

16 January 2024 EMA/544137/2023

Shortage of Integrilin (eptifibatide) 2mg/ml solution for injection and 0.75mg/ml solution for infusion	
Indication	<u>Integrilin</u> is used to prevent a myocardial infarction (heart attack) in adults in the following groups:
	 patients who have unstable angina (a severe type of chest pain that varies in intensity);
	 patients who have already had a non-Q-wave myocardial infarction (a type of heart attack), with chest pain in the last 24 hours and with abnormalities on the electrocardiogram (ECG) or signs of heart problems in the blood.
Reason for shortage	Following a supply issue with the active ingredient eptifibatide, the marketing authorisation holder of Integrilin decided to permanently discontinue manufacturing, distribution and marketing of all formulations with immediate effect. This has led to a shortage of Integrilin.
Member States affected ¹	The shortage affects all Member States where the product is currently marketed.
Monitoring of shortage	EMA's <u>SPOC working party</u> ² is closely monitoring the supply situation and engaging with manufacturers of alternative eptifibatide medicines to supply the EU market.
Information to healthcare professionals	 Manufacturing, distribution and marketing of Integrilin (eptifibatide) were discontinued in October 2023 due to a supply shortage with eptifibatide. Following the discontinuation of Integrilin, eptifibatide-containing medicines are in short supply. Healthcare professionals should not initiate new patients on Integrilin if there are insufficient vials to complete the course of treatment. Healthcare professionals should consider alternative treatments for their patients, including: an alternative glycoprotein IIb/IIIa receptor inhibitor (e.g.

¹ This information may change. For accurate information about the status of a medicine shortage in a particular Member State, please consult the <u>national shortage register</u>.

² The <u>SPOC working party</u> is responsible for monitoring and reporting events that could affect the supply of medicines in the EU. Summaries of the SPOC working party meetings can be found on <u>EMA's website</u>.



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	 tirofiban); another suitable anti-thrombotic medication, as clinically appropriate. A direct healthcare professional communication (DHPC) has been sent to relevant healthcare professionals and is also available on the EMA website. Additional advice may be available from your country's national shortage register or national competent authority
Information to patients	 As of October 2023, the medicine Integrilin (eptifibatide) will no longer be manufactured. This follows a supply shortage with the active substance eptifibatide. As a result, eptifibatide-containing medicines are currently in short supply. Your doctor will check that there are sufficient supplies available before starting treatment with eptifibatide. In case eptifibatide becomes unavailable, your doctor will discuss possible alternatives with you including: an alternative glycoprotein IIb/IIIa receptor inhibitor (e.g., tirofiban). another suitable anti-thrombotic medication, as clinically appropriate. Additional advice may be available from your country's national shortage register or national competent authority
Status	Ongoing