

Please, send the notification by using secure mail via the website  
<https://secmail.fimea.fi/>

1. Nordic Article Number	Marketing authorization / EU-marketing authorization number	
2. Reason for the shortage		
3. Concerning human medicines, is the reason for the notification any of those given in Subsection 2 of Section 27 of the Medicines Act? yes      no		
If you answered yes, this notification has to be appended with two separate reports in English (cover letter and notification report table ' Notification of withdrawn products') which have to be sent both to Fimea and to EMA (withdrawnproducts@ema.europe.eu).		
4. Are there shortages of this product in other EU/EEA Member States?	yes	no
If yes, please fill in the member states you know of?		
5. Have other authorities been informed of the shortage?	yes	no
If yes, which authorities have been notified?		
6. Are there applications pending in Fimea in relation to this shortage?	yes	no
Does the application deal with:		
An exemption from the requirements set in the marketing authorisation?	yes	no
Or obligatory storage?	yes	no
A special licence in relation to an importer?	yes	no
A matter concerning authorisations not covered by those above?	yes	no
7. Are there other medicinal products on the Finnish market with the same indication?	yes	no
If yes, are these medicinal products interchangeable by a pharmacist?	yes	no
8. Estimated sales (packages per month)?		pc
9. How many packages has the wholesaler left in Finland?		pc

10. Estimated package size specific market share in Finland?	%
11. Wholesaler importing the medicinal product	
12. The size of the next confirmed batch and estimated date of arrival (pc. / dd.mm.yyyy)	
13. The risk management activities of the informant of the shortage and preventative measures for reducing the number of shortages	

The fees of shortage notifications are based on the Decree of the Ministry of Social Affairs and Health on fees chargeable by the Finnish Medicine Agency.

**Basis of fee**

<p>Tick only the applicable one</p> <p>Notification which was sent to Fimea at least two months (=60 days or over) before the shortage started or a notification, which did not occur. Fee 70 euros.</p> <p>Notification which was sent to Fimea for exceptional reasons less than two months (=less than 60 days) before the shortage started. Fee 200 euros.</p> <p>Notification which was sent to Fimea for exceptional reasons less than two weeks (= 14 days) before the shortage started. Fee 1000 euros.</p>
<p>We apply for a release from higher fee for a notification sent less than two months before the shortage started on the basis of (tick and fill in only, if applicable, following reasons)</p> <p>Unexpected increase in demand in Finland based on the pandemic</p> <p>Shortage of a competitor which has had over 30 %-units bigger market share prior to notifying the shortage calculated from average sales of past 12 months</p> <p>Natural catastrophe which has led to a blockage of the distribution chain of the product</p> <p>Other reason identical to the above mentioned reasons, which:</p>

If you apply for a release from the higher fee for the notification, you must fill in the detailed grounds for it. In other case, Fimea will charge the higher fee solely based on the time when the notification was received by Fimea.

**Contact information for invoicing**

The official name of the organization	
Billing address	
Postal code	
Area	
Country	
Language	Finnish    Swedish    English
Phone number (with country code)	
E-mail	
VAT-number	
PO (if needed)	

**E-invoice address**

E-invoiceaddress, OVT-number	
Operator ID / Opus Capita	

Please note that Fimea is not able to send invoices by email.