulation of eptifibatide, an alternative glycoprotein IIb/IIIa receptor inhibitor (e.g. tirofiban), or other suitable anti-thrombotic medications, as clinically appropriate.**

Background

Integrilin is a glycoprotein IIb/IIIa receptor inhibitor which is indicated for the prevention of early myocardial infarction in adults presenting with unstable angina or non-Q-wave myocardial infarction, with the last episode of chest pain occurring within 24 hours and with electrocardiogram (ECG) changes and/or elevated cardiac enzymes.

Due to a supply issue with eptifibatide, the active pharmaceutical ingredient in Integrilin, GSK will not be able to manufacture any further batches of Integrilin for at least 18 months. GSK has therefore made the decision to discontinue manufacturing of all formulations of Integrilin with immediate effect, bringing forward a strategic product discontinuation planned for the end of 2024.

This decision applies to the following regions/markets where GSK has a licence - the EU (centralised licence), Armenia, Russia, Switzerland, Ukraine and the United Kingdom.

This discontinuation is not due to concerns regarding the safety or effectiveness of Integrilin.

Due to the discontinuation of Integrilin, healthcare professionals should:

- Not initiate new patients on Integrilin if there are insufficient vials to complete the course of treatment (bolus injection followed by up to 72 hours of infusion).
- Consider prescribing an alternative formulation of eptifibatide, an alternative glycoprotein IIb/IIIa receptor inhibitor (e.g. tirofiban), or other suitable anti- thrombotic medications, as clinically appropriate.

You should share this information with relevant healthcare personnel under your supervision.

Call for reporting

Healthcare Professionals are asked to report any suspected adverse reactions in accordance with the national spontaneous reporting system <include the details (e.g. name, postal address, fax number, website address>, including batch/Lot number if available.

Company contact point

For further information or questions please contact <*local contact point details, including telephone number and/or email*>

GVP Annex II – Templates: Communication Plan for Direct Healthcare Professional Communication

DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Integrilin (eptifibatide) • 2mg/ml solution for injection • 0.75mg/ml solution for infusion
Marketing authorisation holder(s)	GlaxoSmithKline (Ireland) Limited
Safety concern and purpose of the communication	To make healthcare professionals aware of the decision to cease manufacture of Integrilin with immediate effect.
DHPC recipients	To all identified physicians and pharmacists / specialists / physician assistants / nurse practioners / other healthcare staff that are known to be prescribing, dispensing and/or caring for patients taking Integrilin.
Member States where the DHPC will be distributed	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden

Timetable *Delete steps which are not applicable*	**Date**
DHPC and communication plan (in English) agreed by CHMP	**12 October 2023**
Submission of translated DHPCs to the national competent authorities for review	**19 October 2023**
Agreement of translations by national competent authorities	**26 October 2023**
Dissemination of DHPC	**2 November 2023**