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Factsheet FRANCE

This factsheet is part of the EMCDDA [Take-home naloxone – topic overview](#)

General information	Geographical coverage	CSAPAs, CARUUDs and prison treatment units, hospitals, nation-wide since 2016 Community pharmacies, nation-wide since June 2019
	Type of Intervention	Pilot study: Cohort temporary authorization for use (August 2016- December 2017) Regular implementation since 2017, ongoing promotion of access to the medication by Ministry of Health and Medicines Agency
	Starting year	2016
	Settings	<ul style="list-style-type: none"> * low-threshold centers * in-patient detox/ rehab/ treatment * prison * <i>people admitted to emergencies following an overdose</i> * <i>people at risk of overdose seen in treatment centre for addiction</i> * <i>pre-filled syringes with naloxone for IM injection are available in community pharmacies since June 2019</i>
Regulatory challenges	Prescription	In February 2015, the Commission on narcotics and psychotropic substances voted in favour of the nasal route of administration by people who use drugs and third parties. Following a governmental order of October 2015, naloxone dispensing does no longer require a medical prescription. However, it is still a medication only available in pharmacies.
	Distribution	Following the pilot study which examined the results of naloxone dispensing in the context of hospital addiction services (CSAPA) in 2016-2017, naloxone can also be given out by drug treatment and harm reduction services (CAARUD) in France since November 2017. Since June 2019, pre-filled syringes with IM injectable naloxone can be obtained in pharmacies, without prescription. If a prescription is available, 65% of the cost is reimbursed by the national health insurance.
	Administration	N/A
	Barriers	Nalscue ® (0.9mg/0.1ml) was used in the trial under a cohort temporary authorisation (cTAU) for use from November 2015 by the French national agency for medicines and health products safety. It received marketing authorization in July 2017, but due to absence of an agreement on its price with the Economic Committee for Healthcare Products, the company decided to discontinue its production. Nalscue remains available in France while stocks last.
Medication	Product used	Nalscue ® Prenoxad ® (available in community pharmacies and in specialised centres since 2019); a pre-filled syringe containing 5 doses of 0.4ml (injectable formulation of 0.91mg/ml)
	Application	<ul style="list-style-type: none"> * nasal * injecting (IM)
	Content of THN Kit	<ul style="list-style-type: none"> * ready to use nasal spray dispensers * pre-filled syringe * first aid instructions, e.g. emergency telephone number, ABC
	Number of doses per kit	Variable number of devices, depending on medication. Supply sufficient to reverse one opioid overdose.
Distribution, refill and post-training monitoring	Distribution of THN	<ul style="list-style-type: none"> * on-site at outpatient treatment centers * on-site at inpatient treatment centers * to clients of OST programmes * in prison setting/on release * emergency department * pharmacies (Prenoxad)
	Mandatory training	Yes

Content of training	<ul style="list-style-type: none"> * recognising overdose symptoms * overdose management * aftercare procedures * effects of naloxone * possible adverse reactions to naloxone * possible risks and benefits of THN-programme * application of naloxone * how to store naloxone
Training format	<ul style="list-style-type: none"> * standard training with structured teaching session: number of sessions: 1 * THN-training is part of a general overdose-management training
Content of questionnaire for refill	<ul style="list-style-type: none"> * reason for re-fill * description of the drug emergency/ situation * ambulance involved * outcome of emergency * <i>substance causing overdose, administered dose</i>
Post-training monitoring	<ul style="list-style-type: none"> * interview or questionnaire when THN programme client returns for re-fill * systematic follow-up with all THN recipients

Performance and resources	Inception and training development	<ul style="list-style-type: none"> * other: 302 <i>physicians and pharmacists were trained during the cTAU trial (August 2016-December 2017)</i> <p>New information resources published by the Ministry of Health, 2020:</p> <p>Naloxone factsheet for health professionals: https://solidarites-sante.gouv.fr/IMG/pdf/covid-naloxone-annexe-fichememopros.pdf</p> <p>Information for potential bystanders: https://solidarites-sante.gouv.fr/IMG/pdf/covid_naloxone-annexe-fichememousagers.pdf</p> <p>Increasing access to naloxone during the COVID pandemic – Information for health professionals: https://solidarites-sante.gouv.fr/IMG/pdf/covid-fiche_naloxone_.pdf</p>	
	Implementation and monitoring	Period project reports during pilot study, see below.	
	Price of THN kits	In the context of the naloxone take-home programme, the medication is available for free for trainees. Training and naloxone distribution takes place in treatment centers, low-threshold centers, in prisons and in hospitals. Pre-filled syringes with naloxone for IM injection are available in pharmacies for purchase; a prescription is not obligatory. If it is prescribed, 65% of its cost (23 EUR) are reimbursed by the national health insurance	
	Source of funding	Programme	<ul style="list-style-type: none"> * specific national funding (for the trial) * national health insurance (if obtained on prescription)
	Training (if different)	* pharmaceutical industry	

Additional information	Project reports, evaluations and scientific papers	<p>Pilot study (cTAU): ANSM and INDIVIOR UK Ltd (2018) <i>Autorisation temporaire d'utilisation de cohorte. Résumé du rapport de synthèse périodique n° 13. Nalscue 0,9mg/0,1ml solution pour pulvérisation nasale en récipient unidose. Période du 25/9/2017-07/01/2018.</i> 2018.p 1-2. Available from: https://ansm.sante.fr/var/ansm_site/storage/original/application/5c8d832400b3de2f650f567b1f5a877b.pdf</p> <p>Barré, T., Vorspan, F., Fortias, M., Veyrier, M., Cavagna, P., Azuar, J. et al. (2018). Pratique de l'ATU de cohorte de la naloxone intranasale (Nalscue®) : mise en place dans un CSAPA parisien [Temporary approval for intranasal naloxone: Setting up in a French addiction center]. <i>Thérapie</i> 73 (6) 495-500.</p> <p>Frauger, E., Kheloufi, F., Boucherie, Q., Monzon, E., Jupin, L., Richard, N. et al. (2018). Intérêt de la mise à disposition de la naloxone auprès des usagers de drogues pour le traitement d'urgence de surdosage d'opioïdes [Interest of take-home naloxone for opioid overdose]. <i>Thérapie</i> 73 (6) 511-520.</p> <p>Guillou, M., Doudet, E., Donnadiou-Rigole, H. and Benslimane, M. (2019). Naloxone, la difficile mise à disposition des kits anti-overdose. <i>Le Flyer</i> (75) 2.</p>	
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Training materials	<p><i>Guide pour le patient, l'usager de drogue e son entourage: Overdose aux opioïdes. Utiliser NALSCUE® (naloxone) en situation d'urgence.</i> Available at: https://ansm.sante.fr/var/ansm_site/storage/original/application/d22b757087a8af9e0a345bb60b82e25e.pdf</p> <p>Powerpoint presentation: <i>Nalscue® (naloxone), traitement d'urgence des surdosages aux opioïdes.</i> Available at : https://ansm.sante.fr/var/ansm_site/storage/original/application/3eb9661a442b4eaff0f074456ce6f170.pdf</p> <p>www.naloxone.fr https://prenoxad.fr/</p> <p>Centre d'Addictovigilance de Paris (CEIP-A). <i>Comparison Nalscue-Prenoxad.</i> Available at: http://addictovigilance.aphp.fr/2019/05/28/nalscue-prenoxad/</p> <p>Ministry of Health: <i>La naloxone est utilisable par tous et peut sauver la vie.</i> Collection of downloadable posters. https://solidarites-sante.gouv.fr/prevention-en-sante/addictions/article/surdoses-overdose-d-opioides-la-naloxone-est-utilisable-par-tous-et-peut-sauver</p>
Contacts	<p>Anne-Claire Brisacier anbri@ofdt.fr www.ofdt.fr</p>

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